IN THE MATTER OF

AARON'S, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4442; File No. 122 3264 Complaint, March 10, 2014 – Decision, March 10, 2014

This consent order addresses Aaron's, Inc.'s use of PC Rental Agent, a privacyinvasive software that many of its franchisees installed on computers rented to The complaint alleges that Aaron's knowingly assisted its consumers. franchisees by allowing them to access DesignerWare's website, which was necessary in order for them to use PC Rental Agent to activate Detective Mode and secretly monitored consumers' activities on rented computers. Second, Aaron's corporate server was used to transmit and store a voluminous number of emails containing Detective Mode content. The complaint further alleges that Aaron's knew the data being gathered by Detective Mode could be highly intrusive and invaded consumers' privacy; and that, as a result of Aaron's practices, consumers were substantially harmed. The consent order requires the destruction of any data using monitoring or tracking technology without the requisite notice and consent or obtained under false pretenses, and mandates the encryption of any properly collected data when it is transmitted. The order also requires Aaron's to oversee and monitor its franchisees to ensure that their conduct complies with the core constraints imposed on Aaron's, which prohibits the deceptive gathering of consumer information such as using fake software registration notices or similar deceptive tactics.

Participants

For the Commission: Julie K. Mayer and Tracy S. Thorleifson.

For the *Respondent*: *Kristy Brown* and *Jim Harvey*, *Alston & Bird LLP*.

COMPLAINT

The Federal Trade Commission, having reason to believe that Aaron's, Inc., has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Aaron's, Inc., ("Aaron's" or "respondent"), is a Georgia corporation with its principal office or place of business at 309 E. Paces Ferry Road, N.E., Atlanta, Georgia 30305.

Aaron's is a national "rent-to-own" ("RTO") retailer of consumer electronics, residential furniture, and household appliances. RTO retailers allow consumers to rent goods with an option to purchase them.

2. The acts and practices of respondent as alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

RESPONDENT'S BUSINESS PRACTICES

3. Aaron's does business through a network of more than 1,300 company-owned stores and 700 independently owned franchised stores that operate across the United States. Since at least 2009 through January 2012, some Aaron's franchisees licensed a software product known as PC Rental Agent from DesignerWare, LLC ("DesignerWare") and installed it on computers rented to consumers. Aaron's knew that some of its franchisees had installed PC Rental Agent on computers rented to consumers because, among other things, Aaron's provided these stores with the technical capacity to access and use PC Rental Agent, as detailed below. Company-owned Aaron's stores did not license or use PC Rental Agent.

4. When installed on a rented computer, PC Rental Agent enabled Aaron's franchisees to disable a computer remotely. PC Rental Agent also enabled Aaron's franchisees to remotely install and activate an add-on program called Detective Mode. Using Detective Mode, Aaron's franchisees could - and did surreptitiously monitor the activities of computer users, including by logging keystrokes, capturing screenshots, and using the computer's webcam. Through Detective Mode, Aaron's franchisees could – and did – secretly gather consumers' personal information using fake software registration windows. In addition, using a different PC Rental Agent feature, Aaron's franchisees tracked the physical location of rented computers using WiFi hotspot location information. Aaron's franchisees used this illicitly gathered data to assist in collecting past-due payments and recovering computers after default.

5. Detective Mode data sent to Aaron's franchisees revealed private, confidential, and personal details about consumers using Keystroke logs displayed usernames and rented computers. passwords for access to email accounts, social media websites, and financial institutions. Screenshots captured additional confidential details, including medical information, applications containing Social Security numbers, and bank and credit card statements. Webcams operating secretly inside computer users' homes took photographs of computer users and anyone else within view of the camera. These included images of minor children as well as individuals not fully clothed and engaged in intimate conduct. The presence of PC Rental Agent was not detectible to computer users and computer renters could not uninstall it. In numerous instances, Aaron's franchisees did not obtain consent from their rental customers and did not disclose to them or the rental computers' users that PC Rental Agent was installed and could be used to track consumers' physical locations and remotely spy on their activities.

6. To use PC Rental Agent and activate Detective Mode, Aaron's franchisees needed to access DesignerWare's website and direct PC Rental Agent to take the desired action. Aaron's franchisees also needed to provide DesignerWare with an email address to which DesignerWare could send data captured by Detective Mode. DesignerWare forwarded immediately all data collected by Detective Mode to the email address provided by the Aaron's franchisee. Because at one activation level Detective Mode would capture screen shots, log keystrokes, and take webcam pictures every two minutes that the computer was connected to the Internet until directed to stop, and because this data was contemporaneously emailed to the Aaron's franchisees requesting it, Detective Mode activations often generated an enormous volume of data.

7. Aaron's requires its franchisees to have companyprovided, Aarons.com email addresses. Aaron's also provides these franchisees with email accounts and server space to store email messages. Such email messages are routed through Aaron's corporate headquarters and stored on computer servers owned, controlled, and maintained by Aaron's. Under the franchise agreement that governs each Aaron's franchisee, Aaron's may terminate a franchisee that breaches any Aaron's policy or

practice or that violates federal, state, or local laws, regulations, or ordinances. In addition, Aaron's policies and training materials for franchisees prohibit "unlawful" computer and Internet use, and set standards for fair collection practices.

8. Aaron's protects its computer network with certain DesignerWare's website, through which security features. Aaron's franchisees needed to access PC Rental Agent and activate Detective Mode, did not interface smoothly with Aaron's network configurations. In numerous instances, Aaron's franchisees had to seek written permission from Aaron's to access the DesignerWare website so that they could use PC Rental Agent. Senior Aaron's management approved these requests and authorized franchisees to access the DesignerWare website using Absent this permission, many Aaron's the Aaron's network. franchisees could not have used PC Rental Agent, activated Detective Mode, and surreptitiously monitored consumers' activities on rented computers.

9. Aaron's also provided its franchisees with troubleshooting advice relating to installation of PC Rental Agent software on rental computers. Technical conflicts between PC Rental Agent and the antivirus program already installed on computers in rental inventory prevented franchisees from readily installing PC Rental Agent. Aaron's published step-by-step instructions for installing PC Rental Agent on Aaron's rental computers in a newsletter for franchisees and posted those instructions on its website.

10. In numerous instances, Aaron's franchisees used the Aaron's computer network to access the DesignerWare website, and then, often using instructions provided by Aaron's, installed PC Rental Agent on computers rented to consumers. Aaron's franchisees directed DesignerWare to send Detective Mode data to the email accounts provided to them by Aaron's. Aaron's computer network was used to receive, store, and access upwards of 100,000 Detective Mode messages, including messages containing private and confidential consumer information about consumers who rented computers from Aaron's franchisees. Aaron's has stored such messages on its computer network since at least 2009.

11. Aaron's knew that Detective Mode captured confidential and personal information from consumer computer users without notice to those users. Aaron's IT personnel were aware that company server space was being used to store Detective Mode emails and knew what data those emails contained. One IT employee who reviewed Detective Mode images sent to a franchisee described the program as "very intrusive" in an email to Aaron's chief information officer.

12. Aaron's employees responsible for franchisee development and oversight, "franchise representatives," also knew that Aaron's franchisees were installing PC Rental Agent and using Detective Mode without notice to consumers. Franchise representatives discussed PC Rental Agent with franchisee employees, via email and in-person, including at Aaron's-sponsored conferences attended by franchisee employees where PC Rental Agent was an agenda item. Some franchisee employees first heard about PC Rental Agent from Aaron's franchise representatives. Through these communications, Aaron's employees also learned about the privacy-invasive capabilities of Detective Mode. For example, one franchisee owner suggested to an Aaron's franchise representative that PC Rental Agent use be put on the agenda for an upcoming meeting in part because he said he was "a little uncomfortable with the ability to see the customer through the webcam."

13. Beginning at least in 2010 and throughout 2011, Aaron's senior corporate management not only knew that its franchisees were using PC Rental Agent and activating Detective Mode without notice to computer users, they also knew that data and information gathered by Detective Mode could be highly intrusive and invaded consumers' privacy. Aaron's managers specifically discussed whether to purchase PC Rental Agent for installation on Aaron's corporate-owned stores. As part of that discussion, Aaron's reviewed the use of PC Rental Agent by some of its franchisees, as well as Detective Mode's capabilities. Among other things, managers received email communications that included examples of images captured by Detective Mode. Ultimately, Aaron's decided not to purchase PC Rental Agent for its corporate stores.

14. Aaron's management learned even more about PC Rental Agent and Detective Mode when, in May 2011, Aaron's was sued by a franchisee customer who alleged that an Aaron's franchisee's use of Detective Mode invaded her privacy and violated state and federal law. The lawsuit, which also named the Aaron's franchisee and DesignerWare, was styled as a class action. The complaint described, inter alia, the alleged properties of Detective Mode, including its capacity to capture computer users' keystrokes, screenshots of their computer activities, and webcam images.

15. Aaron's did not close its web portal and revoke franchisee access to the DesignerWare website and Detective Mode emails until December 2011. Following that action by Aaron's, its franchisees that used Aaron's network could no longer receive and view emails from DesignerWare containing Detective Mode-captured data about their customers. Aaron's computer servers received the last Detective Mode email in January 2012. Aaron's failed to act earlier despite clear authority to control its franchisees' access to and use of Aaron's computer network.

16. Aaron's conduct in permitting and participating in the gathering and storage of private and confidential information about individuals caused or was likely to cause substantial harm Because of Aaron's actions, private and to consumers. confidential information was captured, stored on Aaron's computer system, and revealed to Aaron's franchisees. This conduct placed consumers at risk from the exposure of their personal, financial account access, and medical information. Consumers also were injured by the unwarranted invasion into the peaceful enjoyment of their homes. Detective Mode's surreptitious capture of the private details of individual and family life – including images of visitors, children, family interactions, partially undressed individuals, and people engaged in intimate conduct - caused actual consumer harm. Because Detective Mode functioned secretly, consumers were unable to reasonably avoid this harm, which was neither trivial nor speculative. Further, the harm caused by the knowing and unauthorized gathering and storage of private and confidential information is not outweighed by countervailing benefits to consumers or to competition.

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VIOLATION OF THE FTC ACT

17. Through the means described in Paragraphs 3 through 16, respondent's actions have caused or are likely to cause substantial injury to consumers that cannot be reasonably avoided and is not outweighed by countervailing benefits to consumers or competition. Therefore, respondent's practices constitute unfair acts or practices in violation of Section 5 of the FTC Act, 15 U.S.C. § 45(a).

THEREFORE, the Federal Trade Commission, this tenth day of March, 2014, has issued this complaint against respondent.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C § 45 et seq.; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), which includes: a statement by respondent that it neither admits nor denies any of the allegations in the draft complaint, except as specifically stated in the Consent Agreement, and, only for purposes of this action, admits the facts necessary to establish jurisdiction; and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent

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has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

- 1. Respondent Aaron, Inc. ("Aaron's"), is a Georgia corporation with its principal office or place of business at 309 E. Paces Ferry Road, N.E., Atlanta, Georgia 30305.
- 2. The Commission has jurisdiction of the subject matter of this proceeding and of respondent, and the proceeding is in the public interest.

<u>ORDER</u>

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

- A. Unless otherwise specified, "respondent" shall mean Aaron's and its successors and assigns.
- B. "Commerce" shall be defined as it is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- C. "Computer" shall mean any desktop or laptop computer, handheld device, tablet, smartphone, or other electronic product or device that has a platform on which to download, install, or run any software program, code, script, or other content.

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- D. "Clear(ly) and prominent(ly)" shall mean:
 - 1. In textual communications (e.g., printed publications or words displayed on the screen of a computer or mobile device), the required disclosures are of a type, size, and location sufficiently noticeable for an ordinary consumer to read and comprehend them, in print that contrasts highly with the background on which they appear;
 - 2. In communications disseminated orally or through audible means (e.g., radio or streaming audio), the required disclosures are delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend them;
 - 3. In communications disseminated through video means (e.g., television or streaming video), the required disclosures are in writing in a form consistent with subpart (a) of this definition and shall appear on the screen for a duration sufficient for an ordinary consumer to read and comprehend them, and in the same language as the predominant language that is used in the communication;
 - 4. In communications made through interactive media, such as the Internet, online services, and software, the required disclosures are unavoidable and presented in a form consistent with subpart (a) of this definition, in addition to any audio or video presentation of them; and
 - 5. In all instances, the required disclosures are presented in an understandable language and syntax; in the same language as the predominant language that is used in the communication; and include nothing contrary to, inconsistent with, or in mitigation of any statement contained within the disclosure or within any document linked to or referenced therein.

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- E. "Consumer product" shall mean any item that is primarily for personal, family, or household use.
- F. "Covered rent-to-own transaction" shall mean any transaction where a consumer enters into an agreement for the purchase or rental of any consumer product where the consumer's contract or rental agreement provides for payments over time with options to purchase the product.
- G. "Franchisee" shall mean an independently owned business that operates under a franchise agreement with respondent.
- H. "Geophysical location tracking technology" shall mean any hardware, software, or application that collects and reports data or information that identifies the precise geophysical location of an item. Geophysical location tracking technologies include, but are not limited to, technologies that report the GPS coordinates of a computer or other item; the WiFi signals available to or actually used by a computer to access the Internet; the telecommunication towers or connections available to or actually used by a computer; the processing of any such reported data or information through geolocation lookup services; or any information derived from any combination of the foregoing.
- I. "Monitoring technology" shall mean any hardware, software, or application utilized in conjunction with a computer that can cause the computer to (1) capture, monitor, or record, and (2) report information about user activities by:
 - 1. Recording keystrokes, clicks, or other usergenerated actions;
 - 2. Capturing screenshots of the information displayed on a computer monitor or screen; or
 - 3. Activating the camera or microphone function of a computer to take photographs or record audio or

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visual content through the computer's webcam or microphone.

INJUNCTION

I.

MONITORING TECHNOLOGY PROHIBITED

IT IS HEREBY ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and its officers, agents, servants, employees, and all persons or entities in active concert or participation with them who receive actual notice of this order, by personal service or otherwise, in connection with any covered rent-to-own transaction, are hereby permanently restrained and enjoined from:

- A. Using any monitoring technology to gather data or information from or about a consumer from any computer rented to a consumer; or
- B. Receiving, storing, or communicating any data or information from or about a consumer that was gathered from a computer rented to a consumer using any monitoring technology.

