

Complaint

IN THE MATTER OF

SCHERING-PLOUGH CORPORATIONCONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT*Docket C-4211; File No. 071 0132**Complaint, December 28, 2007 – Decision, December 28, 2007*

This consent order addresses the \$14.4 billion acquisition by Schering-Plough Corporation (“Schering-Plough”) of Organon BioSciences N.V. from Akzo-Nobel N.V. The complaint alleged that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening competition in the U.S. market for the manufacture and sale of certain live vaccines used in poultry. The consent order requires Schering-Plough to divest or license all of the assets relating to Schering-Plough’s live vaccine for the Georgia 98 strain of infectious bronchitis (Avimune IB98); Intervet’s live fowl cholera vaccine (CHOLERV AC-PM-I); and Schering-Plough’s live MG vaccine (F V AX-MG) to Wyeth’s Fort Dodge division. Schering-Plough must also divest research and development; customer, supplier and manufacturing contracts; and certain intellectual property, including existing licenses, to Wyeth so that they can effectively compete in the live vaccines market.

Participants

For the *Commission*: Michael R. Barnett, Daniel P. Ducore, Mark Frankena, Jacqueline K. Mendel, Michael R. Moiseyev, Aylin Ozyildirim, Robert Pickett, David Schmidt, and Michael Vita.

For the *Respondent*: William Henry, Ethan Litwin, and Stephen Weissman, Howrey LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Schering-Plough Corporation (“Schering-Plough”), a corporation

Complaint

subject to the jurisdiction of the Commission, has agreed to acquire certain assets and voting securities of Akzo Nobel N.V. (“Akzo Nobel”), a corporation subject to the jurisdiction of the Commission, in violation 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 it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT SCHERING-PLOUGH CORPORATION

1. Respondent Schering-Plough is a corporation organized, existing, and doing business under and by virtue the laws of the state of New Jersey, with its headquarters address at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033-1310.

2. Respondent Schering-Plough is engaged in, among other things, the research, development, manufacture, distribution, and sale of animal health products, including live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry.

3. Respondent Schering-Plough is, and at all times herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. §12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

Complaint

II. THE ACQUIRED COMPANY

4. Akzo Nobel is a for-profit corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its headquarters address at Velperweg 76, 6824 BM Arnhem, The Netherlands. Its principal place of business in the U.S. at 120 White Plains Road, Suite 300, Tarrytown, New York 10591-5522.

5. Organon Biosciences N.V. (“Organon Biosciences”) is a corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its offices and principal place of business located at Wethouder van Eschstraat 1, 5342 AV Oss, The Netherlands. Organon Biosciences is a wholly owned subsidiary of Akzo Nobel.

6. Akzo Nobel, through its wholly-owned subsidiary, Organon Biosciences, is engaged in, among other things, the research, development, manufacture, distribution, and sale of animal health products, including live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry.

III. THE PROPOSED ACQUISITION

7. Pursuant to the terms of a Letter of Intent dated March 12, 2007 (the “Agreement”), Schering-Plough proposes to acquire 100 percent of the Organon BioSciences voting stock in a transaction valued at approximately \$14.4 billion (the “Acquisition”).

Complaint

IV. THE RELEVANT MARKETS

8. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the acquisition are the research, development, manufacture, and sale of: (a) live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry; (b) live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry; and (c) live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry.

9. For the purposes of this complaint, the United States is the relevant geographic area in which to analyze the effects of the acquisition in each of the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKET

10. The relevant market for the manufacture, distribution, and sale of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry in the United States is highly concentrated when measured by the Herfindahl-Hirschman Index ("HHI"). Respondent Schering-Plough and Akzo Nobel are the only suppliers of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry in the United States. Schering-Plough is the market leader with Avimune IB98, while Intervet competes with its MILDVAC GA-98 product. The acquisition would create a monopoly by combining the only two companies with products on the market.

11. The relevant market for the manufacture, distribution, and sale of live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry in the United States is highly concentrated when measured by the Herfindahl-Hirschman Index ("HHI"). Respondent Schering-Plough and Akzo Nobel are two of only three suppliers of live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry in the United

Complaint

States. Akzo Nobel is the market leader with its CHOLERVAC-PM-1 product, while Schering-Plough is the second leading supplier with its PM-ONEVAC-C and M-NINEVAX products. Together, Schering-Plough and Akzo Nobel account for over eighty percent of the sales in this highly concentrated market. Accordingly, the Acquisition would significantly increase the concentration levels in the United States in the market for live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, leaving Schering-Plough as the dominant supplier.

