1410142

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	)	
ELI LILLY AND COMPANY,	)	
a corporation;	)	
and	)	**Docket C-**
NOVARTIS AG,	)	
a corporation.	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Eli Lilly and Company ("Eli Lilly") of certain assets comprising the animal health division of Respondent Novartis AG ("Novartis"), 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 Eli Lilly is a corporation organized, existing and doing business under and by virtue of the laws of the State of Indiana, with its headquarters address located at Lilly Corporate Center, Indianapolis, Indiana 46285.

2. 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, CH4056, and the address of its United States subsidiary, Novartis Corporation, located at 230 Park Avenue, New York, New York 10169.

3. 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. "Eli Lilly" means, the following: Eli Lilly and Company, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Eli Lilly and Company, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Eli Lilly shall include the Novartis Animal Health Group.

B. "Novartis" means, the following: 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, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Novartis shall not include the OTC Joint Venture.

C. "Novartis Animal Health Group" means:

1. the following entities acquired or to be acquired by Eli Lilly from Novartis pursuant to the Acquisition Agreement: Novartis Animal Health Australasia Pty (Commonwealth of Australia); Novartis Saúde Animal Ltda. (Federative Republic

of Brazil); Novartis Animal Health Canada Inc. (Canada); Shanghai Novartis Animal Health Co., Ltd. (People's Republic of China); Novartis Santé Animale S.A.S. (French Republic); Novartis Tiergesundheit GmbH (Federal Republic of Germany); Novartis Animal Health S.p.A. (Italian Republic); Novartis Animal Health K.K. (Japan); Novartis Salud Animal, S.A. de C.V. (United Mexican States); Novartis Veterina d.o.o. (Republic of Slovenia); Novartis Sanidad Animal S.L. (Kingdom of Spain); Novartis Centre de Recherche Santé Animal SA (Swiss Confederation); Novartis Tiergesundheit AG (Swiss Confederation); Novartis Animal Health UK Limited (United Kingdom of Great Britain and Northern Ireland); Novartis Animal Vaccines Limited (United Kingdom of Great Britain and Northern Ireland); Vericore Limited (United Kingdom of Great Britain and Northern Ireland); Novartis Animal Health US, Inc. (United States of America);

2. the respective directors, officers, employees, agents, representatives, successors, and assigns of each of the foregoing entities;

3. the assets acquired or to be acquired by Eli Lilly from Novartis pursuant to the Acquisition Agreement and referred to as Transferred Assets in Section 2.01(b) of the Acquisition Agreement; and

4. the Businesses related to all of the foregoing entities and assets.

D. "Respondents" means Eli Lilly and Novartis, individually and collectively; *provided, however,* that from the later to occur of (i) the OTC Joint Venture Date, or (ii) the Closing Date, "Respondents" shall mean Eli Lilly.

E. "Commission" means the Federal Trade Commission.

F. "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.

G. "Acquisition" means Respondent Eli Lilly's acquisition of the Novartis Animal Health Group from Novartis pursuant to the Acquisition Agreement.

H. "Acquisition Agreement" means the *Stock and Asset Purchase Agreement* between Novartis AG and Eli Lilly and Company dated as of April 22, 2014, that was submitted by Eli Lilly to the Commission in this matter. The Acquisition Agreement is contained in Non-Public Appendix II.

I. "Acquisition Date" means the earlier of the following dates: (i) the date on which Respondent Eli Lilly acquires fifty percent (50%) or more of the voting securities of any of the entities listed in the definition of Novartis Animal Health Group; or, (ii) the date on which Respondent Eli Lilly acquires any of the assets related to such entities.

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. "Animal Study(ies)" means a controlled study in animals of the safety and/or efficacy of a Product, and includes, without limitation, such animal studies as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other animal study used in research and Development of a Product.

L. "Application(s)" means all of the following, as defined in the United States Federal Food, Drug, and Cosmetic Act, as amended: "Investigational New Animal Drug Application" ("INADA"), "New Animal Drug Application" ("NADA"), "Abbreviated New Animal Drug Application" ("ANADA"), or "Conditional New Animal Drug Application" ("CNADA"), for a Product filed or to be filed with the FDA, 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.

M. "Biological Manufacturing and Testing Materials" means:

1. Reagents;
2. assays (including, without limitation, potency and microorganism cell protein assays);
3. Master Cells;
4. Master Seeds;
5. hybridomas;
6. antibodies;
7. cell culture media and similar materials;
8. nutrient feed for cells and microorganisms;
9. challenge materials; and
10. references;

to the extent any of the foregoing are being used, have been used, or are being planned to be used for the manufacture, use, Development, or commercialization of Milbemycin.

N. "Business" means, the following: (i) the commercialization, distribution, marketing, advertisement and sale of a Product(s) within the Geographic Territory; and, (ii) the research, Development, manufacture of such Product(s) throughout the world for the purposes of the commercialization, distribution, marketing, advertisement and sale of such Product(s) within the Geographic Territory.

O. "Canine Health Product(s)" means:

1. all Products in Development, manufactured, marketed, or sold, pursuant to the following Applications, and any supplements, amendments, or revisions to such Applications:
    a. NADA #141-084 (a.k.a., Sentinel® Flavor Tabs®);
    b. NADA #141-204; and,
    c. NADA #141-333 (a.k.a., Sentinel® Spectrum®); and,
2. the following active pharmaceutical ingredients:
    a. Milbemycin;
    b. Lufenuron; and,
    c. Praziquantel.