Provided that this Part does not apply to respondent's use of any monitoring technology to gather data or information from or about a consumer from any computer rented to a consumer, with notice to and consent from the consumer, in connection with a request for technical assistance initiated by the consumer, where respondent only uses the information to provide, or attempt to provide, the requested technical assistance and for no other purpose.

II.

USE OF TRACKING TECHNOLOGY LIMITED

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and its officers, agents, servants, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by

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personal service or otherwise, in connection with any covered rent-to-own transaction, are hereby permanently restrained and enjoined from:

- A. Gathering any data or information from any consumer product via any geophysical location tracking technology without providing clear and prominent notice to the consumer who rented the product at the time it is rented and also obtaining affirmative express consent from the consumer at the time the consumer product is rented;
- B. Failing to provide clear and prominent notice to consumers and obtaining affirmative express consent from consumers at the time any consumer product is rented, to the extent that such notice and consent are required by subpart A, above, by the following means:
 - 1. Clear and Prominent Notice: respondent shall provide a clear and prominent notice to the user. separate and apart from any "privacy policy," "data use policy," "terms of service," "end-user license agreement," "lease agreement," or other similar document, that discloses (1) that geophysical location tracking technology is installed and/or currently running on the rented consumer product; (2) the types of user activity or conduct that is being captured by such technology; (3) the identities or specific categories of entities with whom any data or information that is collected will be shared or otherwise provided; (4) the purpose(s) for the collection, use, or sharing of such data or information: and (5) where and how the consumer can contact someone for additional information: and
 - 2. Affirmative Express Consent: respondent shall obtain affirmative express consent by giving the renter an equally clear and prominent choice to either agree or not agree to any geophysical location tracking technology, and neither option may be highlighted or preselected as a default

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setting. Activation of any geophysical location tracking technology must not proceed until the renter provides affirmative express consent. Notwithstanding the foregoing, nothing in this Section shall require respondent to rent an item to a consumer who declines to consent to installation or activation of any geophysical tracking technology; and

C. In connection with the rental of computers, installing or activating on rented computers geophysical location tracking technology where that technology does not provide clear and prominent notice to the computer user immediately prior to each use of the geophysical location tracking technology, as clear and prominent is defined above, and by the installation of a clear and prominent icon on the computer on which the technology is installed, such as on the desktop and in the desktop system tray of the computer. Clicking on the icon must clearly and prominently disclose: (1) that geophysical location tracking technology is installed and currently running on the computer; (2) the types of user activity or conduct that is being captured by such technology; (3) the identities or specific categories of entities with whom any data or information that is collected will be shared or otherwise provided; (4) the purpose(s) for the collection, use, or sharing of such data or information; and (5) where and how the user can contact someone for additional information.

Provided that respondent may suspend the notice requirements of this Part and activate geophysical location tracking technology if a) the consumer reports that a rented consumer product has been stolen or respondent otherwise has a reasonable basis to believe that a rented consumer product has been stolen, and b) either the consumer or respondent has filed a police report stating that the consumer product has been stolen. Provided further that respondent shall retain documents establishing (a) and (b). For purposes of this Order, "filing of a police report" means the filing of the consumer's or respondent's complaint with the police department in any form recognized in the jurisdiction.

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Provided further that this Part does not apply to respondent's use of geophysical location tracking technology, with notice to and consent from a consumer to the extent that such notice and consent are required by subpart A, to gather data or information in connection with a request for technical assistance initiated by a consumer, where respondent only uses the information to provide, or attempt to provide, the requested technical assistance and for no other purpose.

III.

NO DECEPTIVE GATHERING OF CONSUMER INFORMATION

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and its officers, agents, servants, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with any covered rent-to-own transaction, are hereby permanently restrained and enjoined from making or causing to be made, or assisting others in making or causing to be made, any false representation or depiction in any notice, prompt screen, or other software application appearing on the screen of any computer that results in gathering data or information from or about a consumer.

IV.

NO USE OF IMPROPERLY OBTAINED INFORMATION IN COLLECTIONS

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and its officers, agents, servants, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, are hereby permanently restrained and enjoined from using, in connection with collecting or attempting to collect a debt, money, or property pursuant to a covered rent-to-own transaction, any data or information from or about a consumer obtained in a manner that does not comply with Parts I, II, and III of this Order.

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V.

PROTECTION OF DATA

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and its officers, agents, servants, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, shall:

- A. Delete or destroy data or information from or about a consumer previously gathered or stored using any monitoring or geophysical location tracking technology that does not comply with Parts I, II, and III of this Order, unless such action is otherwise prohibited by court order or other legal obligation and after the expiration of any such court order or other legal obligation the information is deleted or destroyed; and
- B. Only transfer any data or information from or about a consumer that was gathered by any monitoring or geophysical location tracking technology from the computer upon which the technology is installed to respondent's server(s), and from the respondent's server(s) to any other computers or servers, if the information collected is rendered unreadable, unusable, or indecipherable during transmission.

VI.

NO MISREPRESENTATIONS ABOUT PRIVACY

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and its officers, agents, servants, employees, and all persons or entities in active concert or participation with it who receive actual notice of this Order, by personal service or otherwise, in connection with any covered rent-to-own transaction shall not misrepresent, in any manner, expressly or by implication, the extent to which respondent maintains and protects the security, privacy, or confidentiality of any data or information from or about a consumer. Decision and Order

VII.

OVERSIGHT AND MONITORING OF FRANCHISEES

IT IS FURTHER ORDERED that respondent shall:

- A. Require its franchisees to delete or destroy data or information from or about a consumer previously gathered or stored using any monitoring or geophysical location tracking technology that does not comply with Parts I, II, and III of this Order, unless such action is otherwise prohibited by court order or other legal obligation, in which case, after the expiration of any such court order or other legal obligation, respondent shall require its franchisees to delete or destroy the data or information;
- B. Within thirty (30) days after the date of service of this Order, prohibit each of its franchisees from, in connection with a covered rent-to-own transaction:
 - 1. Using any monitoring technology to gather data or information from or about a consumer from any computer rented to a consumer;
 - 2. Receiving, storing, or communicating any data or information from or about a consumer that was gathered from a computer rented to a consumer using any monitoring technology;
 - 3. Gathering any data or information from any consumer product via any geophysical location tracking technology in a manner that:
 - a. does not comply with Part II of this Order; and
 - b. that respondent has not approved in advance of the franchisee's use of such technology;
 - 4. Using, in connection with collecting or attempting to collect a debt, money, or property pursuant to a covered rent-to-own transaction, any data or information from or about a consumer obtained in

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a manner that does not comply with Parts I, II, and III of this Order; and

- 5. Making, or causing to be made, any false representation or depiction in any notice, prompt screen, or other software application appearing on the screen of any computer that results in gathering data or information from or about a consumer;
- C. Monitor compliance by each franchisee with the requirements of Parts VII.A and VII.B, including but not limited to by annually reviewing each franchisee's compliance with Parts VII.A. and VII.B.; and
- D. When respondent knows, or has reason to know, whether as a result of monitoring required by Part VII.C. or otherwise, that a franchisee has violated any requirement imposed on that franchisee by respondent in compliance with Parts VII.A. or VII.B.:
 - 1. Immediately take action to ensure that the franchisee corrects its practices; and
 - 2. Terminate any such franchisee that fails to make such correction.

VIII. DISTRIBUTION OF ORDER

IT IS FURTHER ORDERED that respondent must deliver a copy of this Order to all current and future principals, officers, directors, and managers who have responsibilities related to the subject matter of this Order and to all franchisee principals. Delivery must occur within thirty (30) days after the date of service of the Order for current personnel and franchisee principals. For new personnel and franchisee principals, delivery must occur before they assume their responsibilities. From each individual to whom respondent delivers a copy of this Order, respondent must obtain a signed and dated acknowledgment of receipt of this Order, with any electronic signatures complying with the requirements of the E-Sign Act, 15 U.S.C. § 7001 et seq.

IX. COMPLIANCE REPORTING

IT IS FURTHER ORDERED that:

- A. Respondent, and its successors and assigns, shall, within sixty (60) days after the date of service of this Order, and at such other times as the Commission may require, file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form in which they have complied with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate written reports;
- Β. Respondent, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this Order, including, but not limited to, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or related entity that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, the respondent shall notify the Commission as soon as is practicable after obtaining such knowledge; and
- C. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *In re Aaron's, Inc.*, File No. 1223264. *Provided, however*, that, in lieu of overnight courier, notices may be sent by first class mail, but

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only if an electronic version of each such notice is contemporaneously sent to the Commission at DEbrief@ftc.gov.

X. RECORDKEEPING

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of any act or practice covered by Parts I - VII of this Order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying, any documents, whether prepared by or on behalf of respondent, that:

- A. Comprise or relate to complaints or inquiries, whether received directly, indirectly, or through any third party, concerning consumer privacy, specifically including complaints or inquiries related to any monitoring or geophysical tracking technologies and any responses to those complaints or inquiries;
- B. Are reasonably necessary to demonstrate full compliance with each provision of this Order, including but not limited to, all documents obtained, created, generated, or which in any way relate to the requirements, provisions, or terms of this Order, and all reports submitted to the Commission pursuant to this Order;
- C. Contradict, qualify, or call into question respondent's compliance with this Order; or
- D. Acknowledge receipt of this Order obtained pursuant to Part VIII.

XI. TERMINATION OF ORDER

This Order will terminate on March 10, 2034, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any

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violation of the Order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this Order that terminates in less than twenty (20) years; and
- B. This Order if such complaint is filed after the Order has terminated pursuant to this Part.

Provided, further, that, if such complaint is dismissed or a federal court rules that respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Aaron's, Inc.

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

The Commission's administrative complaint alleges that respondent Aaron's engaged in unfair practices that caused, or are

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likely to cause, substantial injury to consumers that cannot be reasonably avoided and are not outweighed by countervailing benefits to consumers or competition.

Aaron's, an operator and franchisor of more than 1,300 corporate and nearly 750 franchisee rent-to-own ("RTO") stores across the country and Canada, played an important role in the use of PC Rental Agent, a privacy-invasive software that many of its franchisees installed on computers rented to consumers. PC Rental Agent surreptitiously collected private, confidential, and personal information about consumers who used rented computers. RTO stores that licensed PC Rental Agent from its manufacturer, DesignerWare, could use this illicitly gathered data about their customers to assist in collecting on past-due accounts and recovering computers after default. When in its "Detective Mode," PC Rental Agent could log keystrokes, capture screenshots, and activate a computer's webcam. Detective Mode also allowed users to deceptively gather consumers' personal information through fake software registration notices. Information that Detective Mode collected was transmitted from rented computers to DesignerWare, which in turn would email it to its licensees, including Aaron's franchisees. Another feature of PC Rental Agent allowed RTO stores to track the physical location of rented computers using WiFi hotspot information, which RTO store licensees could access by logging onto DesignerWare's website.

Commission's According to the complaint, Aaron's knowingly assisted its franchisees in using PC Rental Agent in a First, Aaron's specifically allowed its variety of ways. franchisees to access DesignerWare's website, which was necessary in order for them to use PC Rental Agent. Without this permission from Aaron's, many of its franchisees could not have activated Detective Mode and secretly monitored consumers' activities on rented computers. Second, Aaron's corporate server was used to transmit and store a voluminous number of emails containing Detective Mode content. Aaron's provided email accounts to its franchisees that many of them used to receive messages sent from DesignerWare containing Detective Modecaptured information. Emails sent to and from these accounts were routed through Aaron's corporate headquarters and stored on computer servers owned, controlled, and maintained by Aaron's.

Analysis to Aid Public Comment

As a result, Aaron's maintained on its corporate server upwards of 100,000 Detective Mode messages containing covertly gathered consumer information. Finally, Aaron's provided franchisees with vital technical support about PC Rental Agent. For example, Aaron's published trouble-shooting advice about installing the program on rented computers and avoiding conflicts with antivirus software.

The proposed complaint alleges that, as a result of Aaron's practices, consumers were substantially harmed. It further alleges that Aaron's knew the data being gathered by Detective Mode could be highly intrusive and invaded consumers' privacy. This knowing support of franchisees' use of Detective Mode without notice to computer users placed those consumers at risk from exposure of their personal, financial account access, and medical information. Consumers were also injured by the unwarranted invasion into the peaceful enjoyment of their homes. Detective Mode's surreptitious capture of the private details of individual and family life - including images of visitors, children, family interactions, partially undressed individuals, and people engaged in intimate conduct – caused actual consumer harm. Because Detective Mode functioned secretly, consumers were unable to reasonably avoid this harm, which was neither trivial nor speculative. Further, there were no countervailing benefits to consumers or to Aaron's that outweighed this harm.

The proposed consent order contains provisions designed to prevent Aaron's and its franchisees from engaging in the challenged practices and similar future conduct. Section I of the order prohibits Aaron's from using monitoring technology on computers and from receiving, storing, or communicating information about consumers collected with such technology. Section II prohibits Aaron's use of geophysical location tracking technology on any consumer product without notifying and obtaining consent from renters. Aaron's must also notify a user of a rented computer immediately prior to activating tracking technology on that device, unless Aaron's has a reasonable basis to believe that the computer has been stolen and a police report filed. Both Sections I and II also contain provisos that permit Aaron's to use monitoring or geophysical location tracking technology for purposes of providing requested customer assistance, where the consumer has consented to the use of the

Analysis to Aid Public Comment

technology and any information collected is used only to provide the requested assistance.

Section III of the proposed order prohibits the deceptive gathering of consumer information, which will bar Aaron's from using fake software registration notices or similar deceptive tactics. Section IV will prevent Aaron's from using any consumer information to collect on rental contracts that was improperly obtained through monitoring technology, tracking technology, or deceptive notices that appear on computer screens. Section V requires the destruction of any data using monitoring or tracking technology without the requisite notice and consent or obtained under false pretenses, and mandates the encryption of any properly collected data when it is transmitted. Section VI prohibits Aaron's from making any misrepresentations about the privacy or security of consumer information it collects.

