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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Maureen K. Ohlhausen, Acting Chairman**
Edith Ramirez
Terrell McSweeny

In the Matter of	)	
C.H. Boehringer Sohn AG & Co. KG **a corporation.**	)	**Docket No. C-4601**

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent C.H. Boehringer Sohn AG & Co. KG of the animal health business of Sanofi, and Respondent having been furnished thereafter with a copy of a draft of the

1. Respondent C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing, and doing business under and by virtue of the laws of Germany with its headquarters address at Binger Strasse 173, Ingelheim am Rhein, Germany, 55216 and the address of its United States subsidiary, Boehringer Ingelheim Vetmedica, Inc., located at 3902 Gene Field Rd., St. Joseph, Missouri 64506.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER

I.

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

A. "Boehringer" means C.H. Boehringer Sohn AG & Co. KG, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Boehringer, including but not limited to Boehringer Ingelheim Vetmedica, Inc. ("BIVI"), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Boehringer shall include Merial.

B. "Sanofi" means Sanofi, a corporation organized, existing and doing business under and by virtue of the laws of France and its principal executive offices are located at 54, Rue La Boetie, 75008 Paris, France. Sanofi includes its wholly-owned subsidiaries Merial, S.A.S. and Merial Inc. and all other assets and shares comprising its animal health business.

C. "Merial" means all assets and shares comprising Sanofi's animal health business, including without limitation Merial, S.A.S. and Merial, Inc.

D. "Bayer" means Bayer AG, a corporation organized, existing and doing business under and by virtue of the laws of Germany, with its principal executive offices located at Kaiser Wilhelm-Allee, 51368 Leverkusen, Germany, and its successors, assigns, subsidiaries and divisions, including Bayer Healthcare US Funding LLC, a Delaware Limited Liability Company and Bayer HealthCareLLC, a Delaware Limited Liability Company.

E. "Elanco" means Eli Lilly and Company, a corporation organized, existing and doing business under and by virtue of the laws of the state of Indiana, with its principal executive offices located at Lilly Corporate Center, Indianapolis, Indiana, 46285, and its successors, assigns, subsidiaries and divisions, including Elanco US Inc., a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with

G. “Acquirer” means the Companion Animal Products Acquirer or the Cydectin Products Acquirer.

H. “Acquisition” means the transaction contemplated by the agreements executed by Boehringer and Sanofi on June 2, 2016, through which Boehringer will acquire the assets and shares comprising Sanofi’s animal health business and in exchange, Sanofi will acquire the assets and shares comprising Boehringer’s consumer healthcare business (excluding the consumer healthcare business in China) and receive a cash payment of approximately $5.1 billion.

I. “Acqu

limitation, potency and microorganism cell protein assays); Master Cells; Master Seeds; hybridomas; antibodies; cell culture media and similar materials; nutrient feed for cells and microorganisms; challenge material; and references that Respondent is using, are suitable for use, has used, or is planning to use in the manufacture, use, Development, or commercialization of a Companion Animal Product or a Companion Animal Pipeline Product.

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

P. "Clinical Trial(s)" means a controlled study in animals, including the target species with respect to a particular Product, of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or

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including without limitation, all dosages, strengths, formulations, routes of administration, and presentations of the Products, all Product Improvements related to the Products, and all medical and/or veterinary devices that are proprietary to Respondent and used for the administration or application of the Products:

1. Bronchi-Shield Products, meaning all Products, other than Naramune Products, that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the Bordetella bronchiseptica bacterium;
2. Calicivax Products, meaning all Products that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the calicivirus;
3. Duramune® Products, and ULTRA-Duramune Products, meaning all Products (other than Solo-Jec Products),

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c) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the virus that causes feline viral rhinotracheitis (FVR),

d) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the Chlamydia psittaci bacterium,

e) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the virus that causes feline leukemia virus (FeLV), and

f) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the feline immunodeficiency virus;

5. LeptoVax Products, meaning all Products (other than Solo-Jec Products) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the Leptospira bacterium, including without limitation, Leptospira grippotyphosa, Leptospira icterohaemorrhagiae, Leptospira canicola, and Leptospira pomona; and

6. Rabvac Products, meaning all Products that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the rabies virus marketed and sold by Respondent for use in animals prior to the Acquisition.

S. "Companion Animal Products Acquirer" means Elanco or any other Person approved by the Commission to acquire the Companion Animal Products Assets pursuant to this Order.

T. "Companion Animal Products Assets" means the Divestiture Product Assets for all Companion Animal Products and Companion Animal Pipeline Products.