P. "Canine Health Product Assets" means all assets and rights of Novartis related to the Business of the Canine Health Products, wherever located throughout the world, as such assets and rights are in existence as of the date the Respondents sign the Agreement Containing Consent Orders in this matter (and as such rights and assets shall be maintained by the Respondents in accordance with the Asset Maintenance Order until the Closing Date), including, the following:

1. all rights to all of the following Applications:
    a. NADA #141-084;
    b. NADA #141-204;
    c. NADA #141-333;
    d. INAD #010-416;
    e. INAD #011-044;
    f. INAD #009-165; 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 to the foregoing Applications;

2. Biological Manufacturing and Testing Materials related to Milbemycin, *provided, however*, that Respondent Eli Lilly may retain certain rights to the Biological Manufacturing and Testing Materials (to the extent such retention of rights by Respondent Eli Lilly is approved by the Commission in a Remedial Agreement);

3. all Animal Studies related to the Canine Health Products including, without limitation, all such Animal Studies for which Novartis has filed a protocol prior to the date Novartis signed the Agreement Containing Consent Orders and such protocol has been approved by the FDA, whether or not such Animal Study(ies) has been completed, *provided, however*, that for those Animal Studies solely related to expanded product labeling in order to add the indications of (i) Microfilaricide, and/or (ii) the Dipylidium caninum, Respondent Eli Lilly may receive a license from the Acquirer to the raw data for use in connection with any Retained Product;

4. all rights to the Veterinary Master File #005-225;

5. all rights to the Drug Master File #13999 (Praziquantel) to the full scope and extent licensed to Novartis from the holder and/or owner of such DMF;

6. all Product Intellectual Property related to each of the Canine Health Products, including, without limitation:

    a. the Sentinel Patents;

    b. the Sentinel® trademark (U.S. registration #2193259);

    c. Sentinel Spectrum® trademark (U.S. registration #3713732);

    d. Spectrum® trademark (U.S. registration #3508817); and,

    e. Flavor Tabs® trademark (U.S. registration #2810751), *provided, however*, that Eli Lilly may obtain a license to use the Flavor Tabs® trademark for a limited transitional period (as such transitional period is approved by the Commission in a Remedial Agreement) for use in connection with the sale or marketing of Products that use the Interceptor® , Program® or Capstar® trademarks;

7. all Product Approvals related to each of the Canine Health Products, to the extent such Products Approvals are permitted to be transferred by applicable Law;

8. all Product Manufacturing Technology, related to each of the Canine Health Products to the extent that such Product Manufacturing Technology is not: (i) Product Licensed Intellectual Property; (ii) Easy Chew Patents and Technology; (iii) the Flavor Tabs Patents and Technology; or (iv) the Flavorings;

9. all Product Marketing Materials related to each of the Canine Health Products;

10. all Product Scientific and Regulatory Materials related to each of the Canine Health Products;

11. all Process Analytical Documents related to Milbemycin;

12. all Website(s) related exclusively to each of the Canine Health Products;

13. the content related exclusively to each of the Canine Health Products that is displayed on any Website that is not dedicated exclusively to such Canine Health Product;

14. a list of all of the NDC Numbers related to each of the Canine Health Products, and rights, to the extent permitted by applicable Law:

    a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of each of the Canine Health Products *except* for existing inventory, returns, rebates, allowances, and adjustments for such Canine Health 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 Respondents 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 Respondent Eli Lilly of any such cross-referencing that is discovered by Respondent Eli Lilly);

    d. to seek cross-referencing from a customer of Novartis's NDC Numbers related to such Canine Health Product with the Acquirer's NDC Numbers related to such Canine Health Product;

    e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of each of the Canine Health Products *except* for returns, rebates, allowances, and adjustments for such Canine Health 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; and

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

15. all Product Development Reports related to each of the Canine Health Products;

16. at the option of the Acquirer, all Product Contracts related to each of the Canine Health Products;

17. for each Canine Health Product that has been marketed or sold at any time during the year immediately preceding the Closing Date:

    a. a list of all customers and targeted customers for that Canine Health Product;

    b. a profile of each customer, by customer type (*e.g.*, product distributor, retail store chains, individual veterinarian clinics, veterinarian clinic chains) including to the extent available: contact information, order history, credit levels;

    c. all customer visit reports that have been inputted into any customer relations management database;

    d. a listing of the net sales (in units and in dollars) of such Canine Health Product to such customers on a 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) of each High Volume Account that is or has been responsible for the purchase of such Canine Health Product on behalf of the High Volume Account and his or her business contact information;

18. For each Canine Health Product Core Employee that accepts an offer of employment from the Acquirer, at the Acquirer's option and to the extent transferrable, the employee's work cell phone number, cell phone, and related service provider contract;

19. for each 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;

20. at the option of the Acquirer, 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 each of the Canine Health Products;

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

22. at the option of the Acquirer, all unfilled customer purchase orders for each of the Canine Health Products;

23. at the option of the Acquirer, copies of any adverse event reports, adverse experience information, and descriptions of material events concerning safety or lack of efficacy related to any Product marketed or sold prior to April 22, 2014, by Novartis that contains Lufenuron, Milbemycin, and/or Praziquantel; and

24. all of the books, records, and files directly related to the foregoing;

provided, however, that the term "Canine Health Product Assets" *excludes*: (i) documents related to any Respondents' general business strategies or practices relating to the conduct of its Business of Products for the health of animals, where such documents do not discuss with particularity any of the Canine Health Products; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of any of the Canine Health Products by the Interim Monitor or the Acquirer; (iv) rights that are exclusively related to a Retained Product; (v) any real estate and the buildings and other permanent structures located on such real estate; (vi) all Product Licensed Intellectual Property; (vii) rights that are exclusively related to Products distributed, marketed, or sold outside the Geographic Territory; (viii) rights that are exclusively related to Products in Development that contain either Lufenuron, Milbemycin, or Praziquantel in combination with active pharmaceutical ingredients other than Lufenuron, Milbemycin or Praziquantel; (ix) rights in Milbemycin, Lufenuron, or Praziquantel for human use; and, (x) accounts receivable related to the Canine Health Products as of the Closing Date;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates, on the one hand, to a Canine Health Product and to a Retained Product, on the other hand, and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Canine Health Product; or, (ii) for which any Respondent has a legal obligation to retain the original copies, the Respondents 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 Respondents 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 Respondents provides the Acquirer with the above-described information without requiring the Respondents completely to divest themselves of information that, in content, also relates to Retained Product(s).