The order also contains provisions that require Aaron's to oversee and monitor its franchisees to ensure that their conduct complies with the core constraints imposed on Aaron's. Section VII mandates that Aaron's require its franchisees to delete or destroy any consumer information improperly gathered via monitoring technology, tracking technology, or deceptive notices that appear on computer screens. Under that section, Aaron's must also prohibit its franchisees from: 1) using any monitoring technology to gather consumer information from a leased computer; 2) receiving, storing, or communicating any data gathered using monitoring technology; 3) using any geophysical location tracking technology that Aaron's has not approved in advance; 4) gathering any data from any consumer product using geophysical location tracking technology without providing notice and consent; 5) using any improperly gathered consumer information to collect a debt; and 6) making a false representation to a consumer through the use of fake software registration notices or other deceptive statements that appear on the screen of a computer. Aaron's must also monitor, on an annual basis or more frequently, its franchisees' compliance with these requirements and, if Aaron's learns through this process or otherwise has reason to know that a franchisee has violated Section VII of the order, it must take immediate action to ensure that the franchisee corrects its practices. If it does not, Aaron's must terminate that franchisee.

AARON'S, INC.

Analysis to Aid Public Comment

Sections VIII - XI of the proposed order contain order distribution, compliance reporting, and recordkeeping provisions. Section VIII requires Aaron's to disseminate the order to persons with responsibilities related to the subject matter of the order, including franchisee principals. It also requires Aaron's to secure a signed and dated statement acknowledging receipt of the order from all persons who receive a copy. Section IX imposes standard reporting requirements, requiring Aaron's to file compliance reports to the Commission within sixty (60) days and periodically thereafter upon request. This section also requires that Aaron's notify the Commission of any changes in corporate status. Section X mandates that, for five (5) years, Aaron's retain documents relating to its compliance with the order and about complaints or inquiries concerning consumer privacy. Finally, Section XI is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

Complaint

IN THE MATTER OF

DOWN TO EARTH DESIGNS, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4443; File No. 122 3268 Complaint, March 18, 2014 – Decision, March 18, 2014

This consent order addresses Down to Earth Designs, Inc. d/b/a gDiapers' marketing, sale, and distribution of diapers and baby wipes with claims of various environmental benefits. The complaint alleges that respondent represented that its diapers and wipes are biodegradable, "certified 100% biodegradable," garbage free when trashed or flushed, and plastic free. The complaint further alleges that respondent failed to disclose adequately that consumers can safely compost only wet used inserts and wipes. The consent order requires respondent to clearly and prominently disclose the time to complete decomposition or the rate and extent of decomposition with a further disclosure that the stated rate and extent of decomposition does not mean that the item will continue to decompose, if the item does not completely decompose within one year after customary disposal. The order also prohibits respondent from making specific environmental claims about any product or package unless the claim is true, not misleading, and substantiated by competent and reliable scientific evidence.

Participants

For the Commission: Matthew Wilshire and Boris Yankilovich.

For the *Respondent*: Ann M. Begley and Zachary A. Rothstein, Morgan, Lewis & Bockius LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that Down to Earth Designs, Inc., d/b/a gDiapers ("Respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is an Oregon corporation with its principal place of business at 2808 NE Martin Luther King Jr. Boulevard, Portland, Oregon, 97212.

2. Respondent has advertised, labeled, offered for sale, sold, and distributed the following products throughout the United States:

- a. gDiapers: A diaper system that consists of two components: (i) a reusable outer shell (gPants), and (ii) an inner liner, either a disposable pad (gRefills) or a reusable cloth insert. Respondent has offered for sale and sold gPants and gRefills separately and in combination with each other.
- b. gWipes: Moist wipes for use on babies' skin.

3. Respondent has advertised, offered for sale, and sold gRefills and gWipes as disposable products on its website, www.gdiapers.com, and through other online media, including but not limited to advertisements on third-party websites, social media advertisements, and email advertisements sent to potential customers. Additionally, Respondent has advertised, offered for sale, sold, and distributed these products through various retailers and distributors throughout the United States.

4. The acts and practices of Respondent alleged in this Complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

5. Respondent disseminates, has disseminated, or has caused the dissemination of promotional materials relating to its gDiapers and gWipes products to retailers and consumers. In numerous instances, including but not limited to the promotional materials shown in Exhibits 1-19, Respondent has represented that:

a. gRefills and gWipes are biodegradable:

100% ecodorable* *cute & biodegradable.

Ex. 1 (gDiapers website).

Complaint

100% biodegradable

Exs. 2, 3 (gDiapers website). *See also* Exs. 4, 5 (online advertising).

100% biodegradable for a happy planet. Ex. 4 (online advertising).

disposable. biodegradable. adorable.

Exs. 6, 7 (online advertising).

biodegradable* gRefills

Ex. 8 (packaging).

biodegradable gWipes

Ex. 9 (packaging).

b. gRefills and gWipes biodegrade when trashed:

100% biodegradable disposable diaper inserts So gentle on the earth you can flush, compost, or toss.

Ex. 1 (gDiapers website).

Flush. Compost. Toss. gDiapers. No garbage.

Ex. 10 (online advertising). *See also* Ex. 11 (online advertising).

a diaper shouldn't last forever. 50 million diapers enter the landfill every day. Each one takes up to 500 years to break down.

gDiapers are the only earth-friendly diapers that are 100% biodegradable. gDiapers biodegradable gRefills can be flushed, home composted, or tossed.

Ex. 3 (gDiapers website).

Put the poop in the toilet and toss the baby wipe. You can breathe easier knowing that a gWipe will break down much faster than other disposable baby wipes on the market.

Ex. 12 (gDiapers website).

toss a plastic-free option that's easier on the planet

Ex. 13 (gDiapers website). See also Ex. 8 (packaging).

no landfill necessary.

Ex. 15 (online advertising).

c. gRefills biodegrade when flushed:

100% Biodegradable

So gentle on the earth you can flush, compost, or toss.

Ex. 1 (gDiapers website).

gDiapers biodegradable gRefills can be flushed, home composted, or tossed.

Ex. 3 (gDiapers website). *See also* Ex. 2 (gDiapers website).

Complaint

d. gRefills are "certified" biodegradable:

gRefills are certified 100% biodegradable.

Exs. 13 (gDiapers website), 16 (email advertising), 8 (packaging).

e. gRefills and gWipes are compostable, including in home composts:

gRefills can be . . . home composted

Exs. 2, 3 (gDiapers website).

gWipes can be home composted

Ex. 12 (gDiapers website).

Flush. Compost. Toss. gDiapers. No garbage.

Ex. 10 (online advertising).

Flush, compost, or throw them away!

Ex. 11 (online advertising).

gRefills in your own backyard.

Collect your yard waste, your fruit and veggie scraps from the kitchen, your coffee grounds and your baby's wet gRefills and watch how they work together to break down into useful and valuable compost.

Ex. 14 (gDiapers website).

f. gRefills offer an environmental benefit because they can be flushed:

Earth-friendly diapers Flush your diapers.

Ex. 17 (online advertising).

Eco-friendly diapers.

Flush, compost, or throw them away!

Ex. 11 (online advertising).

Flush You're putting poop where it belongs

Exs. 13 (website); see also 8 (packaging).

g. gDiapers are plastic free:

plastic free, naturally.

Ex. 18 (online advertising).

No plastic, chlorine, or guilt!

Ex. 11 (online advertising).

End plastic diaper use.

Ex. 19 (online social media advertising).

6. In numerous instances, no disclaimers accompanied the representations listed in Paragraph 5. *See*, *e.g.*, Exs. 9, 10, 11. In other instances, Respondent made qualifying statements – *e.g.*, disclaimers that only wet gRefills or gWipes can be composted, or that gRefills and gWipes are biodegradable only in composting environments – but in numerous instances those qualifiers were not clear and conspicuous or proximate to the claim. For example, while Respondent's home page advertised gRefills with unqualified compostable claims, *see* Ex. 1, it disclosed that only "wet ones" (*i.e.*, wet gRefills) can be composted on different web pages. *See*, *e.g.*, Exs. 3, 13. Similarly, in contrast to the unqualified biodegradable claims on the front of gRefills and

Complaint

gWipes packaging, Respondent revealed on back and side panels that the products biodegrade in only "home and commercially-approved composts." *See*, *e.g.*, Exs. 8, 9.

7. Consumers likely interpret unqualified degradable claims to mean that the entire product or package will completely decompose into elements found in nature within a reasonably short period of time after customary disposal. For items entering the solid waste stream, consumers likely interpret unqualified degradable claims to mean that the item will completely decompose within one year after customary disposal. 16 C.F.R. § 260.8(b),(c).

8. Consumers likely interpret unqualified compostable claims to mean that all the materials in the item will break down into, or otherwise become part of, usable compost (*e.g.*, soil-conditioning material, mulch) in a safe and timely manner (*i.e.*, in approximately the same time as the materials with which it is composted) in an appropriate composting facility, or in a home compost pile or device. 16 C.F.R. § 260.7(b).

9. Approximately 92 percent of total municipal solid waste in the United States is disposed of in landfills, incinerators, or recycling facilities. Landfills, incinerators, and recycling facilities do not present conditions for biodegradation or composting within a reasonably short period of time.

10. Consumers of gRefills dispose of the majority of used gRefills by throwing them away in the trash ("trashing"). Trashing gRefills and gWipes leads to their final disposal in a landfill or incinerator.

11. In fact, gRefills and gWipes do not biodegrade in landfills or incinerators in a reasonably short period of time.

12. Municipal wastewater facilities filter out a portion of flushed gRefills and send that material to landfills. Of the material that is not filtered out, only a part may degrade in the wastewater stream during the treatment process. Of the remainder, a portion is landfilled or incinerated. As a result, a significant portion of flushed gRefills do not biodegrade.

13. Only wet used gRefills and gWipes are safe to compost.

14. Respondent has not obtained any independent, third-party certification that gRefills are biodegradable.

15. gDiapers are not plastic free. The gPants component of the gDiapers system contains, among other things, plastic.

VIOLATIONS OF SECTION 5 OF THE FTC ACT

<u>COUNT I: FALSE OR MISLEADING</u> <u>REPRESENTATIONS</u>

16. Through the means described in Paragraph 5, Respondent has represented, expressly or by implication, that:

- a. gRefills and gWipes are biodegradable—*i.e.*, will completely break down and decompose into elements found in nature within one year after customary disposal;
- b. gRefills and gWipes will biodegrade when trashed;
- c. gRefills will biodegrade when flushed;
- d. gRefills are "certified" biodegradable;
- e. No part of used gRefills will end up in a landfill or incinerator after disposal by trashing or flushing; and/or
- f. gDiapers are plastic free.
- 17. In truth and in fact:
 - a. gRefills and gWipes will not completely break down and decompose into elements found in nature within one year after customary disposal;
 - b. gRefills and gWipes will not biodegrade when trashed;
 - c. gRefills will not biodegrade when flushed;

Complaint

- d. gRefills are not "certified" biodegradable;
- e. Part of used gRefills will end up in a landfill or incinerator after disposal by trashing or flushing; and/or
- f. gDiapers are not plastic free.

18. Therefore, the representations set forth in Paragraph 16 were, and are, false or misleading.

19. Respondent's false or misleading representations constitute deceptive acts or practices in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

COUNT II: FAILURE TO DISCLOSE, OR FAILURE TO DISCLOSE CLEARLY AND CONSPICUOUSLY, THAT COMPOSTABILITY IS LIMITED TO WET GREFILLS AND GWIPES

20. Through the means described in Paragraph 5, Respondent has represented, expressly or by implication, that used gRefills and gWipes are home compostable -i.e., will break down into, or otherwise become part of, usable compost in a safe and timely manner in a home compost pile or device.

21. Respondent has failed to disclose that gRefills and gWipes soiled with solid waste will not break down into, or otherwise become part of, usable compost in a safe and timely manner in a home compost pile or device. Where Respondent has made such disclosures, in numerous instances they have not appeared in a clear and conspicuous manner.

22. This additional information, described in Paragraph 21, would be material to consumers in deciding whether to purchase gDiapers' products.

23. Respondent's failure to disclose the material information in Paragraph 21, in light of the representations made in Paragraph 20, constitutes a deceptive act and practice in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

COUNT III: UNSUBSTANTIATED REPRESENTATIONS

24. Through the means described in Paragraph 5, Respondent has represented, expressly or by implication, that:

- a. gRefills and gWipes will biodegrade when trashed;
- b. gRefills will biodegrade when flushed;
- c. gRefills offer an environmental benefit because they can be flushed; and/or
- d. gWipes are home compostable.

25. Through the means described in Paragraph 5, Respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 24 at the time the representations were made.

26. In truth and in fact, Respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 24, at the time the representations were made. Therefore, the representation set forth in Paragraph 25 was, and is, false or misleading.

27. Respondent's practices constitute deceptive acts or practices in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

IN WITNESS THEREOF, the Federal Trade Commission has issued this Complaint against Respondent and has caused it to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C. this eighteenth day of March, 2014.

By the Commission.