12. The relevant market for the manufacture, distribution, and sale of live *Mycoplasma gallisepticum* vaccines in the United States is highly concentrated when measured by the Herfindahl-Hirschman Index (“HHI”). Respondent Schering-Plough and Akzo Nobel are two leading suppliers of live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States. Akzo Nobel is the market leader with its MYCOVAC-L product, while Schering Plough competes with its MYCOVAC-L product. Together, they account for over seventy-two percent of the sales in this highly concentrated market. Accordingly, the Acquisition would significantly increase the concentration levels in the United States in the market for live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry, leaving Schering-Plough as the dominant supplier.

VI. ENTRY CONDITIONS

13. Entry into any relevant line of commerce would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Acquisition set forth in Paragraph 14 below. Entry into any of these markets would require overcoming three major obstacles: lengthy development periods, USDA approval requirements, and customer acceptance. As a result, new entry into any of these markets sufficient to achieve a significant market impact within two years is unlikely.

Complaint

VII. EFFECTS OF THE ACQUISITION

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

a. by eliminating actual, direct, and substantial competition between Respondent Schering-Plough and Akzo Nobel for the research, development, manufacture, and sale of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States;

b. by increasing the ability of the merged entity to raise prices unilaterally of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States; and

c. by reducing the merged entity's incentives to improve service or product of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States.

Decision and Order

VIII. VIOLATIONS CHARGED

15. The Acquisition described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

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

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-eighth day of December, 2007, issues its Complaint against said Respondent.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the acquisition by Respondent Schering-Plough Corporation (“Schering-Plough”) of Organon Biosciences N.V. from Akzo Nobel N.V., and Respondent having been furnished thereafter with a copy of a draft of a Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of

Decision and Order

all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having 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, and having duly considered the comment received from an interested person pursuant to section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Decision and Order ("Order"):

1. Respondent Schering-Plough Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its headquarters address at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033-1310.

2. Akzo Nobel N.V. is a corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its headquarters address at Velperweg 76, 6824 BM Arnhem, The Netherlands and its principal place of business in the U.S. at 120 White Plains Road, Suite 300, Tarrytown, New York 10591-5522.

3. Organon BioSciences N.V., with its headquarters address at Wethouder van Eschstraat 1, 5342 AV OSS, The Netherlands, includes Intervet.

Decision and Order

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

ORDER**I.**

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

- A. “Schering-Plough” means Schering-Plough Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Schering-Plough Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Schering-Plough Corporation shall include Organon BioSciences and Intervet.
- B. “Akzo Nobel” means Akzo Nobel N.V., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Akzo Nobel and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Organon BioSciences” means Organon BioSciences N.V., a corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its offices and principal place of business located at Wethouder van Eschstraat 1, 5342 AV Oss, The Netherlands. Organon Biosciences is a wholly owned subsidiary of Akzo Nobel.
- D. “Intervet” means Intervet Inc, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters located at

Decision and Order

29160 Intervet Lane, Millsboro, Delaware 19966. Intervet is a wholly owned indirect subsidiary of Organon BioSciences.

- E. "Respondent" means Schering-Plough.
- F. "Commission" means the Federal Trade Commission.
- G. "Acquirer" means the following:
 - 1. Wyeth; or
 - 2. an entity that is approved by the Commission to acquire particular assets that the Respondent is required to assign, grant, license, divest, transfer, deliver or otherwise convey pursuant to this Order. There may be one or more Acquirers under this Order.
- H. "Acquisition" means the Respondent Schering-Plough's acquisition of one hundred percent (100%) of the voting stock of Organon BioSciences N.V. from Respondent Akzo Nobel N.V. pursuant to a letter of intent dated March 12, 2007.
- I. "Agency(ies)" means any governmental regulatory authority or authorities 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 Divestiture Product in the Territory. The term "Agency" includes, but is not limited to, the United States Department of Agriculture ("USDA").
- J. "Avimune IB98" means any Schering-Plough poultry Product that includes an antigen avirulent live modified strain 2820 of Georgia 98 infectious bronchitis virus which is manufactured, marketed or sold by Schering-Plough pursuant to USDA License No. 1231.1J.