Q. "Canine Health Product Core Employees" means the Product Marketing Employees, the Product Research and Development Employees, the Product Manufacturing Employees and the Product Sales Employees.

R. "Canine Health Product Divestiture Agreements" means the following:

1. The *Amended and Restated Asset Purchase Agreement* between Eli Lilly and Company and Virbac S.A., dated as of October 22, 2014, and as submitted to the Commission on December 5, 2014;

2. The *Technology License Agreement* between Eli Lilly and Company and Virbac Corporation, as contained as an Exhibit to the *Asset Purchase Agreement*, to be executed on the Closing Date;

3. The *Transition Services Agreement* between Eli Lilly and Company and Virbac Corporation, as contained as an Exhibit to the *Asset Purchase Agreement*, to be executed on the Closing Date;

4. The *Manufacturing and Supply Agreement* between Eli Lilly and Company and Virbac Corporation as contained as an Exhibit to the *Asset Purchase Agreement*, to be executed on the Closing Date; and

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

S. "Canine Health Product License" means the following for use in any of the Species, to the extent applicable:

1. a perpetual, non-exclusive, fully paid-up, fully transferable, and royalty-free license(s) with rights to sublicense under all Product Licensed Intellectual Property and all Product Manufacturing Technology (to the extent any Product Manufacturing Technology is not either licensed or assigned to the Acquirer under another license or assignment pursuant to this Order) related to general manufacturing know-how that was owned, licensed, or controlled by Novartis:

    a. to research and Develop the Canine Health Products for marketing, distribution or sale of the Canine Health Products within the Geographic Territory;

    b. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Canine Health Products within the Geographic Territory;

    c. to import or export the Canine Health Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the Canine Health Products in the Geographic Territory; and

    d. to have the Canine Health Products 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 Novartis, 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 Novartis; and

2. a perpetual, non-exclusive, fully paid-up, fully transferable, royalty-free, full, complete, and unlimited Right of Reference or Use with rights to sublicense to the following Applications: NADA #140-915, NADA #141-338, NADA #141-105, NADA #141-026, NADA #141-205, NADA #141-035, and NADA #141-062 and any INAD filed related thereto, to reference or use in the following NADAs: NADA #141-084, NADA #141-204, NADA #141-333, and any New Application;

3. a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to the Easy Chew Patents and Technology for any Product that is all of the following: (i) a Parasiticide, (ii) for use in the field of the prevention or treatment of any disease or indication recognized by the FDA in any of the Species, and (iii) to be distributed, marketed or sold within the Geographic Territory;

4. a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to the Flavor Tabs Patents and Technology (other than the Sentinel Patents) for any Product that is all of the following: (i) a Parasiticide, (ii) for use in the field of the prevention or treatment of any disease or any indication recognized by the FDA in any of the Species, and (iii) to be distributed, marketed or sold within the Geographic Territory; and

5. a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to the Flavorings for any Product that is all of the following: (i) a Parasiticide, (ii) for use in the field of the prevention or treatment of any disease or any indication recognized by the FDA in any of the Species, and (iii) to be distributed, marketed or sold within the Geographic Territory; and,

6. at the Acquirer's option, a non-exclusive, fully paid up and royalty-free license for a transitional period (as such period is approved by the Commission in the Remedial Agreements) under the Capstar® Trademark (U.S. registration #2510863) to use in the labeling for Products approved under NADA #141-333 and NADA #141-204.

T. "Canine Health Product Releasee(s)" means the following Persons:

1. the Acquirer for the Canine Health Product 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, in each such case, as related to the Canine Health Products.

U. "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.

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

W. "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 any Canine Health Product. 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 any Canine Health Product;
2. information specifically excluded from the Canine Health Product Assets conveyed to the Acquirer;
3. information that is contained in documents, records or books of any Respondent that is provided to the Acquirer by a Respondent that is unrelated to any Canine Health Product 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.

X. "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; and/or,
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.

Y. "Contract Manufacture Product(s)" means the Canine Health Products that are the subject of the following Applications:

1. NADA #141-084;
2. NADA #141-333; and,
3. any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient, excipients or packaging materials to the extent necessary to produce the final end-use Product;

provided, however, that, with the consent of the Acquirer, 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.

Z. "Development" means all pre-animal study and animal study drug development activities (including formulation), 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 Animal Studies 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.

AA. "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, that 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, "Direct Cost" means such cost as is provided in such Remedial Agreement.

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. The term "Domain Name" *excludes* any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

DD. "Easy Chew Patents and Technology" means:

1. the following Patents (as registered in the countries listed, and the European Union):
    a. United States of America patent application #14/103,373 (pending);
    b. United States of America patent #8,541,019;
    c. United States of America patent #8,628,794;
    d. European Union patent #1675474 (with associated national registrations);
    e. Commonwealth of Australia patent #2004262492;
    f. Canada patent #2531150;
    g. Republic of China patent #200480021551.0;
    h. Republic of Columbia patent #19245;
    i. Hellenic Republic patent #3067891;
    j. United Mexican States patent #267922;
    k. New Zealand patent #544890; and,
    l. Russian Federation patent #2356534;

2. all trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information related to the foregoing Patents; and,

3. 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 Patents.