Complaint

Exhibit 1

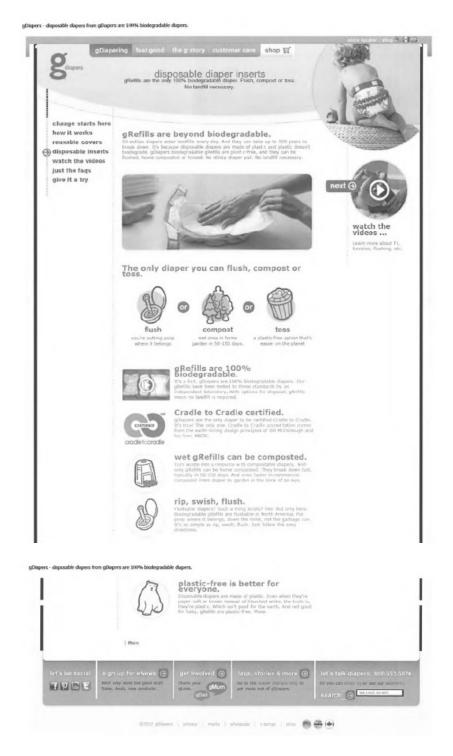


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div diapers for a lappry pla

Exhibit 2



Complaint

Exhibit 3

By diagets that are cole and easy as 1, 2, 3 ίđ. Dispering shop 🛒 change starts here G change starts here next how it works reusable covers gDiapers, cute bum, small footprint. disposable inserts watch the videos less waste q just the faqs a diaper shouldn't last forever. now it t one takes up to 500 years to lapers that are 100% be flushed, home composited, a give it a try posted, or the only diaper you can flush, compost or toss. flush toss More • nere 🕥 TPEE 0

1 62012 gOwers | privacy | inside ; whelesaw | stemar ; shop 🌐 🏶 🕑



Complaint

Exhibit 5

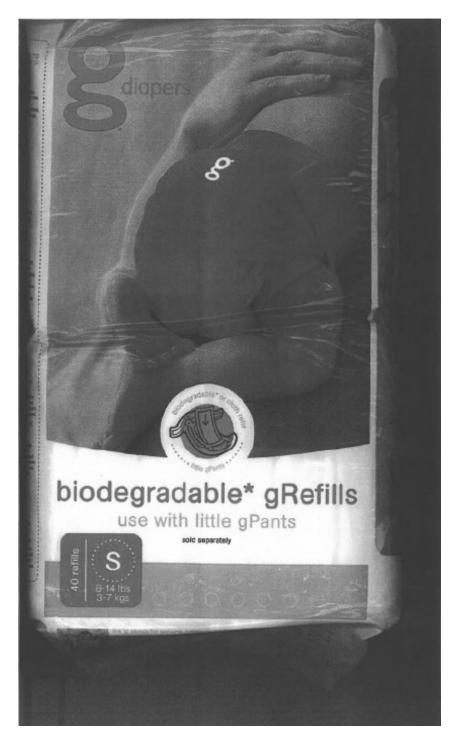




Complaint

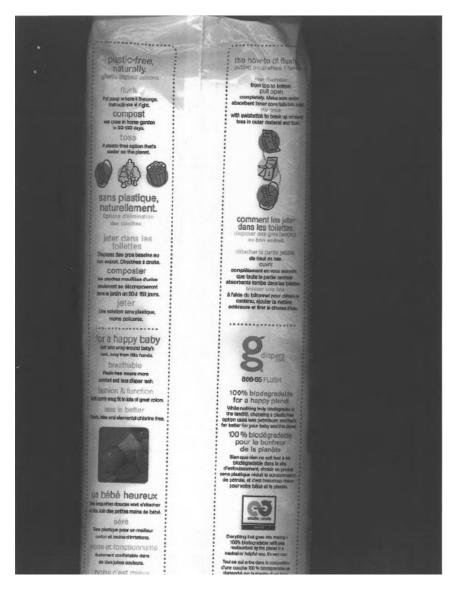
Exhibit7





Complaint





Complaint

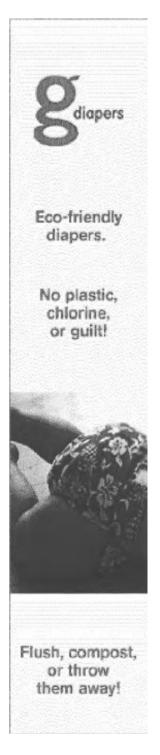
Exhibit 9





Complaint





Complaint

Exhibit 12

gDiapers - gillipes biodegradable baby wipes package. Clean up roturally SHOW SHOW shop T (1) (201 - 100g) classical. getting started little gPants head-to-toe softness, naturally. diaper inserts \$4.49 groups libered admin. Using women dates out barby values only one offer head to not software work a trach, of also and vitament E. Line glappers harby were no clean up or records, abody frigues and wet betterns -() wipes & extras top & bottom sets iy also glit certficates age and raw stres. Each packs offices case contains 17 packs my loast They're hyposilegen i, fragronce-free and alrahtig-free. Replick to holy's sanstrive size, gwiges can to home composited (seet ones only, placed) at thrown wwy. And the poop in the toolet and tole the bally wipe. You can instative assess instanting that is gripps will instal three. ton lit von Account D 175+ OKDERS SHIP FREE (Inclosed) third a state. ble derived), phospholip 0 CDM Skm Chamien), polytor basis 25 \$49,99 try it! \$10 off your first order Line caupon suit - Aller - there sign up for elilevis 🧿 lagaj stories & morio 🤕 lved 🗿 Will dray send the start shit LDV \$4000 up to the second second Survey of gMum TPET starch 🕞 🗖 O CARE

Exhibit 13



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gDispers - biodegradable gRefilis case				
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	GREEN SUPPOR	AuthorizeNet	@	

Complaint

Exhibit 14





Complaint

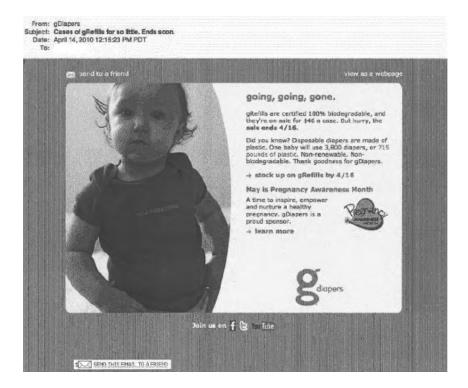


Exhibit 17



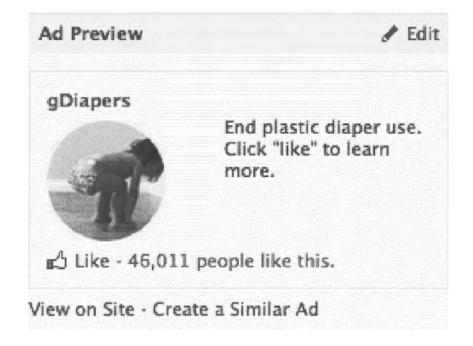
Earth-friendly diapers Flush your diapers.





Decision and Order

Exhibit 19



DECISION AND ORDER

The Federal Trade Commission, having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of a Complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued, would charge the respondent with violations of the Federal Trade Commission Act; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), which includes: a statement by respondents that they neither admit nor deny any of the allegations in the draft complaint, except as specifically stated in

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the Consent Agreement, and, only for purposes of this action, admit the facts necessary to establish jurisdiction; and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

- 1. Respondent is an Oregon Corporation with its principal office or place of business at 2808 NE Martin Luther King Jr. Boulevard, Portland, Oregon, 97212.
- 2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER DEFINITIONS

For purposes of this order, the following definitions shall apply:

- A. "Clearly and prominently" means as follows:
 - 1. In print communications, the disclosure shall be presented in a manner that stands out from the accompanying text, so that it is sufficiently prominent, because of its type size, contrast, location, or other characteristics, for an ordinary consumer to notice, read, and comprehend it;

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- 2. In communications made through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the communication. In any communication presented solely through visual or audio means, the disclosure shall be made through the same means through which the communication is presented. In any communication disseminated by means of an interactive electronic medium such as software, the Internet, or online services, the disclosure must be unavoidable. Any audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. Any visual disclosure shall be presented in a manner that stands out in the context in which it is presented, so that it is sufficiently prominent, due to its size and shade, contrast to the background against which it appears, the length of time it appears on the screen, and its location, for an ordinary consumer to notice, read, and comprehend it; and
- 3. Regardless of the medium used to disseminate it, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any communication.
- B. "Close proximity" means on the same print page, web page, online service page, or other electronic page, and proximate to the triggering representation, and not accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.
- C. "Commerce" means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. "Competent and reliable scientific evidence" means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by

Decision and Order

qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true. Specifically:

- 1. For unqualified biodegradability claims, any scientific technical protocol (or combination of protocols) substantiating such claims must assure complete decomposition within one year and replicate, *i.e.*, simulate, the physical conditions found in landfills, where most trash is disposed.
- 2. For qualified biodegradability claims, any scientific technical protocol (or combination of protocols) substantiating such claims must both:
 - a. assure the entire product will (1) completely decompose into elements found in nature in the stated timeframe or, if not qualified by time, within one year; or (2) decompose into elements found in nature at the rate and to the extent stated in the representation; and
 - b. replicate, *i.e.*, simulate, the physical conditions found in the type of disposal facility or method stated in the representation or, if not qualified by disposal facility or method, the conditions found in landfills, where most trash is disposed.
- E. "Customary disposal" means any disposal method whereby respondent's products ultimately will be disposed of in a landfill, in an incinerator, or in a recycling facility.
- F. "Degradable" includes biodegradable, oxobiodegradable, oxo-degradable, or photodegradable, or any variation thereof.

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- G. "Landfill" means a municipal solid waste landfill that receives household waste. "Landfill" does not include landfills that are operated as bioreactors or those that are actively managed to enhance decomposition.
- H. Unless otherwise specified, "respondent" means Down to Earth Designs, Inc., a corporation, and its successors and assigns.

I.

IT IS ORDERED that respondent, and its officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, package, or service, in or affecting commerce, shall not represent, in any manner, directly or indirectly, expressly or by implication:

- A. That any product or package is degradable, unless
 - 1. the entire item will completely decompose into elements found in nature within one year after customary disposal; or
 - 2. the representation is clearly and prominently and in close proximity qualified by:
 - a. Either (1) the time to complete decomposition into elements found in nature; or (2) the rate and extent of decomposition into elements found in nature, provided that such qualification must disclose that the stated rate and extent of decomposition does not mean that the product or package will continue to decompose; and
 - b. If the product will not decompose in a customary disposal facility or by a customary method of disposal, both (1) the type of non-customary disposal facility or method and (2) the availability of such disposal facility or

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method to consumers where the product or package is marketed or sold

and such representation is true, not misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

- B. That any product or package is compostable, unless all materials in the item will break down into, or otherwise become part of, usable compost (*e.g.*, soil-conditioning material, mulch) in a safe and timely manner (*i.e.*, in the same time as the materials with which it is composted):
 - 1. in a home composting pile or device;
 - 2. in a municipal or institutional composting facility that is available to a substantial majority of consumers or communities where the item is sold, and respondent discloses clearly and prominently and in close proximity to the representation that the item is only compostable in such a facility; or
 - 3. in a municipal or institutional composting facility that is not available to a substantial majority of consumers or communities, and respondent discloses clearly and prominently and in close proximity to the representation: (a) that the item is only compostable in such a facility and (b) the limited availability of municipal or institutional composting facilities that compost the item, such as by disclosing the percentage of consumers or communities that have access to such facilities,

and such representation is true, not misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

C. That any product respondent markets in whole or in part as capable of handling human waste, including,

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but not limited to, any disposable diaper product or disposable wipe, is compostable, unless respondent discloses clearly and prominently and in close proximity to the representation that the product cannot be composted if soiled with anything other than urine.

- D. That any product or package is free of, or does not contain or use, a substance, unless the representation is true, not misleading, and, at the time it is made respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation; and
 - 1. the product or package does not contain or use substances that pose the same or similar environmental risks as the substance that is not present; and
 - 2. the substance has been associated with the product category.

Provided, however, that this order shall not enjoin respondent from representing that any product or package is free of, or does not contain or use, a substance where: 1) the level of the specified substance is no more than that which would be found as an acknowledged trace contaminant or background level; 2) the substance's presence does not cause material harm that consumers typically associate with that substance; and 3) the substance has not been added intentionally to the product.

E. That any product, package, or service offers a general environmental benefit, unless respondent discloses, clearly and prominently and in close proximity to the representation, a specific environmental benefit or benefits, and, taking into account any such disclosure, all reasonable interpretations of the representation are true, not misleading, and at the time it is made, respondent possesses and relies upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that

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substantiates each reasonable interpretation of the representation.

F. That any product, package, or service offers any environmental benefit, unless the representation is true, not misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, and its officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, package, or service, in or affecting commerce, is permanently restrained and enjoined from making or assisting others in making, expressly or by implication, orally or in writing, any misrepresentation regarding certifications, including:

- A. The fact that, or degree to which, an independent thirdparty certifier or organization with appropriate expertise has evaluated a product, package, or service based on its environmental benefits or attributes; or
- B. That an independent third-party certifier or organization with appropriate expertise has evaluated the environmental benefits or attributes of any product, package, or service based on the application of objective standards.

III.

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

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- A. All advertisements, labeling, packaging and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. All acknowledgments of receipt of this order, obtained pursuant to Part IV.

IV.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this order to all current and future subsidiaries, current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities relating to the subject matter of this order. Respondent shall secure from each such person a signed and dated statement acknowledging receipt of the order, with any electronic signatures complying with the requirements of the E-Sign Act, 15 U.S.C. § 7001 *et seq.* Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

V.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a

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change in the business or corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge.

Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Mail Stop M-8102B, Washington, DC 20580. The subject line must begin: "gDiapers, File No. 122 3268."

VI.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after the date of service of this order, file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form in which respondent has complied with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate written reports. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Mail Stop 8102-B, Washington, DC 20580. The subject line must begin: "gDiapers, File No. 122 3268."

VII.

This order will terminate on March 18, 2034, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided*, *however*, that the filing of such a complaint will not affect the duration of:

Analysis to Aid Public Comment

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Down to Earth Designs, Inc. d/b/a gDiapers, a corporation ("respondent").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

Analysis to Aid Public Comment

This matter involves respondent's marketing, sale, and distribution of diapers and baby wipes with claims of various environmental benefits. According to the FTC's complaint, respondent represented that its diapers and wipes are biodegradable, "certified 100% biodegradable," garbage free when trashed or flushed, and plastic free. The complaint alleges that these claims were false and misleading. The complaint also alleges that respondent failed to disclose adequately that consumers can safely compost only wet used inserts and wipes. Finally, the complaint alleges that respondent did not possess and rely upon a reasonable basis to substantiate its claims that its products biodegrade when trashed or flushed, offer an environmental benefit because they can be flushed, and that its wipes are home compostable. Accordingly, the complaint alleges that respondent engaged in deceptive acts or practices in violation of Section 5(a) of the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts and practices in the future. As detailed below, Part I prohibits respondent from making specific environmental claims about any product or package unless the claim is true, not misleading, and substantiated by competent and reliable scientific evidence. Part I.A forbids respondent from making unqualified degradable claims about a product or package unless the item completely decomposes into elements found in nature within one year after customary disposal. Consistent with the FTC's Green Guides, the proposed order limits "customary disposal" to landfills, incinerators, or recycling facilities. If the item does not completely decompose within one year after customary disposal, Part I.A requires respondent to clearly and prominently disclose: (1) either the time to complete decomposition or the rate and extent of decomposition with a further disclosure that the stated rate and extent of decomposition does not mean that the item will continue to decompose; and (2) if the item does not decompose in (or by) a customary disposal facility or method, the type of non-customary disposal facility or method, and the availability of such facility or method to consumers where the item is marketed or sold.