Decision and Order

K. “Avimune IB98 Assets” means all of Respondent’s rights, title and interest not acquired in the Acquisition in and to all assets related to the business of Schering-Plough in the Territory related to Avimune IB98, to the extent legally transferable, including the research, Development, manufacture, distribution, marketing or sale of Avimune IB98, including, without limitation, the following:

1. all Product Intellectual Property;
2. license(s) to all Product Licensed Intellectual Property:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);
3. the Master Seed;

Decision and Order

4. the Challenge Material;
5. the Reagents;
6. the Product Regulatory File;
7. License(s) to use the Product Registrations to the extent required for the distribution, marketing, promoting, offering for sale and selling of the Divestiture Products in the Territory, which license(s) shall be royalty-free, non-exclusive, transferable and sublicensable; *provided however*, that such license(s) shall terminate upon Acquirer's receipt of all Divestiture Product approvals in accordance with Paragraph II.C.5 of this Order;
8. a list of all of the NDC Numbers related to the Product;
9. the existing lists of all current customers for the Divestiture Product and the pricing of the Divestiture Product for such customers;
10. at the Acquirer's option, each of the Product Assumed Contracts;
11. all Product Marketing Materials;
12. rights of reference (if such rights exist) to information similar to the Product Regulatory File submitted to any Agency other than the USDA and relating to the Divestiture Product except as may be retained by Respondent (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order, or (2) for the purposes of conducting Respondent's business related to such Product outside the Territory;

Decision and Order

13. Product Scientific and Regulatory Material;
14. all unfilled customer orders for the Divestiture Product as of the Closing Date (a list of such orders is to be provided to the Acquirer within two days after the Closing Date);
15. license(s) to all Product Manufacturing Technology:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);
16. at the Acquirer's option, all inventories for the Territory in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Divestiture Product specific packaging and labels, which shall include the grant of a license to use

Decision and Order

Product Trademarks and Product Trade Dress for the purposes of marketing and selling such inventories in the Territory; and

17. all Respondent's books, records and files related to the foregoing that are not included in the Product's Regulatory File, including all correspondence with the USDA and other Agencies, all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for Avimune IB98 from January 1, 2000, through the Closing Date, and quality control histories pertaining to Avimune IB98 owned by, or in the possession or control of, Respondent, or to which Respondent has a right of access, in each case such as is in existence as of the Closing Date;

provided, however, that in cases in which documents or other materials included in the Avimune IB98 Assets contain information that (i) relates both to Avimune IB98 and to other Products or businesses of Respondent (including the business outside the Territory), and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to Avimune IB98, Respondent shall be required only to provide copies of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the Acquirer shall have access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than Avimune IB98;

Decision and Order

provided further, however, the term “Avimune IB98 Assets” does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to conduct an animal health business; (v) those assets listed in 1-17 above as used in the conduct of Respondent’s business outside the Territory.

- L. “Asset Purchase Agreement” or “Agreement” means the Amended and Restated Asset Purchase Agreement between Schering-Plough Animal Health Corporation and Intervet Inc., and Wyeth, acting through its Fort Dodge Animal Health division, dated October 18, 2007, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Divestiture Assets to be divested, that have been approved by the Commission to accomplish the requirements of this Order. The Asset Purchase Agreement is attached to this Order as non-public Appendix I.
- M. “Challenge Material” means the materials (other than Retained Challenge Material) used to confirm the immunogenicity of each Divestiture Product and the media formula to propagate the challenge organism.
- N. “CHOLERVAC PM-1” means any Intervet poultry Product that includes as an antigen avirulent live PM-1 strain of *Pasteurella multocida* which is manufactured, marketed or sold by Intervet pursuant to USDA License No. 1871.04.

Decision and Order

O. "CHOLERVAC PM-1 Assets" means all of Respondent's rights, title and interest acquired in the Acquisition in and to all assets related to the business of Organon and Intervet in the Territory, related to CHOLERVAC PM-1, to the extent legally transferable, including the research, Development, manufacture, distribution, marketing or sale of CHOLERVAC PM-1, including, without limitation, the following:

1. all Product Intellectual Property;
2. license(s) to all Product Licensed Intellectual Property:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);