EE. "Flavor Tabs Patents and Technology" means:

1. the following Patents (as registered in the countries listed):

   a. Commonwealth of Australia patent #695656;

   b. Federal Republic of Germany patent #69612088;

   c. Republic of Finland patent #118788;

   d. Hellenic Republic patent #3036058;

   e. State of Israel patent #117226;

   f. Japan patent #3980638;

   g. Republic of Korea patent #418238;

   h. New Zealand patent #302661;

   i. Kingdom of Saudi Arabia patent #1467/96; and,

   j. Canada patent #2213612.

2. all trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information related to the foregoing Patents; and

3. 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 Patents.

FF. "Flavorings" means any flavor developed for or used in a Canine Health Product.

GG. "Geographic Territory" means the United States of America, including all of its territories and possessions, *unless* otherwise specified within this Order.

HH. "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.

II. "High Volume Account(s)" means any retailer, wholesaler, governmental purchaser, or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), first, in terms of units and second, in terms of dollars of sales revenue, of a Canine Health Product in the United States of America from the Novartis

Animal Health Group was, or is projected to be, among the top twenty highest of such purchase amounts by Novartis Animal Health Group's U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the Acquisition Date; (ii) the end of the last quarter that immediately preceded the Closing Date; or, (iii) the end of the last quarter following the Acquisition Date or the Closing Date.

JJ. "Humacao Facility" means the Novartis sites at (i) Route 909 Km 1.3Bo, Mariana, Humacao, PR 00791, Puerto Rico and (ii) Catano Industrial Park road 3 Km 82.2, Humacao, PR 00791, Puerto Rico that will be contributed to the OTC Joint Venture.

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

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

MM. "Lufenuron" means the active pharmaceutical ingredient lufenuron (referenced in the following Applications: NADA #141-084 and/or NADA #141-204) for use in the field of the prevention or treatment any disease or any indication recognized by the FDA in any Species in the Geographic Territory.

NN. "Manufacturing Designee" means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Canine Health Product on behalf of the Acquirer.

OO. "Master Cell(s)" means the master cell(s), working cell(s), and production cell(s) that are (i) in existence, (ii) in which Novartis has rights to, as of the date the Respondents sign the Agreement Containing Consent Orders and (iii) required or used in the production of a Product(s).

PP. "Master File(s)" means submissions made to the FDA in order to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more veterinary drugs, and includes both the master files maintained by the FDA Center for Drug Evaluation and Research (generally referred to as "Drug Master File(s)" or "DMF(s)") and those maintained by the FDA Center for Veterinary Medicine (generally referred to as "Veterinary Master File(s)" or "VMF(s)").

QQ. "Master Seed(s)" means the master seed(s), working seed(s), and production seed(s) (i) in existence, (ii) in which Novartis has rights to, as of the date the Respondents sign the Agreement Containing Consent Orders and (iii) required or used in the production of a Product(s).

RR. "Milbemycin" means the active pharmaceutical ingredient Milbemycin oxime (referenced in the following Applications: NADA #141-084, NADA #141-204, and/or NADA #141-333) for use in the field of the prevention or treatment of any disease or indication recognized by the FDA in any Species in the Geographic Territory.

SS. "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.

TT. "New Application" means any NADA for any Product for use in the field of the prevention or treatment of any disease or indication recognized by the FDA in any of the Species and to be distributed, marketed or sold within the Geographic Territory *except* a Product that either: (i) contains as its sole active pharmaceutical ingredient either Milbemycin or Lufenuron, or (ii) contains as its only two active pharmaceutical ingredients Milbemycin and Praziquantel.

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

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

WW. "OTC 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 to the Decision and Order in FTC File Number 141-0141.

XX. "OTC Joint Venture Date" means the date on which the OTC Joint Venture is consummated.

YY. "OTC MSA" means the *OTC Manufacturing and Supply Agreement* between Ex-Lax, Inc., Novartis Consumer Health Inc. and Eli Lilly and Company to be executed by the parties on or before the date of the closing for the OTC Joint venture. The OTC MSA will be contributed to and assumed by the OTC Joint Venture. The OTC MSA is contained in Non-Public Appendix II to this Order.

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

AAA. "Parasiticide" means any substance that kills parasites, whether internal or external to the animal, or inhibits or impairs the parasites' growth or reproduction.

BBB. "Patent(s)" means, whether United States or foreign: (i) patents; (ii) patent applications, including provisional patent applications; (iii) invention disclosures; and, (iv) 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.

CCC. "Praziquantel" means the active pharmaceutical ingredient praziquantel (referenced in the following Application: NADA #141-333) for use in the field of the prevention or treatment of any disease or indication recognized by the FDA in any Species in the Geographic Territory.

DDD. "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.

EEE. "Process and Analytical Documents" means, to the extent in the custody or control of the Respondents, or to the extent the Respondents have a right of access to, the following documents related to the processes and Product Manufacturing Technology used to manufacture Milbemycin and the analytical methods used to manufacture Milbemycin:

1. Master Cell and Master Seed bank documentation, which includes, but is not limited to, the following:

    a. Master Cell Line and Master Seed Generation Technical Report (including: description of the host cell history, cell line generation procedures, vector construction, and selection/cloning, if any, and stability data);

    b. Preliminary Master Cell and Master Seed Bank Preparation Technical Report (including: description of banking procedures and storage conditions, vial thaw results, and in-house and contract lab test reports (sterility, mycoplasma, and any other contaminants));

    c. Master Cell and Master Seed Stability Technical Report (including: description of methodology, evaluation of cell growth and Master Seed titers (at increasing cell age), and any results of genetic mutation studies);

    d. Master Cell and Master Seed Banking Process Description (including: list of raw materials and suppliers, list of consumables, list of equipment, media and solution recipes, culture working volumes and conditions, criteria for transfer, seed ratios and process set points);

    e. Master Cell and Master Seed Bank Specification (including: quality assurance and approved Master Cell and Master Seed Bank specification);

    f. Master Cell and Master Seed Bank Raw Materials Documentation (including: list of raw materials, source and lot numbers used for Master Cell and Master Seed banking and verification of origin);

    g. Master Cell and Master Seed Bank Batch Records (including: executed and released batch records for Master Cell and Master Seed Bank preparation and methodology and certificate of analysis); and,

    h. Master Cell and Master Seed Bank Test Reports (including: copy of test reports for safety and quality assurance testing of Master Cell and Master Seed Bank by in-house and contract lab);

2. Drug and Biological Substance Process Information Documentation, which includes the following:

    a. Cell Culture Process Description for Specified Engineering Run (including: list of raw materials and suppliers, list of consumables, list of equipment, media and solutions recipes, culture working volumes, criteria for transfer, seed ratios, process set points, sampling requirements, criteria for feeding and feed schedule);

    b. Harvest Process Description for Specified Engineering Run (including: list of raw materials and suppliers, list of consumables, list of equipment, solution recipes, process set points, sampling requirements, and criteria for initiating harvest);

    c. Purification Process Description for Specified Engineering Run (including: list of raw materials and suppliers, list of consumables, list of equipment, solution recipes, process set points, analytic and quality assurance data obtained at the beginning, during and ending of the Run, and sampling requirements);

    d. Drug Substance Formulation Process Description for Specified Engineering Run (including: list of raw materials and suppliers, list of consumables, list of equipment, solution recipes, process set points, and sampling requirements);

    e. Cell Culture Process Development Reports (*i.e.*, summary of experiments performed during development of the cell culturing process);

    f. Harvest Process Development Reports (*i.e.*, summary of experiments performed during development of the harvesting process);

    g. Purification Process Development Reports (*i.e.*, summary of experiments performed during development of the purification process);

    h. Formulation Process Development of Reports (*i.e.*, summary of experiments performed during development of the formulation process);

    i. Viral Clearance Study In-House and Contract Lab Reports (*i.e.*, summary of viral clearance/inactivation study results and conclusions (*i.e.*, total logs clearance));

    j. Drug and Biological Substance Specification (*i.e.*, the quality assurance approved drug substance specification and biological quality standards for all Components);

    k. Drug and Biological Substance Process Raw Materials Documentation (including: list of raw materials used for drug and biological substance manufacturing and verification of origin, including specifications and risk assessment);

l. Batch Records for Agency Manufacturing Standards – Purification (*i.e.*, executed and released batch records, including in-process controls and testing results);

m. Batch Records for Agency Manufacturing Standards – Formulation (*i.e.*, executed and released batch records, including in-process controls and testing results);

n. Drug Substance Stability Reports (including: summary of drug substance stability); and,

o. Test Results for Agency Manufacturing Standards (including: antibody concentration, endotoxin, sterility, mycoplasma, *in vitro* viral, and bioburden).

FFF. "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 for the prevention or treatment of disease in any species of non-human animals and/or that is the subject of an Application.

GGG. "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 Geographic Territory, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.

HHH. "Product Contracts" means all of the following contracts, agreements, or legally binding written arrangements that a Respondent is a party to:

1. that make specific reference to a Canine Health Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Canine Health Product from Novartis or the Novartis Animal Health Group;

2. pursuant to which Novartis or the Novartis Animal Health Group 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 a Canine Health Product;

3. relating to any Animal Studies involving a Canine Health Product;

4. with universities or other research institutions for the use of a Canine Health Product in scientific research;

5. relating to the particularized marketing of a Canine Health Product or educational matters to the extent related to a Canine Health Product;

6. pursuant to which a Third Party manufactures a Canine Health Product on behalf of Novartis or the Novartis Animal Health Group;

7. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Canine Health Product on behalf of Novartis or the Novartis Animal Health Group;

8. pursuant to which a Third Party provides the Product Manufacturing Technology related to a Canine Health Product to Novartis or the Novartis Animal Health Group;

9. pursuant to which a Third Party is licensed by Novartis or the Novartis Animal Health Group to use the Product Manufacturing Technology;

10. constituting confidentiality agreements involving a Canine Health Product;

11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving a Canine Health Product;

12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of a Canine Health Product to Novartis or the Novartis Animal Health Group including, but not limited to, consultation arrangements; and/or,

13. pursuant to which any Third Party collaborates with Novartis in the performance of research, Development, marketing, distribution or selling of a Canine Health Product or the Business related to such Canine Health Product;

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

III. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Canine Health 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 pre-animal study, animal study 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 Animal Studies 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 animal study 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) in connection with a divestiture under this Order; 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.

JJJ. "Product Development Reports" means:

1. Pharmacokinetic study reports related to a Product;
2. Bioavailability study reports (including reference listed drug information) related to a Product;
3. Bioequivalence study reports (including reference listed drug information) related to a Product;
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 a Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to a Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to a Product;
8. FDA approved circulars for animal owners or breeders related to a Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to a Product;
10. summary of Product complaints from veterinarians related to a Product;
11. summary of Product complaints from customers related to a Product;
12. Product recall reports filed with the FDA related to a 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 a Product;

14. reports related to a 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 a Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of a Product;

16. analytical methods development records related to a Product;

17. manufacturing batch records related to a Product;

18. stability testing records related to a Product;

19. change in control history related to a Product; and,

20. executed validation and qualification protocols and reports related to a Product.