Part I.A also requires that, at the time of any such representation, respondent must possess and rely upon competent and reliable scientific evidence substantiating the representation.

Analysis to Aid Public Comment

If respondent relies on a scientific technical protocol for substantiation, that protocol must do two things. First, it must assure that the entire product will either completely decompose in one year or the stated timeframe, or that it will decompose at the rate and to the extent stated in the representation. Second, such protocol must replicate (*i.e.*, simulate) the physical conditions found in a landfill or the disposal facility or method stated in the representation.

Part I.B prohibits respondent from making unqualified compostable claims unless all materials in the item will break down into, or otherwise become part of, usable compost in a safe and timely manner (*i.e.*, in the same time as the materials with which it is composted) in a home compost, or in a municipal or institutional composting facility, in which case respondent must clearly and prominently disclose that fact and the limited availability of such facilities.

Under Part I.C, if respondent claims that a disposable diaper or wipe is compostable, it must clearly and prominently disclose that the product cannot be composted if soiled with human waste other than urine.

Part I.D prohibits respondent from representing that any product or package is "free of" any substance unless the representation is true and not misleading, and substantiated, and unless the product or package advertised does not contain substances that pose the same or similar environmental risks and the "free of" substance has been associated with the product category.

Part I.E prohibits respondent from making general environmental benefit representations unless it discloses the product, package, or service's specific environmental benefit, and each reasonable interpretation of the representation is true and substantiated.

Part I.F prohibits the respondent from representing that any product, package, or service offers any environmental benefit unless the representation is true, not misleading, and substantiated, which when appropriate must be competent and reliable scientific evidence.

Analysis to Aid Public Comment

Part II of the proposed consent order prohibits respondent from making misrepresentations about certifications, including misrepresentations that a third-party certifier has evaluated a product, package, or service based on its environmental benefits or attributes, or that the third-party certifier has done so using objective standards.

Parts III through VI are reporting and compliance provisions. Part III requires respondent to keep and, upon request, make available to the Commission for copying: advertisements, labeling, packaging, and promotional materials containing the representations identified in Part I; materials relied upon in disseminating those representations; evidence that contradicts, qualifies, or calls into question the representations, or the basis relied upon for the representations; and all acknowledgments of receipt of the order. Part IV requires respondent to disseminate the order to subsidiaries, principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having supervisory responsibilities relating to the subject matter of the order. Part V requires notification to the FTC of changes in respondent's corporate status. Part VI requires respondent to submit an initial compliance report to the FTC within sixty (60) days of service and subsequent reports upon request.

Finally, Part VII is a "sunset" provision, which provides that the order terminates after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

Complaint

IN THE MATTER OF

ENDO HEALTH SOLUTIONS INC.; BOCA LIFE SCIENCE HOLDINGS, LLC; AND BOCA PHARMACAL, LLC

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. C-4430; File No. 131 0225 Complaint, January 29, 2014 – Decision, March 19, 2014

This consent order addresses the \$225 million acquisition by Endo Health Solutions Inc. of certain assets of Boca Pharmacal, LLC from Boca Life The complaint alleges that the acquisition, if Science Holdings, LLC. consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current and future competition in U.S. markets for (1) generic PolyViFlor 0.25mg multivitamin drops; (2) generic PolyViFlor 0.5mg multivitamin drops; (3) generic PolyViFlor 0.25mg multivitamin drops with iron; (4) generic TriViFlor 0.25mg multivitamin drops; (5) generic Bromfed-DM; (6) generic Zamicet; and (7) generic Vosol HC. The consent order requires Boca to return to Sonar all of Boca's rights related to the four prescription fluoride multivitamin drops and to continue to distribute the multivitamin drops for Sonar for a period of up to six months in order to allow Sonar time to establish itself with a new marketing and distribution partner. Further, Endo is required to divest to Rhodes all of its rights and interests in generic Bromfed-DM and generic Zamicet as well as all of Boca's rights and interests in generic Vosol HC.

Participants

For the *Commission*: *David L. Inglefield, Jacqueline K. Mendel, David von Nirschl*, and *Elyssa L. Wenzel*.

For the *Respondents*: *Robert Skitol* and *Joanne Lewers*, *Drinker Biddle & Reath LLP*; *David Pearl, Ryan Thomas*, and *David Wales, Jones Day*.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Endo

Health Solutions Inc. ("Endo"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Boca Pharmacal, LLC, an entity subject to the jurisdiction of the Commission, from Boca Life Science Holdings, LLC ("Boca") in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Endo is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its corporate office and principal place of business located at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Qualitest, a part of Endo based in Huntsville, Alabama, manufactures and markets all of Endo's generic pharmaceutical products.

2. Respondent Boca and Respondent Boca Pharmacal, LLC are limited liability companies organized, existing, and doing business under and by virtue of the laws of the State of Florida, with their corporate offices and principal places of business located at 3550 NW 126th Avenue, Coral Springs, Florida 33065.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

4. Pursuant to a Membership Purchase and Sale Agreement dated August 27, 2013 ("Agreement"), Endo proposes to acquire all of the non-corporate interests of Boca Pharmacal, LLC from its parent entity, Boca, for approximately \$225 million (the

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"Acquisition"). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT PRODUCT MARKETS

5. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following generic pharmaceutical products:

- a. generic multivitamin drops containing 0.25mg fluoride ("generic PolyViFlor 0.25mg drops");
- b. generic multivitamin drops containing 0.5mg fluoride ("generic PolyViFlor 0.5mg drops");
- c. generic multivitamin drops with 0.25mg fluoride and iron ("generic PolyViFlor 0.25mg drops with iron");
- d. generic multivitamin drops with 0.25mg fluoride and folate ("generic TriViFlor 0.25mg drops");
- e. generic oral syrup containing brompheniramine maleate (2mg/5ml), dextromethorphan hydrobromide (10mg/5ml), and pseudoephedrine hydrochloride (30mg/5ml) ("generic Bromfed-DM");
- f. generic oral solution containing hydrocodone (10mg/15ml) and acetaminophen (325mg/15ml) ("generic Zamicet"); and
- g. generic acetic acid, glacial (2%) with hydrocortisone (1%) ear drops ("generic Vosol HC").

IV. THE RELEVANT GEOGRAPHIC MARKET

6. For the purposes of this Complaint, the United States is the relevant geographic market in which to assess the competitive effects of the Acquisition in each of the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

7. Each of the multivitamin drops described herein ((1) generic PolyViFlor 0.25mg drops; (2) generic PolyViFlor 0.5mg drops; (3) generic PolyViFlor 0.25mg drops with iron; and (4) generic TriViFlor 0.25mg drops), are prescribed for children who do not have access to fluoridated water. The market for generic PolyViFlor 0.25mg drops is highly concentrated with only three current suppliers for the drug: Endo, Boca, and Libertas Pharma Inc. ("Libertas"). Endo has a market share of approximately 36%, and Libertas has a market share of approximately 5%. Thus, the Acquisition would reduce the number of suppliers of generic PolyViFlor 0.25mg drops from three to two and the merged entity would have a market share in excess of 90%. The Acquisition would increase the Herfindahl-Hirschman Index concentration ("HHI") by 4,248 for a post-merger total of 6,918.

8. Only Endo and Boca market generic PolyViFlor 0.5mg drops. Endo has a market share of approximately 61% and Boca has the remaining 39% share of the market. Thus, the Acquisition would create a monopoly in the generic PolyViFlor 0.5mg drops market and would increase the HHI by 4,758 to a total of 10,000.

9. The market for generic PolyViFlor 0.25mg drops with iron is highly concentrated with only three current suppliers: Endo, Boca, and Libertas. Endo has a market share of approximately 38%, and Libertas has a market share of approximately 6%. Thus, the Acquisition would substantially increase concentration in the market by consolidating the number of suppliers of generic PolyViFlor 0.25mg drops with iron from three to two and the merged entity would have a market share in excess of 90%. The Acquisition would increase the HHI concentration by 4,256 for a post-merger total of 8,872.

10. The market for generic TriViFlor 0.25mg drops has four suppliers: Endo, Boca, Libertas, and Sancilio & Company, Inc. ("Sancilio"). Endo has a market share of approximately 51%, Boca has a market share of approximately 22%, Libertas has a market share of approximately 26%, and Sancilio has a market share of approximately 1%. Thus, the Acquisition would

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substantially increase concentration in the market by consolidating the number of suppliers of generic TriViFlor 0.25mg drops from four to three. The Acquisition would increase the HHI concentration by 2,244 for a post-merger total of 6,006.

11. Generic Bromfed-DM is a product used for the treatment of symptoms caused by the common cold, flu, hay fever, sinusitis, bronchitis, and other respiratory illnesses. No company currently markets a generic version of Bromfed-DM in the United States. Endo and Boca are among a limited number of firms that have generic Bromfed-DM products in development. Therefore, the Acquisition would be likely to substantially increase concentration in the market by reducing the number of likely future suppliers of generic Bromfed-DM.

12. Generic Zamicet is prescribed for the relief of moderate to moderately severe pain. No company currently markets generic Zamicet in the United States. Endo and Boca are among a limited number of firms that have generic Zamicet products in development. Thus, the Acquisition would be likely to substantially increase concentration in the market by reducing the number of likely future suppliers of generic Zamicet.

13. Generic Vosol HC is a product used to treat Swimmer's Ear. The market for generic Vosol HC has three suppliers: Actavis plc ("Actavis"), the Taro Pharmaceuticals Industries Ltd. unit of Sun Pharma Industries ("Sun"), and Endo. Boca is one of a limited number of firms that has a generic Vosol HC product in development. Therefore, the Acquisition would be likely to substantially increase concentration in the market by reducing the number of likely future suppliers of generic Vosol HC.

VI. ENTRY CONDITIONS

14. Entry into the relevant markets described in Paragraphs 5 and 6 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. Entry into the markets for generic PolyViFlor 0.25mg drops, generic PolyViFlor 0.5mg drops, generic PolyViFlor 0.25mg drops with

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iron, and generic TriViFlor 0.25mg drops is particularly unlikely because new firms, unlike existing manufacturers whose facilities pre-date the FDA's current regulatory approval process, would be required to invest in filing Abbreviated New Drug Applications ("ANDAs") and wait for approvals for relatively small market opportunities. In addition, no other entry by firms for which the FDA approval process is already underway would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VII. EFFECTS OF THE ACQUISITION

15. The effects of the Acquisition, if consummated, may be to substantially lessen competition and tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- eliminating a. by actual. direct. and substantial competition between Endo and Boca and reducing the number of competitors in the markets for (1) generic PolyViFlor 0.25mg drops; (2) generic PolyViFlor 0.5mg drops; (3) generic PolyViFlor 0.25mg drops with iron; and (4) generic TriViFlor 0.25mg drops, thereby: (a) increasing the likelihood that Endo will be able to unilaterally exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors: and (c) increasing the likelihood that customers would be forced to pay higher prices; and
- b. by eliminating future competition between Endo and Boca and reducing the number of generic competitors in the markets for (1) generic oral syrup containing brompheniramine maleate (2mg/5ml),dextromethorphan hydrobromide (10mg/5ml), and pseudoephedrine hydrochloride (30 mg/5 ml): (2)generic oral solution containing hydrocodone (10mg/15ml) and acetaminophen (325mg/15ml); and generic acid. glacial (3) acetic (2%)with hydrocortisone (1%) ear drops, thereby: (a) increasing

Order to Maintain Assets

the likelihood that the combined entity would forego or delay the launch of these products, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products.

VIII. VIOLATIONS CHARGED

16. The Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

17. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-ninth day of January 2014, issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Endo Health Solutions Inc. ("Endo") of the limited liability company membership interests (referred to as membership interests in certain documents related to this proposed acquisition) of Respondent Boca Pharmacal, LLC ("Boca Pharma"), a wholly-owned affiliate of Respondent Boca Life Science Holdings, LLC ("Boca Life"), collectively "Respondents", and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of

Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

- 1. Respondent Endo is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 1400 Atwater Drive, Malvern, Pennsylvania 19355.
- 2. Respondent Boca Life is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Florida with its headquarters address located at 3550 NW 126th Avenue, Coral Springs, Florida 33065.
- Respondent Boca Pharma is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Florida with its headquarters address located at 3550 NW 126th Avenue, Coral Springs, Florida 33065.

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4. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. "Endo" means Endo Health Solutions Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Endo Health Solutions Inc. (including, without limitation, Generics International (US) Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Endo shall include Boca Pharma.
- B. "Boca Life" means: Boca Life Science Holdings, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Boca Life Science Holdings, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Boca Pharma" means: Boca Pharmacal, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Boca Pharmacal, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- D. "Respondents" means Endo, Boca Life and Boca Pharma, individually and collectively. After the Acquisition, "Respondents" means Endo and Boca Pharma, individually and collectively.
- E. "Commission" means the Federal Trade Commission.
- F. "Decision and Order" means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- G. "Divestiture Product Business(es)" means the Business of Respondents within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondents and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondents.
- H. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order
- I. "New Marketing Partner" means any Third Party(ies) designated by Sonar to market, distribute or sell the Vitamin Products.
- J. "Orders" means the Decision and Order and this Order to Maintain Assets.
- K. "Transition Period for the Vitamin Products" means for each Vitamin Product, the period beginning on the date the Order to Maintain Assets in this matter is

Order to Maintain Assets

issued by the Commission and ending, with respect to each Vitamin Product, on the earlier of the following dates: (i) the date thirty (30) days from a termination notice by Sonar and the New Marketing Partner as provided for in the Vitamin Product Divestiture Agreements; or (ii) the date six (6) months from the Order Date.