Decision and Order

3. the Master Seed;
4. the Challenge Material;
5. the Reagents;
6. the Product Regulatory File;
7. License(s) to use the Product Registrations to the extent required for the distribution, marketing, promoting, offering for sale and selling of the Divestiture Products in the Territory, which license(s) shall be royalty-free, non-exclusive, transferable and sublicensable; *provided however*, that such license(s) shall terminate upon Acquirer's receipt of all Divestiture Product approvals in accordance with Paragraph II.C.5 of this Order;
8. the existing lists of all current customers for the Divestiture Product and the pricing of the Divestiture Product for such customers;
9. at the Acquirer's option, each of the Product Assumed Contracts;
10. all Product Marketing Materials;
11. rights of reference (if such rights exist) to information similar to the Product Regulatory File submitted to any Agency other than the USDA and relating to the Divestiture Product except as may be retained by Respondent Schering-Plough (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order, or (2) for the purposes of conducting Respondent's business related to such Product outside the Territory;

Decision and Order

12. Product Scientific and Regulatory Material;
13. all unfilled customer orders for the Divestiture Product as of the Closing Date (a list of such orders is to be provided to the Acquirer within two days after the Closing Date);
14. license(s) to all Product Manufacturing Technology:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);
15. at the Acquirer's option, all inventories for the Territory in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Divestiture Product specific packaging and

Decision and Order

labels, which shall include the grant of a license to use Product Trademarks and Product Trade Dress for the purposes of marketing and selling such inventories in the Territory; and

16. all Respondent's books, records and files related to the foregoing that are not included in the Product's Regulatory File, including all correspondence with the USDA and other Agencies, all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for CHOLERVAC PM-1 from January 1, 2000, through the Closing Date, and quality control histories pertaining to CHOLERVAC PM-1 owned by, or in the possession or control of, Respondent, or to which Respondent has a right of access, in each case such as is in existence as of the Closing Date;

provided, however, that in cases in which documents or other materials included in the CHOLERVAC PM-1 Assets contain information that (i) relates both to CHOLERVAC PM-1 and to other Products or businesses of Respondent (including the business outside the Territory), and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to CHOLERVAC PM-1, Respondent shall be required only to provide copies of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the Acquirer shall have access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than CHOLERVAC PM-1;

Decision and Order

provided further, however, the term “CHOLERVAC PM-1 Assets” does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to conduct an animal health business; (v) those assets listed in 1-16 above as used in the conduct of Respondent’s business outside the Territory.

- P. “Closing Date” means the date on which Respondent (or a Divestiture Trustee) and an Acquirer close on a transaction to divest, license, or otherwise convey relevant assets pursuant to this Order.
- Q. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, or use of a Divestiture Product; *provided, however*, that the restrictions contained in this Order regarding the use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:
1. Information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent;

Decision and Order

2. Information related to Divestiture Products that Respondent can demonstrate it obtained without the assistance of Akzo Nobel, Organon BioSciences, or Intervet prior to the Acquisition;
 3. Information that is required by Law to be publicly disclosed;
 4. Information that does not directly relate to the Divestiture Product(s);
 5. Information relating to Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of Products that does not discuss with particularity the Divestiture Product(s); or
 6. Information specifically excluded from the Avimune IB98 Assets, F VAX-MG Assets and CHOLERVAC PM-1 Assets.
- R. "Contract Manufacture" means the manufacture of a Divestiture Product to be supplied by Respondent or a Designee specifically identified in this Order for sale to an Acquirer.
- S. "Designee" means any entity other than the Respondent that will manufacture a Divestiture Product for an Acquirer.
- T. "Develop" means to engage in Development.
- U. "Development" means, to the extent applicable for a veterinary vaccine Product, all preclinical and clinical 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

Decision and Order

control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing and sale of a Divestiture Product (including any governmental price or reimbursement approvals), Divestiture Product approval and registration, and regulatory affairs related to the foregoing.

- V. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee; *provided, however*, 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, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.
- W. “Divestiture Assets” means the Avimune IB98 Assets, the CHOLERVAC PM-1 Assets, and the F VAX-MG Assets.
- X. “Divestiture Product Core Employees” means the Product Manufacturing Employee(s), Product Marketing Employee(s), Product Sales Employee(s) and Product Research and Development Employee(s) related to each of the Divestiture Products.
- Y. “Divestiture Products” means any one or more of the following Products: Avimune IB98, CHOLERVAC PM-1, and F VAX-MG.