KKK. "Product Employee Information" means the following, for each Canine Health Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Canine Health Product Core Employee (including former employees who were employed by Novartis within ninety (90) days of the Closing Date);

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 Canine Health Product; *provided*, *however*, that, in lieu of this description, the Respondents 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 Novartis'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); and,

   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; and,

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.

LLL. "Product Intellectual Property" means all of the following related to a Canine Health Product *except* the intellectual property rights that are the subject of the Canine Health Product License:

1. Patents;
2. Product Copyrights;
3. Product Trademarks;
4. Product Trade Dress;
5. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and,
6. rights to obtain and file for patents, trademarks, and copyrights and registrations related to any of the foregoing 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;
7. Master Files related to any Application including, without limitation, Master Files related to any active pharmaceutical ingredient used in a Product that is the subject of an Application; and,
8. Flavorings used in, or developed for, a Product.

The term "Product Intellectual Property" *excludes* the corporate names or corporate trade dress of "Eli Lilly", "Elanco" 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 any Respondent or the related corporate logos thereof, or general registered images or symbols by which Eli Lilly, Elanco, or Novartis can be identified or defined.

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

1. Patents (other than the Sentinel Patents) that are related to a Canine Health Product;
2. Product Software; and,
3. trade secrets, know-how, techniques, data, inventions, practices, methods, technology, formulas, 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 Canine Health Product, but, that a Respondent can demonstrate have been used for any Retained Product as of April 22, 2014;

The term "Product Licensed Intellectual Property" *excludes* the Easy Chew Patents and Technology and the Flavor Tabs Patents and Technology.

NNN. "Product Manufacturing Employee(s)" means all salaried employees of Novartis Animal Health Group who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of a Canine Health 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 twelve (12) month period immediately prior to the Closing Date.

OOO. "Product Manufacturing Technology" means all of the following related to a Canine Health 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, animal study data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance 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.

PPP. "Product Marketing Employee(s)" means all management-level employees of Novartis Animal Health Group who directly have participated (irrespective of the portion of working time involved and regardless of where the employee is physically located throughout the world) in the marketing, contracting or promotion of a Canine Health Product in the United States of America within the twelve (12) month period immediately prior to the Closing Date. These employees include, without limitation, all management-level employees having any responsibilities in the areas of sales management, brand management, sales training, market research, veterinary market and other specialty markets, but excluding administrative assistants.

QQQ. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of a Canine Health 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

dollars and units for each month), 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 a Canine Health Product.

RRR. "Product Research and Development Employee(s)" means all salaried employees of Novartis Animal Health Group who have directly participated in the research, Development, regulatory approval process, or Animal Studies of a Canine Health 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 twelve (12) month period immediately prior to the Closing Date.

SSS. "Product Sales Employee(s)" means all employees of Novartis Animal Health Group who directly have participated (irrespective of the portion of working time involved) in the detailing, marketing or promotion of the Canine Health Products in the United States directly to veterinarians, animal breeders, and/or professional distributors, within the twelve (12) month period immediately prior to the Closing Date. This includes employees trained to perform such detailing for the Canine Health Products within the twelve (12) month period immediately prior to the Closing Date.

TTT. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Animal Study materials and information.

UUU. "Product Software" means computer programs (including hosted software applications, software-as-a-service and enterprise software) related to the Canine Health Products, including all software implementations of algorithms, models, and methodologies whether in source code or object code form, databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, related to any of the foregoing and the content and information contained on any Website. The term "Product Software" includes software purchased, licensed, or used by Novartis from Third Parties that has been modified or customized for use in Business related to the Canine Health Products to the extent necessary to access or use databases and compilations, including any and all data and collections of data and documentation related to the Canine Health Products. The term "Product Software" *excludes* software that is readily purchasable or licensable from sources other than Novartis that has not been modified in a manner material to the use or function thereof (other than through user preference settings).

VVV. "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.

WWW. "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.

XXX. "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.

YYY. "Reagents(s)" means the reagents, microorganisms, antibodies, sera, proteins, clinical and tissue samples and raw materials used to perform the applicable potency, immunogenicity and/or antigen compatibility test with respect to the Product(s).

ZZZ. "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 Canine Health 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 Canine Health 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.

AAAA. "Retained Product(s)" means any product(s) other than a Canine Health Product, including all Products to be marketed or sold pursuant to the following Applications: NADA #140-915, NADA #141-338, NADA #141-105, NADA #141-026, NADA #141-205, NADA #141-035, NADA #141-062; Capstar®, and all Products approved to marketed or sold outside the Geographic Territory. The term "Retained Products" also includes Products in Development by Novartis on or before the Acquisition Date that contain either Lufenuron, Milbemycin, or Praziquantel in combination with active pharmaceutical ingredients other than Lufenuron, Milbemycin, or Praziquantel. The term "Retained Products" *excludes* all Products that are the subject of the Applications listed in the definition of Canine Health Product(s) and any Product(s) Developed by an Acquirer using any such Applications.

BBBB. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation of the quality, safety and/or efficacy of a Product (including any or all such investigations conducted *in vitro, in vivo*, and/or *in silico* and any or all Animal Studies), Product Development Reports, and/or Product Scientific and Regulatory Material for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

CCCC. "Sentinel Patents" means the following Patents (as registered in the countries listed):

1. United States of America patent #5,776,982;
2. United States of America patent #5,994,395;
3. United States of America patent #6,201,012; and,
4. Japan patent #4101898.

DDDD. "Species" means the *Canis Lupus* (canine), *Felis Catus* (feline) and/or *Mustela Putorius* (ferret) species.

EEEE. "Supply Cost" means a cost not to exceed average direct per unit cost in United States dollars of manufacturing the Canine Health Product ascribed to the Novartis Animal Health Group for the twelve (12) month period immediately preceding the Acquisition Date. The term "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 Canine Health Product, the term "Supply Cost" means the cost as specified in such Remedial Agreement for that Canine Health Product.