I.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the related Divestiture Product Businesses.
- B. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic marketability, viability, and competitiveness of such Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the

following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:

- 1. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for such Divestiture Product Business;
- 2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
- 3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;
- providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold by Respondents prior to August 27, 2013, at the related High Volume Accounts;
- 5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all

Order to Maintain Assets

replacements of, the assets related to such business; and

- 6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. During the Transition Period for the Vitamin Products and with respect to the Vitamin Products, Respondents, in consultation with Sonar, for the purposes of ensuring an orderly transition to the New Marketing Partner, shall:
 - develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution and sale of the Marketed Divestiture Products by the New Marketing Partner is not delayed or impaired by the Respondent;
 - 2. designate employee(s) of Respondents knowledgeable about the marketing, distribution and sale related to each of the Marketed Divestiture Products who will be responsible for communicating directly with Sonar and/or Sonar's New Marketing Partner, and the Interim Monitor (if one has been appointed), for the purpose of assisting in the transfer of the Divestiture Product Businesses to the New Marketing Partner;
 - 3. subject to delivery of sufficient levels of supply by Sonar, maintain and manage inventory levels of the

Marketed Divestiture Products in consideration of the transition;

- 4. continue to permit Sonar to use Respondents' existing product packaging and/or labeling (including Respondents' corporate name(s) and logo(s)) in manufacturing each Vitamin Product for Respondents' distribution, marketing and sale for a period of time sufficient to allow Sonar and/or its New Marketing Partner to commence the distribution, marketing and sale of that Vitamin Product (including, without limitation, sufficient time for Sonar and/or its New Marketing Partner to obtain FDA Approval (if necessary) for any new product labeling and/or packaging for each of the Vitamin Products);
- 5. continue to market, distribute and sell the Marketed Divestiture Product on behalf of Sonar;
- 6. ensure that all Confidential Business Information is delivered to Sonar:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
- 7. allow Sonar access at reasonable business hours to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the complete delivery of such Confidential Business Information to Sonar;

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- 8. establish projected time lines for accomplishing all tasks necessary to effect the transition in an efficient and timely manner;
- 9. provide Sonar with a listing of the inventory levels (weeks of supply) for each customer on a regular basis and in a timely manner;
- 10. provide Sonar with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
- 11. enter into any agreements with Sonar and/or its New Marketing Partner, on customary and commercially reasonable terms for the type of transaction or arrangement, to the extent such agreements are necessary to effectuate the foregoing.
- E. For each Acquirer of a Divestiture Product, Respondent Endo shall:
 - 1. for a period of six (6) months from the Closing Date or until the hiring of two (2) Divestiture Product Core Employees by that Acquirer or its Manufacturing Designee or its New Marketing Partner, whichever occurs earlier, provide that Acquirer, its Manufacturing Designee, or its New Marketing Partner with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"
 - 2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent Endo to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the

Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent Endo to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; provided, however, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use, and (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer, its Manufacturing Designee, or its New Marketing Partner of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondent Endo that may deter these employees from accepting employment with that Acquirer, its Manufacturing Designee or its New Marketing Partner, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondents Endo or Boca Pharma that would affect the ability or incentive of those individuals to be employed by that Acquirer, its Manufacturing Designee or its New Marketing

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Partner. In addition, Respondents Endo or Boca Pharma shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer, its Manufacturing Designee, or its New Marketing Partner;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer, its Manufacturing Designee or its New Marketing Partner to that employee;

- 4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include continuation all а of employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and
- 5. for a period of one (1) year from the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer, its Manufacturing Designee or its New Marketing Partner with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment

relationship with the Acquirer, its Manufacturing Designee or its New Marketing Partner; or hire any Divestiture Product Employee;

provided, however, Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer, its Manufacturing Designee, or its New Marketing Partner or who independently applies for employment with a Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition;

provided further, however, that any Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts any Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from any Respondent.

- F. Pending divestiture of the Divestiture Product Assets, Respondents shall:
 - 1. not use, directly or indirectly, any Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;

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- b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
- c. applicable Law;
- 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Assets, (ii) other Persons specifically authorized by such Acquirer to receive such information, (iii) the Commission, or (iv) the Interim Monitor (if any has been appointed);
- 3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the employees associated with the Business related to those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products; and
- 4. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- G. Not later than thirty (30) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the

Divestiture Products by Respondents' personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.

- H. give above-described Respondents shall the notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Respondents shall maintain complete Acquirer. records of all such notifications at Respondents' registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondents shall provide the relevant Acquirer with of all certifications, notifications copies and reminders sent to Respondents' personnel.
- I. Respondents shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- J. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

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III.

IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondent Endo has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Endo of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent Endo shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
 - 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim

Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.

- 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
- 3. The Interim Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and,
 - a. with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture that Divestiture Product and able to manufacture the Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of the Respondents; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent Endo of its intention to abandon its efforts to manufacture such Divestiture Product: or (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product:
 - b. with respect to the Vitamin Products, until the end of the Transition Period for the Vitamin Products;

provided, however, that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Order Date *unless* the Commission decides to

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extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may Respondents' reasonably request, related to compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

- H. Respondents shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders; provided, however, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.B. of the Decision and Order, and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided*, *however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the

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Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets and the Paragraphs that are enumerated in Paragraph VII.B. of the related Decision and Order, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with the Orders. Respondents shall submit at the same time a copy of their report concerning compliance with the Orders to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a detailed description of their efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondents to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
- B. a detailed description of the timing for the completion of such obligations.

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VII of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized

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representative(s) of the Commission and at the expense of the Respondent; and

B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the later of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed and the Interim Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated.

DECISION AND ORDER [Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Endo Health Solutions Inc. ("Endo") of the limited liability company membership interests (referred to as membership interests in certain documents related to this proposed acquisition) of Respondent Boca Pharmacal, LLC

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("Boca Pharma"), a wholly-owned affiliate of Respondent Boca Life Science Holdings, LLC ("Boca Life"), collectively "Respondents", and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

- 1. Respondent Endo is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 1400 Atwater Drive, Malvern, Pennsylvania 19355.
- 2. Respondent Boca Life is a limited liability company organized, existing and doing business under and by

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virtue of the laws of the State of Florida with its headquarters address located at 3550 NW 126th Avenue, Coral Springs, Florida 33065.

- 3. Respondent Boca Pharma is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Florida with its headquarters address located at 3550 NW 126th Avenue, Coral Springs, Florida 33065.
- 4. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

- A. "Endo" means Endo Health Solutions Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Endo Health Solutions Inc. (including, without limitation, Generics International (US) Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Endo shall include Boca Pharma.
- B. "Boca Life" means: Boca Life Science Holdings, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Boca Life Science Holdings, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

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- C. "Boca Pharma" means: Boca Pharmacal, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Boca Pharmacal, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- D. "Respondents" means Endo, Boca Life and Boca Pharma, individually and collectively. After the Acquisition, "Respondents" means Endo and Boca Pharma, individually and collectively.
- E. "Commission" means the Federal Trade Commission.
- F. "Acetic Acid Products" means the generic 2% acetic acid, glacial, hydrocortisone otic solution drop Product in Development by Respondent Boca Pharma.
- G. "Acquirer(s)" means the following:
 - 1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective; or
 - 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- H. "Acquisition" means Respondent Endo's acquisition of the limited liability company membership interest, a.k.a. membership interests, of Boca Pharma. The acquisition is contemplated pursuant to a *Membership Interest Purchase and Sale Agreement* by and among Generics International (US) Inc., Boca Life Science Holdings, LLC, Boca Pharmacal, LLC and certain

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members of Boca Life Science Holdings, LLC, dated as of August 27, 2013, submitted to the Commission.

- I. "Acquisition Date" means the date on which the Acquisition is consummated.
- J. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").
- K. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation and all correspondence between the thereof. Respondent and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto.
- L. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.
- M. "Brompheniramine Products" means the following: the Products in Development, manufactured, marketed,

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sold, owned or controlled by Respondent Endo pursuant to ANDA No. 202955, and any supplements, amendments, or revisions thereto.

- N. "Categorized Assets" means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), as such assets and rights are in existence as of the date the Respondent signs the Agreement Containing Consent Orders in this matter and as are maintained by the Respondent in accordance with the Asset Maintenance Order until the Closing Date:
 - 1. all rights to all of the Applications related to the specified Divestiture Product;
 - 2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
 - 3. all Product Approvals related to the specified Divestiture Product;
 - 4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
 - 5. all Product Marketing Materials related to the specified Divestiture Product;
 - 6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
 - 7. all Website(s) related exclusively to the specified Divestiture Product;
 - the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;

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- 9. a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
 - a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;
 - b. to prohibit Respondent from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
 - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondent of any such cross-referencing that is discovered by Respondent);
 - d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
 - e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is

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necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and

- f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);
- 10. all Product Development Reports related to the specified Divestiture Product;
- 11. at the option of the Acquirer of the specified Divestiture Product, all Product Assumed Contracts related to the specified Divestiture Product (copies to be provided to that Acquirer on or before the Closing Date);
- 12. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);
- 13. for any specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date, a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been

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responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;

- 14. for each specified Divestiture Product that is a Contract Manufacture Product:
 - a. a list of the inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler or distributor) as of the Closing Date; and
 - b. anticipated reorder dates for each customer as of the Closing Date;
- 15. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
- 16. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
- 17. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
- 18. all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include: (i) documents relating to any Respondent's general business strategies or practices relating to the conduct of its Business of

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generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Interim Monitor or the Acquirer of the specified Divestiture Product; (iv) formulas used to determine the final pricing of any Divestiture Product and/or Retained Products to customers and competitively sensitive pricing information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of any Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the specified Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the specified Respondent provides the Acquirer with the abovedescribed information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

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- O. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- P. "Clinical Trial(s)" means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- Q. "Closing Date" means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- R. "Confidential Business Information" means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term "Confidential Business Information" *excludes* the following:
 - 1. information relating to any Respondent's general business strategies or practices that does not discuss with particularity the Divestiture Products;
 - 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 - 3. information that is contained in documents, records or books of any Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and

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- 4. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- S. "Contract Manufacture" means, the following:
 - 1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
 - 2. to manufacture, or to cause to be manufactured, a Product that is the therapeutic equivalent (as that term is defined by the FDA) and in the identical dosage strength, formulation and presentation as a Contract Manufacture Product on behalf of an Acquirer;
 - 3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.
- T. "Contract Manufacture Product(s)" means:
 - 1. the Brompheniramine Products; and
 - 2. any ingredient, material, or component used in the manufacture of the foregoing Product including the active pharmaceutical ingredient, excipients or packaging materials;

provided however, that with the consent of the Acquirer of the specified Product, a Respondent may substitute a therapeutic equivalent (as that term is defined by the FDA) form of such Product in performance of that Respondent's agreement to Contract Manufacture.

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- U. "Development" means all preclinical and clinical drug formulation), development activities (including including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.
- V. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of a Respondent's employees' labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Direct Cost" means such cost as is provided in such Remedial Agreement for that Divestiture Product.

- W. "Divestiture Product(s)" means, the following, individually and collectively:
 - 1. the Generic Divestiture Products; and
 - 2. the Vitamin Products.
- X. "Divestiture Product Assets" means, the following, individually and collectively:

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- 1. the Generic Divestiture Product Assets; and
- 2. the Vitamin Product Divestiture Assets.
- Y. "Divestiture Product Core Employees" means:
 - 1. with respect to the Brompheniramine Products and the Hydrocodone/Acetaminophen Products, the Product Research and Development Employees and the Product Manufacturing Employees related to each Generic Divestiture Product; and
 - 2. with respect to the Vitamin Products, the Vitamin Product Marketing Employees;
- Z. "Divestiture Product License" means a perpetual, nonexclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product):
 - 1. to research and Develop the specified Divestiture Products for marketing, distribution or sale within the Geographic Territory;
 - 2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Products within the Geographic Territory;
 - 3. to import or export the specified Divestiture Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the specified Divestiture Products in the Geographic Territory; and
 - 4. to have the specified Divestiture Products made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

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provided however, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party entered into by a Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

- AA. "Divestiture Product Releasee(s)" means the following Persons:
 - 1. the Acquirer for the assets related to a particular Divestiture Product;
 - 2. any Person controlled by or under common control with that Acquirer; and
 - 3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- BB. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- CC. "Domain Name" means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, "Domain Name" shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- DD. "Drug Master Files" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- EE. "Generic Divestiture Product(s)" means the following:
 - 1. Acetic Acid Products;

- 2. Brompheniramine Products; and
- 3. Hydrocodone/Acetaminophen Products.
- FF. "Generic Divestiture Product Agreements" means, the following:
 - 1. The Asset Purchase Agreement between Generics International (US) Inc. and Rhodes Pharmaceuticals, L.P., dated January 9, 2014;
 - 2. The Assignment and Assumption Agreement between Generics International (US) Inc. and Rhodes Pharmaceuticals, L.P., dated January 9, 2014;
 - 3. The Supply Agreement between Vintage Pharmaceuticals, a wholly-owned subsidiary of Generics International (US) Inc. and doing business as Qualitest Pharmaceuticals, and Rhodes Pharmaceuticals, L.P., dated January 9, 2014; and

all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Generic Divestiture Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Generic Divestiture Product Agreements are contained in Non-Public Appendix I.

- GG. "Generic Divestiture Product Assets" means all rights, title and interest in and to all assets related to the Business within the Geographic Territory of the specified Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) related to each of the respective Generic Divestiture Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Generic Divestiture Products.
- HH. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.

- II. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- JJ. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a companywide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.
- KK. "Hydrocodone/Acetaminophen Products" means the generic Products that are both: (i) oral solutions comprised of 10 mg hydrocodone bitartrate/15ml and 325 mg acetaminophen/15 ml, and (ii) in Development, manufactured, marketed, sold, owned or controlled, by Respondent Endo pursuant to ANDA No. 203744, and any supplements, amendments, or revisions thereto.
- LL. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- MM. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- NN. "Manufacturing Designee" means any Person other than a Respondent that has been designated by an

Acquirer to manufacture a Divestiture Product for that Acquirer.

- OO. "NDC Number(s)" means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- PP. "New Marketing Partner" means any Third Party(ies) designated by Sonar to market, distribute or sell the Vitamin Products.
- QQ. "Orders" means this Decision and Order and the related Order to Maintain Assets.
- RR. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.
- SS. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- TT. "Patent(s)" means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-inpart, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- UU. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.

