1410141

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of	)	
NOVARTIS AG **a corporation.**	)	**DOCKET NO. C-**

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed joint venture between Respondent Novartis AG ("Novartis" or "Respondent") and GlaxoSmithKline PLC ("GSK"), and Respondent 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 Respondent and GSK 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

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent 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 Respondent 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 Respondent has 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 Novartis is a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation with its headquarters address located at Lichtstrasse 35, Basel, Switzerland, CH 4056, and the address of its United States subsidiary, Novartis Corporation, located at 230 Park Avenue, New York, New York 10169.

2. GSK is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom of Great Britain and Northern Ireland, with its headquarters address located at 980 Great West Road, Brentford Middlesex TW8 9GS, England.

3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent , 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. "Novartis" or "Respondent" means: Novartis AG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Novartis AG (including, without limitation, Novartis Consumer Health, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "GSK" means: GlaxoSmithKline plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by GlaxoSmithKline plc, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "Acquirer(s)" means the following:

1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent 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 the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

E. "Acquisition Date" means the date on which the Joint Venture is consummated.

F. "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").

G. "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 thereof, and all correspondence between a 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 a Respondent and the FDA related thereto.

H. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.

I. "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.

J. "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.

K. "Closing Date" means the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Habitrol Assets to the Acquirer pursuant to this Order.

L. "Confidential Business Information" means all information owned by, or in the possession or control of, the Respondent prior to the Acquisition Date that is not in the public domain and that is directly related to the conduct of the Business related to Habitrol. The term "Confidential Business Information" *excludes* the following:

1. information relating to the Respondent's general business strategies or practices that does not discuss with particularity Habitrol;

2. information specifically excluded from the Habitrol Assets;

3. information that is contained in documents, records or books of the Respondent that is provided to the Acquirer by the Respondent that is unrelated to Habitrol or that is exclusively related to Retained Product(s); and

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.

M. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, scale-up, development-stage , 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.

N. "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 the 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 Habitrol, "Direct Cost" means such cost as is provided in such Remedial Agreement for Habitrol.

O. "Divestiture Product License" means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property that was owned, licensed, or controlled by Respondent Novartis:

1. to research and Develop Habitrol for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell Habitrol within the Geographic Territory;
3. to import or export Habitrol to or from the Geographic Territory to the extent related to the marketing, distribution or sale of Habitrol in the Geographic Territory; and
4. to have Habitrol made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

provided however, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party entered into by the 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 the Respondent.

P. "Divestiture Product Releasee(s)" means the following Persons:

1. the Acquirer for the Habitrol Assets;
2. any Person controlled by or under common control with the Acquirer; and
3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of the Acquirer, or of such Acquirer-affiliated entities.

Q. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.

R. "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.

S. "Dr. Reddy's" means Dr. Reddy's Laboratories SA, a corporation organized, existing and doing business under and by virtue of the laws of the of the Swiss Confederation with its headquarters address located at Elizabethenanlage II, 4051, Basel Switzerland, and the address of its United States subsidiary, Dr. Reddy's Laboratories, Inc., 107 College Road East, Princeton, New Jersey 05840.

T. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.

U. "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.

V. "GSK Smoking Cessation Products" means all Products Developed, marketed, sold, owned, or controlled by the GSK under the trade names NicoDerm®, NicoDerm® CQ®, and Nicorette® and all over-the-counter Products indicated for the reduction of withdrawal symptoms, including nicotine craving, associated with quitting smoking.

W. "Habitrol" means all of the over-the-counter Products that both: (i) contain the active pharmaceutical ingredient generically known as nicotine, and (ii) that use a patch as a delivery mechanism for the active pharmaceutical ingredient, in Development, manufactured, marketed, sold, owned or controlled by Novartis prior to the Acquisition Date within the Geographic Territory. "Habitrol" includes, without limitation, all Products marketed or sold by Novartis under the trademark Habitrol® and any of the smoking cessation Products using a patch manufactured, marketed, or sold by Novartis prior to the Acquisition Date under private labels, in each case, within the Geographic Territory.