FFFF. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to the 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 Canine Health 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 each of the Canine Health Products 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 each of the Canine Health Products in the quality and quantities achieved by the Novartis Animal Health Group, or the manufacturer and/or developer of such Product on behalf of the Novartis Animal Health Group;

    b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell each of the Canine Health Products in commercial quantities and to meet all Agency-approved specifications for Products; and

    c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to each of the Canine Health Products.

GGGG. "Third Party(ies)" means any non-governmental Person other than the following: the Respondents; or, the Acquirer.

HHHH. "Virbac" means Virbac S.A., a corporation organized under the laws of the French Republic with its headquarters address located at 13ere rue LID - BP 27. 06511 Carros CEDEX France, and its United States subsidiary, Virbac Corporation, located at 3200 Meacham Blvd., Ft. Worth, Texas 76137.

IIII. "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. The term "Website" *excludes* the following: (i) 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 (ii) content unrelated to any of the Canine Health Products.

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, Respondents shall divest the Canine Health Product Assets and grant the Canine Health Product License, absolutely and in good faith, to Virbac pursuant to, and in accordance with, the Canine Health Product 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 Virbac or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement is incorporated by reference into this Order and made a part hereof;

provided, however, that, if Respondents have divested the Canine Health Product Assets to Virbac 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 Virbac is not an acceptable purchaser of the Canine Health Product Assets, then Respondents shall immediately rescind the transaction with Virbac, in whole or in part, as directed by the Commission, and shall divest the Canine Health 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 Respondents have divested the Canine Health Product Assets to Virbac 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 Canine Health Product Assets to Virbac (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;

provided further, however, that Respondents may retain the rights and assets that are necessary for Novartis or the OTC Joint Venture to provide transitional services to the Acquirer and/or to Contract Manufacture for the Acquirer, until the conclusion of the provision of such services or Contract Manufacture.

B. Prior to the Closing Date, Respondents shall provide the Acquirer with the opportunity to review all contracts or agreements that are Product Contracts for the purposes of determining whether or not to assume such contracts or agreements.

C. 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 Canine Health Product Assets and to grant the Canine Health Product License to an Acquirer, and to permit the Acquirer to continue the Business of each of the Canine Health Products;

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

D. Respondents shall:

1. submit to the Acquirer, at Respondents' 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, upon reasonable written notice and request, 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 each of the Canine Health Products that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any Confidential Business Information that is exclusively related to Sentinel® Spectrum® (NADA 141-333) or Sentinel® Flavor Tabs® (NADA 141-084) other than as necessary to comply with the following:

    a. the requirements of this Order;

    b. Respondents' 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 that is exclusively related to Sentinel® Spectrum® (NADA 141-333) or Sentinel® Flavor Tabs® (NADA 141-084), directly or indirectly, to any Person except (i) the Acquirer, (ii) another Respondent, but solely for the purposes enumerated in Paragraph II.D.4; (iii) other Persons specifically authorized by the Acquirer to receive such information, (iv) the Commission, or (v) the Interim Monitor (if any has been appointed); and,

6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information exclusively related to Sentinel® Spectrum® (NADA 141-333) or Sentinel® Flavor Tabs® (NADA 141-084) to the Respondents' employees associated with the Business related to those Retained Products that are indicated for the prevention or treatment of parasite(s) in any Species.

E. Respondents shall provide, or cause to be provided (through assignment, license, or otherwise) to the Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to each Canine Health Product; and,

2. all rights to all Product Manufacturing Technology (including all related intellectual property) related to each Canine Health Product that is owned by a Third Party and that, prior to the Closing Date, was licensed by Novartis for use in connection with the manufacture of such Products;

Respondents 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 the Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Canine Health Products. 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 the Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to the Acquirer.

F. Respondents shall:

1. upon reasonable written notice and request from the Acquirer to Respondent Eli Lilly, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow the Acquirer (or its Manufacturing Designee) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondents, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) from Persons other than Respondents;

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, 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 Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;

4. make representations and warranties to the 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, 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 the 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 Contract Manufacture Products that are generated or created after the Closing Date;

6. during the term of any agreement to Contract Manufacture, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);

7. in the event Respondents become (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANADA, then Respondents shall provide a therapeutically equivalent (as that term is defined by the FDA) Product from another of Respondents' facility or facilities in those instances where such facilities are being used or have previously been used, and continue to be 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; and,

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 the Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the Contract Manufacture Products in the same quality achieved by, or on behalf of, Novartis and in commercial quantities, and in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of the Acquirer that its personnel (or its 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 (or its Manufacturing Designee(s)) 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 Respondents; (ii) the date the Acquirer notifies the Commission and Respondents of its intention to abandon its efforts to manufacture a particular 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 has abandoned its efforts to manufacture a particular Contract Manufacture Product, or (iv) the date four (4) years from the Closing Date.