U. "Companion Animal Products Business" means the Companion Animal Products Business of Respondent related to the Companion Animal Products and the Companion Animal Pipeline Products to the extent that such Business is owned, controlled, or managed by Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, Respondent.

V. "Companion Animal Products Closing Date" means the date on which the Respondent (or Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Companion Animal Products Assets to the Companion Animal Products Acquirer.

W. "Companion Animal Products Divestiture Agreements" means the following agreements between Respondent and Elanco to accomplish the requirements of the Order (attached hereto as Confidential Appendix B), and all amendments, exhibits, attachments, agreements, and schedules thereto:

1. Fort Dodge Asset Purchase Agreement by and among Boehringer Ingelheim Vetmedica, Inc. and Elanco US Inc. and Eli Lilly and Company (solely for the purposes of Section 12.16);

2. Fort Dodge License Agreement by and among Boehringer Ingelheim Vetmedica, Inc., Boehringer Ingelheim Vetmedica GMBH, and Elanco US Inc.;
3. Fort Dodge Services Agreement by and between Boehringer Ingelheim Vetmedica, Inc. and Elanco US Inc.;
4. St. Joseph Transitional Packaging Services Agreement; and
5.

3. Product Manufacturing Technology that is general manufacturing know-how (i.e. manufacturing know-how not exclusively related to Companion Animal Products or Companion Animal Pipeline Products) that relates to the Companion Animal Products Business or the Companion Animal Products Facility,

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

AA. "Component(s)" means any active ingredient, Antigen, nucleic acids encoding an Antigen, adjuvant, and/or other component of a Product that is intended to affect the efficacy or safety of an active ingredient of such Product; s aigpanion Anid Td [(R)-3(e)4(s)-1(pon3

3. all Product Improvements;
4. all Product Approvals;
5. all Product Manufacturing Technology;
6. all Product Marketing Materials;
7. all Website(s) related exclusively to the Divestiture Products divested to the same Acquirer and all content related exclusively to such Divestiture Products displayed on any other Website;
8. a list of all of the Product Code Numbers, and rights, to the extent permitted by Law:
    a) to require Respondent to discontinue the use of those Product Code Numbers other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Acquisition Date,
    b) to prohibit Respondent from seeking from any customer any type of cross-referencing of those Product Code Numbers with any Retained Products,
    c) to seek to change any cross-referencing by a customer of those Product Code Numbers with any Retained Products (including the right to receive notification from Respondent of any such cross-referencing that is discovered by Respondent),
    d) to seek cross-Res(nt)]TJ 8.82 0 Td ( )Tj [(t)-2(o ds)-1(c)4(ont)-2(i)-2(nue(t)-2(om)-2(e

documents or materials. If Respondent provides

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

DDD. “Master Cell(s)” means the master cell, working cell, and production cell existing as of the Companion Animal Closing Date required or used in the production of a Product.

EEE. “Master Files” 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

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

b) Preliminary Master Cell and Master Seed Bank Preparation Technical Report (including: description of banking procedures including 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 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 Record (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 solution 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 ma

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 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 biologica-10(g)Dualitess Dfi viral cia(a)4(n)-1

purification process, formulation process; transfer reports summarizing the results of the following transfers: cell culture process, harvest process, purification process, formulation process; and

4. Analytical Methods for Technical Transfer: potency, identity, and safety assay development report detailing the development and qualification of the assay; potency and safety assay transfer protocol, detailing responsibilities, procedures, and criteria for transfer success; and potency assay transfer report summarizing the results of the transfer.

MMM. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound that is referenced as the composition's pharmaceutically, biologically, or genetically active ingredient.

NNN. "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 the Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application or Veterinary Biological Product Authorization.

OOO. "Product Assumed Contracts" means contracts or agreements related to a Divestiture Product (cop

8. pursuant to which a Third Pa

(excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to the Divestiture Product(s) 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; all correspondence with the FDA; and all correspondence with the USDA.

RRR. "Product Development Reports" means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence to the Respondent from the FDA or USDA, as applicable to the specified Product, and from the Respondent to the FDA or USDA, as applicable to the specified Product, relating to the Application(s) or Veterinary Biological Product Authorization(s) submitted by, on behalf of, or acquired by, the Respondent related to the Divestiture Product;
5. annual and periodic reports related to the above-described Application(s) or Veterinary Biological Product Authorization(s), including any safety update reports;
6. FDA or USDA, as applicable to the specified Product, approved Product labeling related to the Divestiture Product;
7. currently used product package inserts (including historical change of controls summaries) related to the specified Divestiture Product(s);
8. FDA or USDA, as applicable to the specified Product, approved circulars for animal owners and/or breeders and information related to the Divestiture Product;
9. adverse event/serious adverse event summaries related to the Divestiture Product;
10. summary of Product complaints from physicians or veterinarians related to the Divestiture Product;
11. summary of Product complaints from customers related to the Divestiture Product; and
12. Product recall reports including those filed with the FDA or USDA, as applicable to the specified Product, related to the Divestiture Product.