X. "Habitrol Assets" means the following assets and rights of Respondent, as such assets and rights are in existence as of the date Respondent signs the Agreement Containing Consent Orders in this matter and as are maintained by Respondent in accordance with the Asset Maintenance Order until the Closing Date:

1. all rights to all of the Applications related to Habitrol bearing NDA No. 020076;
2. all Product Intellectual Property related to Habitrol that is not Product Licensed Intellectual Property;
3. all Product Approvals related to Habitrol;
4. all Product Marketing Materials related to Habitrol;
5. all Product Scientific and Regulatory Material related to Habitrol;
6. all Website(s) related exclusively to Habitrol;
7. the content related exclusively to Habitrol that is displayed on any Website that is not dedicated exclusively to Habitrol;
8. a list of all of the NDC Numbers related to Habitrol, 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 Habitrol within an appropriate period of time following the Closing Date *except* for returns, rebates, allowances, and adjustments for sales of such Product 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 Habitrol with the Acquirer's NDC Numbers related to Habitrol;
    e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of Habitrol *except* for returns, rebates, allowances, and adjustments for Habitrol 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; 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);

9. all Product Development Reports related to Habitrol;

10. at the option of the Acquirer of Habitrol, all Product Assumed Contracts related to Habitrol (copies to be provided to the Acquirer on or before the Closing Date);

11. a list of all customers and targeted customers for Habitrol and a listing of the net sales (in either units or dollars) of Habitrol 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 Habitrol on behalf of the High Volume Account and his or her business contact information;

12. at the option of the Acquirer of Habitrol 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, and finished goods related to Habitrol;

13. copies of all unfilled customer purchase orders for Habitrol as of the Closing Date, to be provided to the Acquirer of Habitrol not later than five (5) days after the Closing Date;

14. at the option of the Acquirer of Habitrol, all unfilled customer purchase orders for Habitrol; and

15. all of the Respondent's books, records, and files to the extent directly related to the foregoing;

provided, however, that "Habitrol Assets" shall not include: (i) documents relating to the Respondent's general business strategies or practices relating to the conduct of its Business of marketing over-the-counter pharmaceutical Products, where such documents do not discuss with particularity Habitrol; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of Habitrol by the Interim Monitor or the Acquirer of Habitrol; (v) any real estate and the buildings and other permanent structures located on such real estate; (vi) the employment relationship with any employee of the Respondent; and (vii) 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 Habitrol and to Retained Products or Businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to Habitrol; or (ii) for which the Respondent has a legal obligation to retain the original copies, the 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, the Respondent shall provide the 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 Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

Y. "Habitrol Divestiture Agreements" means, the following:

1. the *Asset Purchase Agreement* by and between Dr. Reddy's Laboratories, SA and Novartis Consumer Health, Inc. dated as of October 18, 2014;

2. the *Habitrol Supply Agreement* (to be executed as attached to the *Asset Purchase Agreement*); and,

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

Z. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of Habitrol in the United States of America from Respondent was, or is projected to be among the top twenty highest of such purchase amounts by Respondent 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 Habitrol Assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.

AA. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.

BB. "Joint Venture" means the consumer health joint venture between GSK and Novartis pursuant to: (i) a *Deed of Amendment and Restatement*, dated May 29, 2014, relating to a *Contribution Agreement* between Novartis, GSK, and Leo Constellation Limited, dated April 22, 2014; and (ii) *Agreed Terms of a Shareholders' Agreement* between GSK, Novartis, and GSK Consumer Healthcare Holdings Limited, dated May 29, 2014 (together the "JV Agreements"). The JV Agreements were submitted to the Commission. The JV Agreements are contained in Non-Public Appendix II.

CC. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

DD. "Manufacturing Designee" means any Person other than the Respondent that has been designated by the Acquirer to manufacture Habitrol for the Acquirer.

EE. "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.

FF. "Orders" means this Decision and Order and the related Order to Maintain Assets.

GG. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.

HH. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

II. "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-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

JJ. "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.

KK. "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.