G. Respondents 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 Canine Health 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 are indicated for the prevention or treatment of parasite(s) in any species of companion animal, 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 as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

H. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information 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. Respondents 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. Respondents shall maintain complete 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 Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

I. Respondents shall:

1. for a period of one (1) year from the Closing Date, provide the Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Canine Health Product Core Employees. Each of these periods is hereinafter referred to as the "Canine Health 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 Respondents to provide the Product Employee Information; or (ii) ten (10) days after written request by the Acquirer, provide the Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Canine Health Product Core Employees *unless* the Law requires a mandatory notice period prior to the release of such information in which case the information shall be provided not later than ten (10) days after the expiration of the notice period. Failure by Respondents to provide the Product Employee Information for any Canine Health Product Core Employee within the time provided herein shall extend the Canine Health 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 Canine Health Product Core Employees the opportunity to enter into employment contracts during the Canine Health 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 Canine Health Product Core Employee Access Period(s), not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of the Canine Health Product Core Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Acquirer or its Manufacturing Designee. In addition, Respondents shall not make any counteroffer to such a Canine Health Product Core Employee who has received a written offer of employment from the Acquirer or its Manufacturing Designee;

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 Canine Health 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 or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Canine Health Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Canine Health Products consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of those Products and to ensure compliance with the Order to Maintain Assets. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date, 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 Canine Health 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 or its Manufacturing Designee with any amount of responsibility related to a Canine Health Product ("Canine Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Canine Product Employee;

provided, however, that Respondents may hire any former Canine Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee 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 Canine Product Employees; or (ii) hire a Canine Product Employee who contacts any Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from any Respondent.

J. Prior to the Closing Date, Respondent Novartis shall take all actions as are necessary to ensure that Respondent Eli Lilly owns or controls (i) all the Canine Health Product Assets, and (ii) the intellectual property subject to the Canine Health Product License for the purposes of the divestitures and licenses required to be effected by Respondent Eli Lilly by this Order. In addition, Respondent Novartis shall ensure that the OTC Joint Venture is fully bound to comply with the provisions of the OTC MSA that affect the Contract Manufacture and technical services related the Canine Health Products (including, without limitation, ensuring the availability of the Humacao Facility for a period of up to four (4) years from the Acquisition Date for the purposes of such Contract Manufacture).

K. Until Respondents complete the divestitures required by this Order and fully provide, or cause to be provided, the Product Manufacturing Technology related to each Canine Health Product to the Acquirer, Respondents shall comply with the Order to Maintain Assets to the extent that the Business and assets related to the Canine Health Product that are required to be divested to the Acquirer pursuant to this Order remain under the Respondents' control.

L. Respondents shall maintain or cause to be maintained a facility that is fully ready capable and approved by the FDA to manufacture the Contract Manufacture Products in commercial quantities, in a manner consistent with cGMP until the earlier of the following dates: (i) four (4) years from the Acquisition Date; or (ii) the date the Acquirer (or its Manufacturing Designee(s)) is approved by the FDA to manufacture (wherever in the world) such Contract Manufacture Product for marketing and sale in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

M. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer or the Canine Health Product Releasee(s) of the 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;

2. 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 the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Canine Health Products for the purposes of the marketing, sale or offer for sale within the United States of America of those Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Canine Health Products. Each Respondent shall also covenant to the 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 the Acquirer or the related Canine Health 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 the Canine Health Products for the purposes of the marketing, sale or offer for sale within the United States of America of those 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 the Canine Health Products. 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.

N. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents 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 any of the Canine Health Products, 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 the Canine Health Products for the purposes of the marketing, sale or offer for sale within the United States of America of such 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 Canine Health Products.

O. 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 Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Canine Health Product(s) for the purposes of the marketing, sale or offer for sale within the United States of America of such 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 the Canine

Health Products, that Respondent shall:

1. cooperate with the Acquirer and provide in a timely manner, at no greater than Direct Cost, any and all necessary technical assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Product;
2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any ongoing patent litigation related to that Product; and,
3. permit the transfer to the 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 Product.

P. Respondents shall not, in the Geographic Territory:

1. use the Product Trademark(s) related to any Canine Health Product or any mark confusingly similar to such Product Trademark(s), as a trademark, trade name, or service mark;
2. attempt to register such Product Trademarks;
3. attempt to register any mark confusingly similar to such Product Trademarks; and/or,
4. challenge or interfere with Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties.

Q. The purpose of the divestiture of the Canine Health Product Assets, the grant of the Canine Health Product License, and the provision of the related Product Manufacturing Technology, to an Acquirer 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 related to each Canine Health Product within the Geographic Territory;
2. to create a viable and effective competitor, that is independent of Respondents in the Business of each Canine Health Product 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 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 Respondents have 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 Respondents 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, Respondents 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 Canine Health 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, with respect to each Canine Health Product that is a Contract Manufacture Product, until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of the Acquirer) is approved by the FDA to manufacture and sell that Canine Health Product and able to manufacture the Canine Health Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (ii) the date the Acquirer notifies the Commission and Respondents of its intention to abandon its efforts to manufacture the particular Canine Health 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 the particular Canine Health Product;

   provided, however, that the Interim Monitor's service shall not exceed four (4) years from the Closing 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 reasonably request, related to Respondents' 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 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 the 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*, that beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.C., and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Canine Health 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 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 Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Canine Health 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(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), 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 § 5(*l*) 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 Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have 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 Respondents of the identity of any proposed Divestiture Trustee, Respondents 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*, that 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 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 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. 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 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, 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 redacted documents or 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 Canine Health Products or the assets and Businesses related to those Canine Health 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 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 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 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 any of the Canine Health Products 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 Eli Lilly shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within five (5) days of the Closing Date, Respondent Eli Lilly shall submit to the Commission a letter certifying the date on which the divestiture required by Paragraph II.A. occurred.

C. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II.A., II.B., II.C., II.D.1. – II.D.3, II.E., II.F., II.G., II.H., II.I. and II.J., Respondents 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. Respondents 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. Respondents shall include in their 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, (ii) transitional services being provided by the Respondents to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

2. a detailed description of the timing for the completion of such obligations.

D. Within five (5) days of OTC Joint Venture Date, Respondent Novartis shall submit to the Commission a letter certifying the date of the closing for the OTC Joint Venture.

E. 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, Respondents 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:

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 DIVESTITURES

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

NON-PUBLIC APPENDIX II
ACQUISITION AGREEMENT
AND
THE OTC MSA

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