SSS. “Product Intellectual Property” means all of the following related to a Divestiture Product (other than Product Licensed Intellectu

polymorphs of such active pharmaceutical ingredients), combination, formulation or line extension of, or derived from, a Cydectin Product or Cydectin Pipeline Product (including, without limitation, the addition, subtraction, substitution and/or modification of one or more Components in a Cydectin Product or Cydectin Pipeline Product).

UUU. "Product Manufacturing Technology" means:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of a Divestiture Product, including, but not limited to, the following: compositions; product specifications; processes; product designs and plans; trade secrets, ideas and concepts; manufacturing, engineering, and other manuals and drawings; standard operating procedures and flow diagrams; chemical and research records; cell culture processes (including all cell culture processes developed or being developed for use in such manufacture, and results of all experiments used to evaluate such processes); product preparation (including vial thaw and inoculum preparation), synthesis, culture (including fed-batch bioreactor culture), recovery and purification (including chromatography and filtration steps); product formulation (including concentration, buffer exchange, and excipient addition); safety, quality assurance and quality control processes, techniques and specifications; analytincep-1(t)l4(a)4(t)-h/d pl tec0a 4(t)-2Tw -21.942ditec-32.6(e)4(s)-1(s)-16(lit

otherwise conveyed, 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;

2. any agreement between Respondent and a Third Party to affect the assignment of assets or rights of Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final;

3. any agreement between Respondent 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 ric 0.012(cq)-4(4(m)f)3(t)-2J 0 -1. a
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1. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer and/or its Designee, and the Monitor, for the purpose of effecting such delivery;

2.

Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), except to the extent that Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Product(s).

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the Companion Animal Products Assets and grant the Companion Animal Products License, absolutely and in good faith, to Elanco pursuant to, and in accordance with, the Companion Animal Divestiture Agreements,

provided, however, that if Respondent has divested the Companion Animal Products Assets and granted the Companion Animal Products License to Elanco prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that Elanco is not an acceptable purchaser of the Companion Animal Products Assets or licensee of the Companion Animal Products License, then Respondent shall immediately rescind the transaction with Elanco, in whole or in part, as directed by the Commission, and shall divest the Companion Animal Products Assets and grant the Companion Animal Products License (as applicable) within one hundred eighty (180) days after this Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, that if Respondent has divested the Companion Animal Products Assets and granted the Companion Animal Products License to Elanco prior to this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture or license grant was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Companion Animal Products Assets or grant of the Companion Animal Products License, as applicable, to Elanco (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.

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Companion Animal Products Licenses to the Companion Animal Products Acquirer and permit the Acquirer to continue the Companion Animal Products Business,

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

C. Within five (5) days after the Companion Animal Products Closing Date, Respondent shall provide to the Companion Animal Products Acquirer,

1. Copies of all unfilled customer purchase orders for the Companion Animal Products as of the Companion Animal Closing Date; and

2. The information identified in Paragraphs I.SS(8), (14) and (15) regarding each Companion Animal Product iovide gdeust to tenovide tenand Companion Anim84(l)-2(P)-4(r)3

F. Respondent shall:

1. submit to the Companion Animal Acquirer, at Respondent's expense, all Confidential Business Information related to the Companion Animal Products, the Companion Animal Pipeline Product, the Companion Animal Facility or the Companion Animal Products Business ("Companion Animal Confidential Information");

2. deliver the Companion Animal Confidential Information to the Companion Animal Products Acquirer in good faith, in a timely manner, i.e., as soon as

Products Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

G. Respondent shall deliver to the Companion Animal Products Acquirer the following information regarding each Companion Animal Products Employee no later than ten (10) days after such information is requested by either the Acquirer or staff of the Commission:

1. direct contact information for the employee, including telephone number;

2. the date of hire and effective service date;

3. job title or position held;

4. a specific description of the employee's responsibilities related to the Companion Animal Products; provided, however, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;

5. the base salary or current wages;

6. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year, and current target or guaranteed bonus, if any;

7. employment status (i.e., active or on leave or disability; full-time or part-time);

8. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

9. at the Acquirer's option, a copy of all applicable employee benefit plans and summary plan descriptions (if any),

provided that, Respondent may condition providing this information for an employee whose principal place of work is not the Companion Animal Products Facility on the Acquirer's written confirmation that it will treat the information as confidential, use the information solely in connection with hiring or considering whether to hire the employees and restrict access to the information to only those employees or representatives who need such access in connection with the specified and permitted uses of the information.