LL. "Product Approval(s)" means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.

MM. "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 Habitrol and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, Habitrol from Respondent unless such contract applies generally to Respondent's sales of Products to that Third Party;
2. pursuant to which 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 Habitrol;
3. relating to the particularized marketing of Habitrol or educational matters relating solely to Habitrol(s);
4. pursuant to which a Third Party manufactures Habitrol on behalf of Respondent;

5. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of Habitrol on behalf of Respondent;

6. constituting confidentiality agreements involving Habitrol (other than confidentiality agreements entered into in connection with the process conducted to find a purchaser for the Habitrol Assets as contemplated by this Order);

7. involving any royalty, licensing, covenant not to sue, or similar arrangement involving Habitrol;

8. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of Habitrol to Respondent including, but not limited to, consultation arrangements; and/or

9. pursuant to which any Third Party collaborates with Respondent in the performance of research, Development, marketing, distribution or selling of Habitrol or the Business related to Habitrol;

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

NN. "Product Copyrights" means rights to all original works of authorship of any kind directly related to Habitrol 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 the Respondent who accept employment with the 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.

OO. "Product Development Reports" means:

1. Pharmacokinetic study reports related to Habitrol;
2. Bioavailability study reports (including reference listed drug information) related to Habitrol;
3. Bioequivalence study reports (including reference listed drug information) related to Habitrol;
4. 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 Habitrol;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to Habitrol;
7. currently used or planned product package inserts (including historical change of controls summaries) related to Habitrol;
8. FDA approved patient circulars and information related to Habitrol;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to Habitrol;
10. summary of Product complaints from physicians related to Habitrol;
11. summary of Product complaints from customers related to Habitrol;
12. Product recall reports filed with the FDA related to Habitrol, 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 Habitrol;
14. reports related to Habitrol 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 Habitrol that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of Habitrol;
16. analytical methods development records related to Habitrol;
17. manufacturing batch records related to Habitrol;
18. stability testing records related to Habitrol;

19. change in control history related to Habitrol; and

20. executed validation and qualification protocols and reports related to Habitrol.

PP. "Product Intellectual Property" means all of the following related to Habitrol (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 "GSK" or "Novartis" 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 GSK or Novartis can be identified or defined.

QQ. "Product Licensed Intellectual Property" means the following:

1. Patents that are related to Habitrol that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product; and

2. trade secrets, know-how, techniques, data, inventions, practices, methods, 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 Habitrol and that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product.

RR. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of Habitrol 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 Habitrol.

SS. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.

TT. "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.

UU. "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.

VV. "Remedial Agreement(s)" means the following:

1. any agreement between the Respondent and the 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 the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to Habitrol to the benefit of the 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 the Respondent and the Acquirer (or between a Divestiture Trustee and the 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 the 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 the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to Habitrol to the benefit of the Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

WW. "Retained Product" means any Product(s) other than Habitrol.

XX. "Third Party(ies)" means any non-governmental Person other than the following: the Respondent; the Joint Venture; or, the Acquirer.

YY. "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 the Respondent; *provided, however*, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to Habitrol.

II.

IT IS FURTHER ORDERED that:

A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the Habitrol Assets and grant the related Divestiture Product License, absolutely and in good faith, to Dr. Reddy's pursuant to, and in accordance with, the Habitrol Divestiture 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 Dr. Reddy's or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Habitrol Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has divested the Habitrol Assets to Dr. Reddy's prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Dr. Reddy's is not an acceptable purchaser of the Habitrol Assets, then Respondent shall immediately rescind the transaction with Dr. Reddy's, in whole or in part, as directed by the Commission, and shall divest the Habitrol 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 has divested the Habitrol Assets to Dr. Reddy's prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Habitrol Assets to Dr. Reddy's (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.

B. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to the Acquirer, and to permit the Acquirer to continue the Business of Habitrol;

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

C. Respondent shall:

1. submit to the Acquirer, at Respondent's expense, all Confidential Business Information;
2. deliver all Confidential Business Information to the 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 Acquirer, provide the Acquirer and the Interim Monitor (if any has been appointed) with access 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 Habitrol 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 Habitrol other than as necessary to comply with the following:
    a. the requirements of this Order;
    b. Respondent's obligations to the 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, (ii) other Persons specifically authorized by the 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 Habitrol to the marketing or sales employees associated with the Business related to the GSK Smoking Cessation Products.

D. Respondent 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 Habitrol within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of the GSK Smoking Cessation 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 Habitrol as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).

E. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to Habitrol by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent 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 shall provide a copy of the notification to the Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's principal business 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 shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

F. Until Respondent completes the divestiture required by this Order,

1. Respondent shall take actions as are necessary to:

    a. maintain the full economic viability and marketability of the Businesses associated with Habitrol;

    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 Habitrol;

    d. ensure that the Habitrol Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with Habitrol; and

2. Respondent shall not sell, transfer, encumber or otherwise impair the Habitrol Assets (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 Habitrol.

G. From the Closing Date, neither the Respondent nor the Joint Venture shall join, file, prosecute or maintain any suit, in law or equity, against the Acquirer or the Divestiture Product Releasee(s) of the Acquirer under the following:

1. any Patent owned by or licensed to the 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;

2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the 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 the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of Habitrol for the purposes of marketing, sale or offer for sale within the United States of America of Habitrol; or (ii) the use within, import into, or the supply, distribution, or sale within, the United States of America of Habitrol. Respondent shall also covenant to the Acquirer that as a condition of any assignment or license from the 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 the Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of Habitrol for the purposes of marketing, sale or offer for sale within the United States of America of Habitrol; or (ii) the use within, import into, or the supply, distribution, or sale or offer for sale within, the United States of America of Habitrol. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

H. Upon reasonable written notice and request from the Acquirer to Respondent, Respondent or the Joint Venture shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent or the Joint Venture to assist the 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 Habitrol, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of Habitrol for the purposes of marketing, sale or offer for sale within the United States of America of Habitrol; or (ii) the use within, import into, or the supply, distribution, or sale within, the United States of America of Habitrol; *provided however*, the provisions of this paragraph do not apply to any employees of the Joint Venture who were not employees of the Respondent prior to the Acquisition Date.

I. For any patent infringement suit filed prior to the Closing Date in which Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that 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 Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of Habitrol for the purposes of marketing, sale or offer for sale within the United States of America of Habitrol; or (ii) the use within, import into, or the supply, distribution, or sale or offer for sale within, the United States of America of Habitrol, Respondent shall:

1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to Habitrol;
2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent the Acquirer in any ongoing patent litigation related to Habitrol; and
3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of the Respondent's outside counsel related to Habitrol.

J. The purpose of the divestiture of the Habitrol Assets and the related obligations imposed on the Respondent by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with Habitrol within the Geographic Territory; and
2. to create a viable and effective competitor that is independent of Respondent and the Joint Venture in the Business of Habitrol within the Geographic Territory; and,
3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

A. At any time after the Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondent expeditiously complies with all of its obligations and perform all of its 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 Respondent, which consent shall not be unreasonably withheld. If Respondent 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 of the identity of any proposed Interim Monitor, Respondent 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 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 Respondent's 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, Respondent 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 Respondent of the divestiture of all Habitrol Assets in a manner that fully satisfies the requirements of the Orders;

   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 Respondent's 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 reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the Habitrol Assets. Respondent 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 Respondent's compliance with the Orders.

F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, 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, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

G. Respondent 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. Respondent 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 Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's 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 Respondent of its obligations under the Order.

I. Respondent 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 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:

A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Habitrol 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(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondent 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 § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent 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 of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

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 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 Divestiture Trustee may request and shall 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 the 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 Respondent, 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 Respondent, 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 Respondent, 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 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.

8. 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. Respondent 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 from providing 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, the 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 the Acquirer or access original documents provided to the Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

A. To assure the 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 Habitrol or the assets and Businesses associated with Habitrol;

provided, however, that the 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 shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if the 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 the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Respondent shall include in each Remedial Agreement 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. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to Habitrol a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

E. 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 any term of the Remedial 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 Date, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A., II.B., II.C.1.-3., II.D., II.E., and II.F., Respondent 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 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 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 rights, and (ii) transitional services being provided by the Respondent to the Acquirer; 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 (9) years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent 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 Respondent shall notify the Commission at least thirty (30) days prior to:

A. any proposed dissolution of the Respondent;

B. any proposed acquisition, merger or consolidation of the Respondent; or

C. any other change in the 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 the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the 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 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.

X.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the Order Date.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED:

NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURE

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

NON-PUBLIC APPENDIX II
JV AGREEMENTS

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