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- VV. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- WW. "Product Approval(s)" means any approvals. registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by related applicable Agencies to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a Product within the United States of America, and without limitation. includes. all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.
- XX. "Product Assumed Contracts" means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
 - 1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from the Respondent unless such contract applies generally to the Respondent's sales of Products to that Third Party;
 - 2. pursuant to which the Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in

connection with the manufacture of the specified Divestiture Product;

- 3. relating to any Clinical Trials involving the specified Divestiture Product;
- 4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
- relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
- 6. pursuant to which a Third Party manufactures the specified Divestiture Product on behalf of the Respondent;
- pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;
- 8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;
- 9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;
- 10. constituting confidentiality agreements involving the specified Divestiture Product;
- 11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
- 12. pursuant to which a Third Party provides any specialized services necessary to the research,

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Development, manufacture or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and/or

13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondent shall assign the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

YY. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product's sales forecasting

models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

- ZZ. "Product Development Reports" means:
 - 1. Pharmacokinetic study reports related to the specified Divestiture Product;
 - 2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
 - 3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
 - all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;

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- annual and periodic reports related to the abovedescribed Application(s), including any safety update reports;
- 6. FDA approved Product labeling related to the specified Divestiture Product;
- 7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
- 8. FDA approved patient circulars and information related to the specified Divestiture Product;
- adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
- 10. summary of Product complaints from physicians related to the specified Divestiture Product;
- 11. summary of Product complaints from customers related to the specified Divestiture Product;
- 12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
- 13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
- 14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;

- 15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
- 16. analytical methods development records related to the specified Divestiture Product;
- 17. manufacturing batch records related to the specified Divestiture Product;
- 18. stability testing records related to the specified Divestiture Product;
- 19. change in control history related to the specified Divestiture Product; and
- 20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- AAA. "Product Employee Information" means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:
 - 1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by the specified Respondent within ninety (90) days of the execution date of any Remedial Agreement);
 - 2. with respect to each such employee, the following information:
 - a. the date of hire and effective service date;
 - b. job title or position held;

- c. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, the specified Respondent may provide the employee's most recent performance appraisal;
- d. the base salary or current wages;
- e. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year and current target or guaranteed bonus, if any;
- f. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
- g. and any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees;
- 3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.
- BBB. "Product Intellectual Property" means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):
 - 1. Patents;
 - 2. Product Copyrights;
 - 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and

4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

provided, however, "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Endo" or "Boca" or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Endo, Boca Life or Boca Pharma can be identified or defined.

- CCC. "Product Licensed Intellectual Property" means the following:
 - 1. Patents that are related to a Divestiture Product that the Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by the Respondent within the two-year period immediately preceding the Acquisition;
 - 2. trade secrets. know-how. techniques, data. methods, inventions, practices, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by the Respondent within the two-year period immediately preceding the Acquisition; and

- 3. all Right(s) of Reference or Use that is either owned or controlled by, or has been granted or licensed to the Respondent that is related to the Drug Master File of an NDA of a Product that is the therapeutic equivalent (as that term is defined by the FDA) of the specified Divestiture Product.
- DDD. "Product Manufacturing Employees" means all salaried employees of a Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.
- EEE. "Product Manufacturing Technology" means all of the following related to a Divestiture Product:
 - 1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, reviews. product regulatory annual communications, control history, current and historical information associated with the FDA conformance Application(s) and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists:

- 2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and,
- 3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.
- "Product Marketing Materials" means all marketing FFF. materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (e.g., detailing reports, vendor lists, sales data), marketing information (e.g., competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research). customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.
- GGG. "Product Research and Development Employees" means all salaried employees of a Respondent who directly participated have in the research. Development, regulatory approval process, or clinical of the specified studies Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) with the eighteen (18) month period immediately prior to the Closing Date.

- HHH. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.
- III. "Product Trade Dress" means the current trade dress of a Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- JJJ. "Product Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- KKK. "Proposed Acquirer" means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to this Order.
- LLL. "Remedial Agreement(s)" means the following:
 - 1. any agreement between a Respondent(s) and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

- 2. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
- 3. any agreement between a Respondent(s) and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order. including all amendments, exhibits. attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by that Respondent(s) to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order: and/or
- 4. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.
- MMM. "Retained Product" means any Product(s) other than a Divestiture Product.
- NNN. "Rhodes" means Rhodes Pharmaceuticals, L.P., a limited partnership organized, existing, and doing business under and by virtue of the laws of the State of

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Delaware with its headquarters address located at 498 Washington Street, Coventry, Rhode Island 02816.

- OOO. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.
- PPP. "Sonar" means Sonar Products, Inc. a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey with its headquarters address located at 609-613 Industrial Road, Carlstadt, New Jersey 07072.
- QQQ. "Supply Cost" means a cost not to exceed the Respondent's (as that Respondent is identified in the definition of the respective Divestiture Product) average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; provided, however, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product.
- RRR. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

- 1. designating employees of the Respondent(s) knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
- 2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
- 3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
- 4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture the specified Divestiture Product in the quality and quantities achieved by the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), or the manufacturer and/or developer of such Divestiture Product;
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and

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- c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.
- SSS. "Third Party(ies)" means any non-governmental Person other than the following: the Respondents; or, the Acquirer of particular assets or rights pursuant to this Order.
- TTT. "Transition Period for the Vitamin Products" means for each Vitamin Product, the period beginning on the date the Order to Maintain Assets in this matter is issued by the Commission and ending, with respect to each Vitamin Product, on the earlier of the following dates: (i) the date thirty (30) days from a termination notice by Sonar and the New Marketing Partner as provided for in the Vitamin Product Divestiture Agreements; or (ii) the date six (6) months from the Order Date.
- UUU. "Vitamin Product(s)" means all of the following Products sold or distributed by Boca Pharma:
 - 1. Multi-Vitamin with Fluoride (0.25 MG) & Iron Drops (50 mL bottles sold under NDC Number 64376-0821-50);
 - Multi-Vitamin with Fluoride (0.25 MG) Drops (50 mL bottles sold under NDC Number 64376-0820-50);
 - Multi-Vitamin with Fluoride (0.50 MG) Drops (50 mL bottles sold under NDC Number 64376-0822-50);
 - Triple Vitamin with Fluoride (0.25 MG) Drops (50 mL bottles sold under NDC Number 64376-0823-50);

including, without limitation, any other package form or size of the foregoing strengths.

- VVV. "Vitamin Product Divestiture Assets" means the following assets and rights of Respondent Boca Pharma:
 - 1. for each Vitamin Product, all of Respondent Boca Pharma's rights to import, Develop, manufacture, process, commercialize, distribute, sell, advertise, market, promote, out-license, or offer for sale, any of the Vitamin Products. Such rights include, without limitation, all of the foregoing rights acquired or held by Respondent Boca Pharma as a result of any agreement with Sonar and all rights to any and all improvements to the Vitamin Products;
 - 2. all rights to all Product Marketing Materials related to each Vitamin Product;
 - all rights to all Website(s) related exclusively to each Vitamin Product;
 - all content related exclusively to each Vitamin Product that is displayed on any Website that is not dedicated exclusively to the specified Vitamin Product;
 - 5. rights, to the extent permitted by Law:
 - a. to require any Respondent to discontinue the use of the NDC Numbers related to each Vitamin Product in the sale or marketing of the specified Vitamin Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the end of the Transition Period for the Vitamin Products and *except* as may be required by applicable Law;
 - b. to prohibit any Respondent from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the end of the Transition Period

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for the Vitamin Products and *except* as may be required by applicable Law;

c. to approve the timing of any Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Vitamin Product *except* for returns, rebates, allowances, and adjustments for such Vitamin Product sold prior to the end of the Transition Period for the Vitamin Products and *except* as may be required by applicable Law;

d. to approve any notification(s) from any Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);

- 6. a list of all customers and targeted customers for each Vitamin Product and, the following:
 - a. a listing of the net sales (in either units or dollars) of the Vitamin Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the Vitamin Product on behalf of the High Volume Account and his or her business contact information;
 - b. a listing of the inventory levels (weeks of supply) for each customer as of the date the Order to Maintain Assets is issued to become final and effective; and
 - c. anticipated reorder dates for each customer as of the date the Order to Maintain Assets is issued to become final and effective.

- 7. at the option of Sonar, copies of all unfilled customer purchase orders for the specified Divestiture Product at any date during the Transition Period;
- 8. copies of all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Vitamin Product Divestiture Assets" shall not include: (i) documents relating to any Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with Vitamin particularity the Product(s): (ii) administrative, financial, and accounting records; (iii) quality control records that are determined by the Interim Monitor or Sonar not to be material to the marketing, distribution or sale of the specified Vitamin Product: (iv) competitively sensitive pricing information to the extent that it is related to the Retained Products; (v) rights to the corporate names or corporate trade dress of "Endo" or "Boca", or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by any Respondent or the related corporate logos thereof, or general registered images or symbols by which Endo, Boca Life or Boca Pharma can be identified or defined; and (vi) information that is contained in documents. records, or books of any Respondent provided to Sonar by such Respondent that is unrelated to the Vitamin Products or that is exclusively related to Retained Product(s):

provided further, however, the Respondents shall provide Sonar access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes and Respondents may require Sonar to enter into an agreement to return such original documents under

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terms that are customary and reasonable for such purposes.

- WWW. "Vitamin Product Divestiture Agreements" means, the following:
 - 1. The *Boca Vitamin Products Agreement* by and among Boca Pharmacal, LLC and Sonar Products Inc. dated January 13, 2014;
 - 2. The *Transitional Services Agreement* attached thereto (to be executed on the Closing Date for the Vitamin Product Divestiture Assets) ; and,
 - 3. all amendments, exhibits, attachments, agreements, and schedules thereto,

related to the Vitamin Product Divestiture Assets that have been approved by the Commission to accomplish the requirements of this Order. The Vitamin Product Divestiture Agreements are contained in Non-Public Appendix I.

- XXX. "Vitamin Product Marketing Employee(s)" means all employees of Respondent Boca Pharma that have been directly involved in the marketing or sales of the Vitamin Products to any High Volume Account.
- YYY. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; *provided, however*, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that:

K. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent Endo shall divest the Generic Divestiture Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Rhodes pursuant to, and in accordance with, the Generic Divestiture Product Agreement(s) (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Rhodes or to reduce any obligations of Respondent Endo under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Divestiture Product Assets is incorporated by reference into this Order and made a part hereof;

> provided, however, that if Respondent Endo has divested the Generic Divestiture Product Assets to Rhodes prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Endo that Rhodes is not an acceptable purchaser of the Generic Divestiture Product Assets, then Respondent Endo shall immediately rescind the transaction with Rhodes, in whole or in part, as directed by the Commission, and shall divest the Generic Divestiture Product Assets within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

> *provided further, however,* that if Respondent Endo has divested the Generic Divestiture Product Assets to Rhodes prior to the Order Date, and if, at the time the Commission determines to make this Order final and

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effective, the Commission notifies Respondent Endo that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Endo, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Generic Divestiture Product Assets to Rhodes (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

L. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondents shall divest the Vitamin Product Divestiture Assets (to the extent that such assets are not already owned, controlled or in the possession of Sonar), absolutely and in good faith, to Sonar pursuant to, and in accordance with, the Vitamin Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Sonar or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Vitamin Product Divestiture Assets is incorporated by reference into this Order and made a part hereof;

> *provided, however*, that if Respondents have divested the Vitamin Product Divestiture Assets to Sonar prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Vitamin Product Divestiture Assets to Sonar (including, but not limited to, entering into additional agreements or arrangements) as the Commission may

determine are necessary to satisfy the requirements of this Order.

M. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

- N. Respondents shall:
 - 1. submit to each Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
 - 2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
 - 3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees

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who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

- 4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
- 5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information, (iii) the Commission, or (iv) the Interim Monitor (if any has been appointed); and
- 6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products.
- O. For each Acquirer of a Generic Divestiture Product, Respondents shall provide, or cause to be provided to that Acquirer in a manner consistent with the Technology Transfer Standards the following:

- 1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
- 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to any Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondent Endo shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

- P. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent Endo shall:
 - 1. upon reasonable written notice and request from that Acquirer to Respondent Endo, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products related to the

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Divestiture Products acquired by that Acquirer at Supply Cost, for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the Approvals relevant Product necessarv to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent Endo, and to of supply of secure sources the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of the relevant Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) for the Divestiture Product(s) acquired by that Acquirer from Persons other than Respondent Endo;

2. make representations and warranties to such Acquirer that the Contract Manufacture Product(s) supplied by a Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the supplying Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving that Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that a Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with that Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however*,

that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by a Respondent to the Acquirer in an agreement to Contract Manufacture;

provided further, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

- 3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
- 4. make representations and warranties to each Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;

provided, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability for such a failure;

- 5. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
- 6. during the term of any agreement to Contract Manufacture, Respondent Endo shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
- 7. in the event Respondent Endo becomes unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer, then Respondent Endo shall provide a therapeutically equivalent (as that term is defined by the FDA) Product from another of Respondent Endo's facility or facilities in those instances where such facilities are being used or have previously been used, and are able to be used, by Respondents to manufacture such Product(s);
- 8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Interim Monitor to monitor compliance with the obligations to Contract Manufacture;
- 9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondents and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that

Acquirer in the same quality achieved by, or on behalf of, the relevant Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent Endo and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products;

The foregoing provisions, II.F.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer of that Contract Manufacture Product (or the Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Endo; (ii) the date the Acquirer of a particular Contract Manufacture Product notifies the Commission and Respondent Endo of its intention to abandon its efforts to manufacture such Contract Manufacture Product: (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of a particular Contract Manufacture Product has abandoned its efforts to manufacture such Contract Manufacture Product, or (iv) the date five (5) years from the Closing Date.

Q. Respondent Endo shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that

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are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent Endo (other than as necessary to comply with the requirements of this Order).