H. For a period ending twelve (12) months after the Companion Animal Closing Date, Respondent shall:

1. provide the Companion Animal Acquirer with the opportunity to enter into employment contracts with the Companion Animal Products Employees. This period is hereinafter referred to as the "Companion Animal Products Employee Access Period;"

2. not interfere with the hiring or employing by the Companion Animal Acquirer of the Companion Animal Products Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with the Acquirer, including without limitation, any non-compete or nondisclosure provision of employment with respect to a Companion Animal

Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Companion Animal Acquirer;

3. not make any counteroffer to any Companion Animal Products Employee who has received a written offer of employment from the Companion Animal Acquirer; and

4. not directly or indirectly, hire, solicit or otherwise attempt to induce any employee of the Acquirer to terminate his or her employment relationship with the Acquirer;

provided, however, Respondent may hire any former employee of Respondent whose employment has been terminated by the Acquirer or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the terms of the Order, and

provided further, that Respondent may advertise for employees in newspapers, trade publications, or other media not targeted specifically at employees of the Acquirer; and may hire an employee of the Acquirer who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent;

Failure by Respondent to provide any information requested in Paragraph II.G above within the time provided therein shall extend the time period in this Paragraph II.H in an amount equal to the delay.

I. Until the Companion Animal Closing Date, Respondent shall provide all Companion Animal Products Employees with reasonable financial incentives to continue in their positions and to research, Develop, market, sell, and manufacture the Companion Animal Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Companion Animal Product(s) and to ensure successful execution of the pre-Acquisition plans for such Companion Animal Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Companion Animal Products Closing Date, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law).

J. Respondent shall:

1. upon reasonable written notice and request from the Companion Animal Acquirer to Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, in a timely manner and under reasonable terms and conditions, a supply of any requested Contract Manufacture Product at the Supply Cost, for a period of time sufficient to allow the Acquirer 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 Respondent;

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

   provided, however, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondent's aggregate liability to the Acquirer for such a breach;

3. give priority to supplying a Contract Manufacture Product to the Companion Animal Products Acquirer over manufacturing and supplying Products for Respondent's own use or sale;

4. make representations and warranties to the Companion Animal Products Acquirer that Respondent shall hold harmless and indemnify the Companion Animal Products 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 Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent,

   provided, however, that where (i) an agreement to divest the Companion Animal Products Assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, the agreement may contain limits on the Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture, upon written request of the Companion Animal Products Acquirer or the Monitor, make available to the Companion Animal Products Acquirer and the Monitor all records generated or created after the Closing Date that relate to the manufacture of the Contract Manufacture Products;

6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Products; and

7. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture.

The foregoing provisions shall remain in effect with respect to each Contract Manufacturer Product until the date the Companion Animal Products Acquirer is able to finish, fill, and package the Product in commercial quantities, in a manner consistent with Agency and Manufacturing Standards, independently of Respondent.

K. Respondent shall cease having the Naramune Products manufactured at the Companion Animal Products Facility as soon as practicable after the Companion Animal Closing Date, and in no event later than one year after the Companion Animal Closing Date.

L. Until Respondent completes the divestiture of the Companion Animal Products Assets (including fully providing Product Manufacturing Technology to the Companion Animal Acquirer) Respondent shall take all actions necessary to:

1. maintain the full economic viability and marketability of the Business associated with the Companion Animal Products;

2. minimize any risk of loss of competitive potential for that Business;

3. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Companion Animal Products;

4. ensure the assets related to the Companion Animal Products are provided to the Companion Animal Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the associated Business; and

5. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology.

M.

shall immediately rescind the transaction with Bayer, in whole or in part, as directed by the Commission, and shall divest the Cydectin Product Assets and grant the Cydectin Product License (as applicable) within one hundred eighty (180) days after this Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further that if Respondent has divested the Cydectin Product Assets and granted the Cydectin Product License to Bayer prior to this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture or license grant was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Truste20(s)-1(a)-6((nt)]TJ 2..(s)-1(,.13 i652(m)-2Tte)4(od4(nd i)-2L)21(i)-2()-2(ha)4(s)-

monitor, in consultation with Commission staff, determines that such extensions are reasonably necessary to fulfill the requirements of this Paragraph.