Decision and Order

- Z. “Divestiture Trustee” means a trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- AA. “Effective Date” means the date the Respondent and Akzo Nobel close on the Acquisition.
- BB. “Employee Access Period” means a period of twelve (12) months from the Closing Date.
- CC. “Employee Notification” means the “Notice of Divestiture and Requirement for Confidentiality” attached to this Order as public Appendix II.
- DD. “F VAX-MG” means any Schering-Plough Product that includes as an antigen live F strain of *Mycoplasma gallisepticum* which is manufactured, marketed or sold by Schering-Plough pursuant to USDA License No. 1751.00.
- EE. “F VAX-MG Assets” means all of Respondent’s rights, title and interest not acquired in the Acquisition in and to all assets related to the business of Schering-Plough in the Territory related to F VAX-MG, to the extent legally transferable, including the research, Development, manufacture, distribution, marketing or sale of F VAX-MG, including, without limitation, the following:
1. all Product Intellectual Property;
 2. license(s) to all Product Licensed Intellectual Property:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;

Decision and Order

- (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);
3. the Master Seed;
 4. the Challenge Material;
 5. the Reagents;
 6. the Product Regulatory File;
 7. License(s) to use the Product Registrations to the extent required for the distribution, marketing, promoting, offering for sale and selling of the Divestiture Products in the Territory, which license(s) shall be royalty-free, non-exclusive, transferable and sublicensable; *provided however*, that such license(s) shall terminate upon Acquirer's receipt of all Divestiture Product approvals in accordance with Paragraph II.C.5 of this Order;
 8. a list of all of the NDC Numbers related to the Product;

Decision and Order

9. the existing lists of all current customers for the Divestiture Product and the pricing of the Divestiture Product for such customers;
10. at the Acquirer's option, each of the Product Assumed Contracts;
11. all Product Marketing Materials;
12. rights of reference (if such rights exist) to information similar to the Product Regulatory File submitted to any Agency other than the USDA and relating to the Divestiture Product except as may be retained by Respondent (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order, or (2) for the purposes of conducting Respondent's business related to such Product outside the Territory;
13. Product Scientific and Regulatory Material;
14. all unfilled customer orders for the Divestiture Product as of the Closing Date (a list of such orders is to be provided to the Acquirer within two days after the Closing Date);
15. license(s) to all Product Manufacturing Technology:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered

Decision and Order

for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,

(iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);

16. at the Acquirer's option, all inventories for the Territory in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Divestiture Product specific packaging and labels, which shall include the grant of a license to use Product Trademarks and Product Trade Dress for the purposes of marketing and selling such inventories in the Territory; and

17. all Respondent's books, records and files related to the foregoing that are not included in the Product's Regulatory File, including all correspondence with the USDA and other Agencies, all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for F VAX-MG from January 1, 2000, through the Closing Date, and quality control histories pertaining to F VAX-MG owned by, or in the possession or control of, Respondent, or to which Respondent has a right of access, in each case such as is in existence as of the Closing Date;

Decision and Order

provided, however, that in cases in which documents or other materials included in the F VAX-MG Assets contain information that (i) relates both to F VAX-MG and to other Products or businesses of Respondent (including the business outside the Territory), and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to F VAX-MG, Respondent shall be required only to provide copies of the documents and materials containing this information.

In instances where such copies are provided to the Acquirer, the Acquirer shall have access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than F VAX-MG;

provided further, however, the term “F VAX-MG Assets” does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to conduct an animal health business; (v) those assets listed in 1-17 above as used in the conduct of Respondent’s business outside the Territory.

FF. “Government Entity” means any Federal, state, local or non-U.S. government or any court, legislature, government

Decision and Order

agency or government commission, or any judicial or regulatory authority of any government.

GG. “Interim Monitor” means a monitor appointed by the Commission pursuant to the relevant provisions of this Order.

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

II. “Master Seed” means the following (other than Retained Master Seed): (i) the isolated strain of organism selected and permanently stored by Respondent from which all other seed passages are derived within permitted levels for each Divestiture Product and (ii) the isolated strain of organism for the Divestiture Products produced by, and permanently stored by, Respondent from master seed identical to the seed set forth in clause (i) from which all other seed passages are derived within permitted levels for each Divestiture Product.

JJ. “Patents” means all patents, patent applications and statutory invention registrations, in each case existing as of the Effective Date (except where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the Territory, related to any Divestiture Product of or owned by Respondent as of the Closing Date.

KK. “Poultry Business” means the business within Respondent’s Animal Health Corporation responsible for the research, Development, manufacture, distribution, marketing,

Decision and Order

promotion, sale, or after sales support of any product sold for use with poultry as of the Closing Date.