- R. Not later than thirty (30) days after the Closing Date, Respondent Endo shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent Endo's personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent Endo shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent Endo shall provide a copy of the notification to the relevant Acquirer. Respondent Endo shall maintain complete records of all such notifications at Respondent Endo's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent Endo shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent Endo's personnel.
- S. For each Acquirer of a Divestiture Product, Respondent Endo shall:
 - 1. for a period of six (6) months from the Closing Date or until the hiring of two (2) Divestiture Product Core Employees by that Acquirer or its

Manufacturing Designee or its New Marketing Partner, whichever occurs earlier, provide that Acquirer, its Manufacturing Designee, or its New Marketing Partner with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"

2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent Endo to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent Endo to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; provided, however, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use, and (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends;

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3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer, its Manufacturing Designee, or its New Marketing Partner of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondent Endo that may deter these employees from accepting employment with that Acquirer, its Manufacturing Designee or its New Marketing Partner, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondents Endo or Boca Pharma that would affect the ability or incentive of those individuals to be employed by that Acquirer, its Manufacturing Designee or its New Marketing Partner. In addition, Respondents Endo or Boca Pharma shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer, its Manufacturing Designee, or its New Marketing Partner;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer, its Manufacturing Designee or its New Marketing Partner to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful

execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer, its Manufacturing Designee or its New Marketing Partner with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer, its Manufacturing Designee or its New Marketing Partner; or hire any Divestiture Product Employee;

provided, however, Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer, its Manufacturing Designee, or its New Marketing Partner or who independently applies for employment with a Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that any Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product

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Employee who contacts any Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from any Respondent.

- T. Until Respondents complete the divestitures required by this Order and fully provide, or cause to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,
 - 1. Respondents shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that Business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
 - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product;
 - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
 - 2. Respondents shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses associated with that Divestiture Product.

- U. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer under the following:
 - 1. any Patent owned by or licensed to a Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;
 - any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to a Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the (i) the research, Development, or following: manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s): or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. Each Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from that Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United

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States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from a Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

- V. Upon reasonable written notice and request from an Acquirer to Respondent Endo, Respondent Endo shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent Endo to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.
- W. For any patent infringement suit filed prior to the Closing Date in which any Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that any Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for

the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of such Divestiture Product(s), that Respondent shall:

- 1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
- 2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
- 3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of that Respondent's outside counsel related to that Divestiture Product.
- X. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:
 - 1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory; and
 - 2. to create a viable and effective competitor, that is independent of Respondent Endo in the Business of each Divestiture Product within the Geographic Territory; and,
 - 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the

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Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondent Endo has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Endo of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent Endo shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
 - 1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with

the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

- 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
- 3. The Interim Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and,
 - a. with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture manufacture Product and able to the Divestiture Product in commercial quantities, in а manner consistent with cGMP, independently of Respondent Endo; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent Endo of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;
 - b. with respect to the Vitamin Products, the end of the Transition Period for the Vitamin Products.

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provided, however, that, the Interim Monitor's service shall not exceed five (5) years from the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may Respondents' reasonably request, related to compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent Endo, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent Endo, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence,

willful or wanton acts, or bad faith by the Interim Monitor.

- H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order. provided, however, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.B., and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

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- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

If Respondents have not fully complied with the A. obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(1) of the Federal Trade Commission Act, 15 U.S.C. § 45(1), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court appointed Divestiture Trustee, pursuant to \S 5(1) of the Federal Trade Commission Act, or any other statute enforced by the

Commission, for any failure by Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Endo, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Endo has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent Endo of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the

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end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; provided, however, the Commission may extend the divestiture period only two (2) times.

- 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Trustee may request and shall Divestiture cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court appointed Divestiture Trustee, by the court.
- 4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission. subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the

Commission; provided further, however, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.

- 5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents. such consultants. accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
- 6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or

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wanton acts, or bad faith by the Divestiture Trustee.

- 7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; provided, however, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
- The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
- 9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; provided, however, that such agreement shall not restrict the Divestiture Trustee providing from any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own

initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph V, the Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter

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into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. For each Divestiture Product that is a Contract Manufacture Product, Respondents shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondents, all as soon as reasonably practicable.
- E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with

the terms of this Order or the remedial purposes thereof.

F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding term of the Remedial any Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VII.

IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondent Endo shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- Β. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent Endo has fully complied with Paragraphs II.A., II.B., II.C., II.D.1.-II.D.3., II.E., II.F., II.I., and II.J., Respondent Endo shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent Endo shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent Endo shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:
 - 1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and

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rights, (ii) transitional services being provided by the Respondents to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

- 2. a detailed description of the timing for the completion of such obligations.
- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent Endo shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

VIII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- D. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- E. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on March 19, 2024.

By the Commission.

NON-PUBLIC APPENDIX I

AGREEMENTS RELATED TO THE DIVESTITURES

[Redacted From the Public Record Version, But Incorporated By Reference]

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Endo Health Solutions Inc. ("Endo") that is designed to remedy the anticompetitive effects in seven generic pharmaceutical markets resulting from Endo's acquisition of the non-corporate interests of Boca Pharmacal, LLC from Boca Life Science Holdings, LLC ("Boca"). Under the terms of the proposed Consent Agreement, Boca is required to relinquish all rights and assets related to Boca's four prescription fluoride multivitamin drops: (1) generic PolyViFlor 0.25mg multivitamin drops; (2) generic PolyViFlor 0.5mg multivitamin drops; (3) generic PolyViFlor 0.25mg multivitamin drops with iron; and (4) generic TriViFlor 0.25mg multivitamin drops to Sonar Products, Inc. ("Sonar"), the current manufacturer of all four multivitamin drops products. Furthermore, the parties are required to divest to Rhodes Pharmaceuticals, Inc. ("Rhodes") all of Endo's rights and interests relating to: (1) generic oral syrup containing brompheniramine maleate (2mg/5ml), dextromethorphan hydrobromide (10mg/5ml),and pseudoephedrine hydrochloride (30mg/5ml) ("generic Bromfed-DM"); (2) generic oral solution containing hydrocodone (10mg/15ml) and acetaminophen (325mg/15ml) ("generic Zamicet"); as well as Boca's rights and interests relating to generic glacial acetic acid (2%) with hydrocortisone (1%) otic drops ("generic Vosol HC").

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, or make final the Decision and Order ("Order").

Pursuant to a Purchase and Sale Agreement dated August 27, 2013, Endo proposes to acquire the non-corporate interests of Boca Pharmacal, LLC from Boca, for approximately \$225 million

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(the "Proposed Acquisition"). The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening current and future competition in U.S. markets for the following generic pharmaceutical products: (1) generic PolyViFlor 0.25mg multivitamin drops; (2) generic PolyViFlor 0.5mg multivitamin drops; (3) generic PolyViFlor 0.25mg multivitamin drops with iron; (4) generic TriViFlor 0.25mg multivitamin drops; (5) generic Bromfed-DM; (6) generic Zamicet; and (7) generic Vosol HC (collectively, the "Products"). The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of suppliers in the relevant markets, each of which has or will have a limited number of market participants. In pharmaceutical product markets with generic competition, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the number of suppliers within each relevant market would have a direct and substantial anticompetitive effect on pricing.

The Proposed Acquisition would reduce current competition in four generic prescription multivitamin markets: (1) generic PolyViFlor 0.25mg multivitamin drops; (2) generic PolyViFlor 0.5mg multivitamin drops; (3) generic PolyViFlor 0.25mg multivitamin drops with iron; and (4) generic TriViFlor 0.25mg multivitamin drops. Each of these generic multivitamin drops products contains fluoride and is prescribed for children who do not have access to fluoridated water. The structure of these markets is as follows:

• The generic PolyViFlor 0.25mg multivitamin drops market currently has three suppliers: Endo, with a market share of approximately 59%, Boca, with a market share of approximately 36%, and Libertas Pharma Inc. ("Libertas"), with a market share of approximately 5%. The proposed transaction would reduce the number of

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suppliers in this market from three to two, and would give the merged firm a market share in excess of 90%.

- Endo and Boca are the only two firms that market generic PolyViFlor 0.5mg multivitamin drops. Endo has a market share of approximately 61% and Boca has a market share of approximately 39%. Thus, the proposed transaction would create a monopoly in the generic PolyViFlor 0.5mg multivitamin drops market.
- The generic PolyViFlor 0.25mg multivitamin drops with iron market currently has three suppliers: Endo, with a market share of approximately 56%, Boca, with a market share of approximately 38%, and Libertas, with a market share of approximately 6%. The proposed transaction would reduce the number of suppliers in this market from three to two, and would give the merged firm a market share in excess of 90%.
- The generic TriViFlor 0.25mg multivitamin drops market has four participants: Endo, with a market share of approximately 51%, Libertas, with a market share of approximately 26%, Boca, with a market share of approximately 22%, and Sancilio & Company, Inc. ("Sancilio") with a market share of approximately 1%. The proposed transaction would reduce the number of suppliers of generic TriViFlor 0.25mg multivitamin drops from four to three, and would give the merged firm a market share in excess of 70%.

In addition to reducing current competition in the four generic prescription multivitamin markets, the proposed transaction would significantly reduce future competition in the generic Vosol HC market. Generic Vosol HC ear drops are prescribed for the treatment of Swimmer's Ear. Three firms currently supply generic Vosol HC: Actavis plc ("Actavis"), Sun Pharma Industries ("Sun"), and Endo. Actavis has a market share of approximately 79% and Sun has a market share of approximately 21%. Although Endo's recent market share has been minimal because it withdrew its product last year, its market share was 32% as recently as two years ago. Endo owns the Abbreviated New Drug Application for generic Vosol HC and could relaunch

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its product at any time. Boca appears poised to be the next entrant with a generic Vosol HC product. Endo's acquisition of Boca would therefore deprive consumers of the increased competition and likely price reductions that would have occurred as a result of Boca's entry.

The transaction will also reduce future competition in two generic markets that do not yet exist, but will be highly concentrated at the time Endo and Boca enter: the generic Bromfed-DM market and the generic Zamicet market. When generic entry occurs, Endo and Boca would likely be among a limited number of suppliers in both markets. Thus, the proposed transaction would significantly reduce the number of likely future suppliers of these products to the detriment of consumers.

- Generic Bromfed-DM is prescribed for the treatment of symptoms caused by the common cold, flu, sinusitis, and other respiratory illnesses. Currently, there are no generic versions of Bromfed-DM available in the United States. Endo and Boca are two of a limited number of likely potential suppliers of generic Bromfed-DM. The Proposed Acquisition would eliminate a likely entrant into what will be a concentrated market for generic Bromfed-DM.
- Generic Zamicet is prescribed for the relief of moderate to moderately severe pain. Currently, there are no generic versions of Zamicet available in the United States. Endo and Boca are two of a limited number of likely potential suppliers of generic Zamicet. The Proposed Acquisition would eliminate a likely entrant into what will be a concentrated market for generic Zamicet.

Entry

Entry into the markets for the Products would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. The combination of drug development times and regulatory requirements, including U.S. Food and Drug Administration ("FDA") approval, is costly and lengthy. Entry into the four multivitamins with fluoride markets is particularly unlikely

Analysis to Aid Public Comment

because new firms, unlike existing manufacturers whose products pre-date the FDA's current regulatory approval process, would be required to file Abbreviated New Drug Applications ("ANDAs") and wait for approvals for relatively small market opportunities.

Effects

The Proposed Acquisition would likely cause significant anticompetitive harm to consumers in the relevant generic pharmaceutical markets by eliminating current and/or future competition in concentrated existing markets or in future generic markets.

In generic pharmaceuticals markets, price is heavily influenced by the number of participants with sufficient supply. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the prices of the generic pharmaceutical products at issue continue to decrease with new entry even after a number of suppliers have entered these generic markets. Further, customers generally believe that having at least four suppliers in a generic pharmaceutical market produces more competitive prices than if fewer suppliers are available to them.

The evidence shows that anticompetitive effects are likely to result from the proposed transaction, due to a decrease in the number of independent competitors in the markets at issue. In each of the current prescription fluoride multivitamin drops markets, industry participants have indicated that the presence of Boca as a competitor has allowed them to negotiate lower prices from other suppliers, including Endo.

The evidence also shows that the Proposed Acquisition would eliminate significant future competition between Endo and Boca. Although neither Endo nor Boca currently has a marketed product in the generic Vosol HC market, and no generic product has yet gained approval in either the generic Zamicet or generic Bromfed-DM markets, the Proposed Acquisition eliminates one likely future entrant from a very limited pool of future entrants in each of these markets.

Analysis to Aid Public Comment

By eliminating the significant current and future competition between the parties, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic drugs, absent a remedy.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each of the relevant product markets. Pursuant to the Consent Agreement, Boca is required to return to Sonar all of Boca's rights related to the four prescription fluoride multivitamin drops. Sonar owns and manufactures these products and, prior to the Proposed Acquisition, had an exclusive marketing and distribution agreement with Boca for these products. Under the proposed Asset Maintenance Order, Boca is required to continue to distribute the multivitamin drops for Sonar for a period of up to six months in order to allow Sonar time to establish itself with a new marketing and distribution partner. Sonar will choose another marketing and distribution partner from among several interested parties, thereby replicating the competition in the relevant markets posed by pre-acquisition Boca.

Further, Endo is required to divest to Rhodes all of its rights and interests in generic Bromfed-DM and generic Zamicet as well as all of Boca's rights and interests in generic Vosol HC. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the acquisition.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Rhodes is not an acceptable acquirer of the divested assets, or that the manner of the divestitures is not acceptable, the parties must unwind the sale of rights to Rhodes and divest the Products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the Products if the parties fail to divest the Products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order

Analysis to Aid Public Comment

requires Endo and Boca to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Endo and Boca must transfer their respective manufacturing technologies for the Products to Rhodes and must supply Rhodes with these products during a transitional period.

The Commission has agreed to appoint a representative of Quantic Regulatory Services, LLC to act as an interim monitor to assure that Endo and Boca expeditiously comply with all of their obligations and perform all of their responsibilities pursuant to the Consent Agreement. In order to ensure that the Commission remains informed about the status of the transfer of rights and assets, the Consent Agreement requires Endo and Boca to file reports with the interim monitor who will report in writing to the Commission concerning performance by the parties of their obligations under the Consent Agreement.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.