E. Respondent shall:

1. not enforce any agreement that limits or otherwise impairs the ability of the Cydectin Acquirer to use or to acquire the Cydectin

at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and

5. not later than thirty (30) days after the Cydectin Closing Date, provide written notification of the restrictions on the use and disclosure of Cydectin Confidential Information to all of its employees who may be in possession of or have access to Cydectin Confi

H. For a period ending twelve (12) months after the Cydectin Closing Date, Respondent shall:

1. provide the Cydectin Acquirer with the opportunity to enter into employment contracts with the Cydectin Product Employees. This period is hereinafter referred to as the "Cydectin Product Employee Access Period;"

2. not interfere with the hiring or employing by the Cydectin Acquirer of the Cydectin Product Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with the Acquirer, including without limitation, any non-compete or nondisclosure provision of employment with respect to a Cydectin Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Cydectin Acquirer;

3. not make any counteroffer to any Cydectin Product Employee who has received a written offer of employment from the Cydectin Acquirer; and

4. not directly or indirectly, hire, solicit or otherwise attempt to induce any employee of the Acquirer to terminate his or her employment relationship with the Acquirer;

provided, however, Respondent may hire any former employee of Respondent whose employment has been terminated by the Acquirer or who i
with

J. Until Respondent completes the divestiture of the Cydectin Product Assets (including fully providing Product Manufacturing Technology to the Cydectin Acquirer) Respondent shall take all actions necessary to:

1. maintain the full economic viability and marketability of the Business associated with the Cydectin Products;

2. minimize any risk of loss of competitive potential for that Business;

3. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Cydectin Products;

4. ensure the assets related to the Cydectin Products are provided to the Cydectin Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the associated Business; and

5. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology.

K. Respondent shall not sell, transfer, encumber, or otherwise impair the Cydectin Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Business related to the Cydectin Products.

IV.

IT IS FURTHER ORDERED that

A. Respondent sh ensur(e)4(l)- 1.1C[nesupt(a)4(t)-1(.)]TJ (l)-10(or)3(m)-2(pa)4(i)nupt(a)4(ti)-2(n P)-4(

a) does not use, directly or indirectly, any Confidential Business Information related to the Naramune Products other than as necessary to comply with the Fort Dodge Transitional Manufacturing and Supply Agreement by and between Boehringer Ingelheim Vetmedica, Inc. and Elanco US Inc., or any applicable Law

b) does not disclose or convey any Confidential Business Information related the Naramune Products directly or indirectly, to any Person except (i) the Respondent, other Persons specifically authorized by Respondent to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); and

c) does not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Naramune Products the marketing or sales employees associated with the Companion Animal Products Business.

B. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer, any Person controlled by or under common control with an Acquirer, the Manufacturing Designee of an Acquirer, or any Person that has an agreement with an Acquirer to commercialize, distribute, market or import a Divestiture Product:

1. under any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or

2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that

States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

C. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

D. For any patent infringement suit filed prior to the relevant Divestiture Closing Date in which Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that Respondent has prepared or is preparing to defend against as of such Divestiture Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer, Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;

2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and

3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of the Respondent's outside counsel related to that Divestiture Product.

E. The purpose of the divestiture of the Divestiture Product Assets and the related obligations imposed on the Respondent by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory;

E. Respondent

Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the

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 Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.

8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

VII.

IT IS FURTHER ORDERED that

A. I

IX.

IT IS FURTHER ORDERED that:

A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Respondent shall submit to the Commission and to the Monitor verified written reports within thirty (30) days after the date this Order is issued and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II and III, setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

   1. a detailed description of all substantive contacts, negotiations, or recommendations related to: (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) any agreement to Contract Manufacture; and

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

C. One (1) year after the Order is issued, and annually for the next nine (9) years on the anniversary of the date this Order is issued, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

X.

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

A. any proposed dissolution of Respondent;

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

C. any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance

In re C.H. Boehringer Sohn AG & Co. KG

Docket No. C-4601

Appendix A

Monitor Agreement

In re C.H. Boehringer Sohn AG & Co. KG

Docket No. C-4601

CONFIDENTIAL Appendix A-1

Exhibit to the Monitor Agreement

[Redacted From the Public Record Version,

But Incorporated By Reference]

In re C.H. Boehringer Sohn AG & Co. KG

Docket No. C-4601

In re C.H. Boehringer Sohn AG & Co. KG

Docket No. C-4601

CONFIDENTIAL Appendix C

Cydectin Products Divestiture Agreements