LL. “Product” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient.

MM. “Product Assumed Contracts” means all of the following contracts or agreements related to the Territory:

1. pursuant to which any Third Party purchases any Divestiture Product from the Respondent;
2. pursuant to which the Respondent purchases any materials from any Third Party for use in connection with the manufacture of any Divestiture Product;
3. relating to any clinical trial involving any Divestiture Product;
4. constituting the material transfer agreements involving the transfer of any Divestiture Product;
5. relating to the marketing of any Divestiture Product or educational matters relating to any Divestiture Product;
6. relating to the manufacture of any Divestiture Product;
7. constituting confidentiality agreements involving any Divestiture Product;
8. involving any royalty, licensing or similar arrangement involving any Divestiture Product;
9. pursuant to which any services are provided with respect to any Divestiture Product or any Divestiture Product business, including consultation arrangements; and/or

Decision and Order

10. pursuant to which any Third Party collaborates with the Respondent in the performance of research or Development of any Divestiture Product or any Divestiture Product business.

provided, however, that where any such contract or agreement also relates to a Product of Respondent other than any Divestiture Product, Respondent shall assign the Acquirer all such rights in the Territory under the contract or agreement as are related to the Product required to be divested pursuant to this Order, but concurrently may retain similar rights for the purposes of the other Product.

NN. “Product Copyrights” means rights to all original works of authorship of any kind related to any Divestiture Product and any registrations and applications for registrations thereof, including, but not limited to, the following: educational materials for the sales force; copyrights in all pre-clinical, clinical and process development data and reports relating to the research and Development of any Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of any Divestiture Product, including all raw data relating to clinical trials of any Divestiture Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, any Divestiture Product sales forecasting models, medical education materials, sales training materials, website content and advertising and display materials; all records relating to employees that accept employment with the Acquirer

Decision and Order

(excluding any personnel records the transfer of which is prohibited by applicable Law); all 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 data contained in laboratory notebooks relating to any Divestiture Product or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic data bases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the USDA.

OO. “Product Employee Information” means the following for each Divestiture Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each relevant employee from ninety (90) days prior to Closing Date through the Closing Date. This list shall be organized by the relevant respective employee categories defined in this Order, (*i.e.*, “Product Manufacturing Employee(s),” “Product Marketing Employee(s),” “Product Research and Development Employee(s),” or “Product Sales Employee(s),” as applicable);
2. with respect to each such employee:
 - 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 Divestiture Product; provided, however, in lieu of this description,

Decision and Order

Respondent may provide the employee's most recent performance appraisal;

- d. the base salary or current wages;
 - e. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year and current target or guaranteed bonus, if any;
 - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
 - g. 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.

PP. "Product Intellectual Property" means all of the following (regardless of whether physically located in or outside the Territory) related to a Divestiture Product that is sold in the Territory (other than Retained Product Licensed Intellectual Property):

- 1. Patents;
- 2. Product Copyrights;
- 3. trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, Development and other

Decision and Order

information, other than Product Licensed Intellectual Property;

4. rights to obtain and file for Patents and registrations thereof; and
5. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach of any of the foregoing;

provided, however, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Schering-Plough,” “Akzo Nobel,” “Intervet” or the corporate names or corporate trade dress of any other corporations or companies owned by Respondent or related logos.

QQ. “Product Licensed Intellectual Property” means all of the following (regardless of whether physically located in or outside of the Territory):

1. Patents that are related to a Divestiture Product that Respondent can demonstrate have been routinely used, prior to the Effective Date, by either Respondent or Organon BioSciences or Intervet (whichever is relevant to such Divestiture Product) for a Retained Product(s); and
2. trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, Development and other information, and all rights in the Territory to limit the use or disclosure thereof, that are related to a Divestiture Product that Respondent can demonstrate have been routinely used, prior to the Effective Date, by Respondent or Organon BioSciences or Intervet (whichever is relevant to such Divestiture Product) for a Retained Product(s).

Decision and Order

RR. “Product Manufacturing Employee(s)” means all salaried employees of Respondent who directly participated (irrespective of the portion of working time involved) in the manufacture of the Divestiture Product for the Territory, including, but not limited to, those involved in the quality assurance and quality control of the Divestiture Product for the Territory, within the eighteen (18) month period immediately prior to the Closing Date

SS. “Product Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information related to the manufacture, validation, packaging, release testing, stability and shelf life of the Divestiture Product, including the Divestiture Product’s formulation, in existence and in the possession of Respondent as of the Closing Date, including, but not limited to, the percentages and specifications of ingredients, the manufacturing processes and flow diagrams thereof, the Production Outlines, specifications, technology, inventions, assays, quality control and testing procedures, know-how, trade secrets and trade art, whether tangible or intangible and used to manufacture, formulate, test and package the Divestiture Products for sale, marketing and distribution in the Territory.

TT. “Product Marketing Employee(s)” means all management level employees of Respondent who directly participated (irrespective of the portion of working time involved) in the marketing, contracting, or promotion of the Divestiture Product in the Territory within the eighteen (18) 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 and market research, but excluding administrative assistants.

Decision and Order

UU. “Product Marketing Materials” means the content of all marketing materials used in the Territory related to the Divestiture Product as of the Closing Date, including, without limitation, all tangible copies of all advertising materials, training materials, product data, price lists, mailing lists, sales materials (e.g., detailing reports; vendor lists; sales data; reimbursement 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 sales information; sales forecasting models; medical educational materials; website content and advertising and display materials; speaker lists), promotional and marketing materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Product.

VV. “Product Registrations” means all 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 or sale of the Divestiture Product in the Territory.

WW. “Product Regulatory File” means all data submitted to and all correspondence with the USDA and other Agencies related to the Divestiture Product except as may be retained by Respondent (in which case, Acquirer will receive a copy from Respondent) (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order or (2) for the purposes of Respondent’s business related to such Product outside the Territory.

XX. “Product Research and Development Employee(s)” means all employees of Respondent who directly participated (irrespective of the portion of working time involved) in the research, Development, regulatory approval process, or

Decision and Order

clinical studies of the Divestiture Product for the Territory within the eighteen (18) month period immediately prior to the Closing Date.

YY. “Product Sales Employee(s)” means all employees of Respondent who directly participated (irrespective of the portion of working time involved) in the detailing, marketing or promotion of the Divestiture Product directly in the Territory within the eighteen (18) month period immediately prior to the Closing Date.

ZZ. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information related to the Divestiture Product, and all rights thereto, (regardless of whether physically located in or outside of the Territory) in the Territory except as may be retained by Respondent (in which case, Acquirer will receive a copy from Respondent) (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order or (2) for the purposes of Respondent’s business related to such Product outside the Territory.

AAA. “Product Trade Dress” means the current trade dress of the Divestiture Product, including, but not limited to, product packaging associated with the sale of the Divestiture Product and the lettering of the Divestiture Product’s trade name or brand name.

BBB. “Product Trademark(s)” means all trademarks, 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 the Divestiture Product in the Territory.

Decision and Order

CCC. "Production Outline" means all Respondent's production instructions and processes for each Divestiture Product for the Territory.

DDD. "Proposed Acquirer" means an entity proposed by Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondent pursuant to this Order.

EEE. "Reagents" means all of the reagents (other than the Retained Reagents) that are proprietary or unavailable from commercial sources used in the research, Development, manufacture, distribution, marketing or sale of any one or more of the Divestiture Products to confirm the identification of the Master Seed and to perform the potency tests of the Divestiture Products, including the reference vaccine for each Divestiture Product for the Territory.

FFF. "Remedial Agreement(s)" mean:

1. The agreement between Respondent and Wyeth, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered or 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 effect the assignment of assets or rights of Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced in or attached to this Order, including all amendments, exhibits,

Decision and Order

attachments, agreements, and schedules thereto, 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;

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, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order; or,
4. Any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

GGG. "Retained Challenge Material" means the quantities of materials used to confirm the immunogenicity of each Divestiture Product and the media formula to propagate the challenge organism, which are not conveyed to Acquirer as Divestiture Assets and are retained by Respondent for the conduct of its business outside the Territory.

HHH. "Retained Master Seed" means the quantities of isolated strain of organism selected and permanently stored by Respondent from which all other seed passages are derived within permitted levels for each Divestiture Product, which are not conveyed to Acquirer as Divestiture Assets and are

Decision and Order

retained by Respondent for the conduct of its business outside the Territory.

- III. “Retained Product” means any Product(s) other than a Divestiture Product.
- JJJ. “Retained Reagents” means the quantities of the reagents that are proprietary or unavailable from commercial sources used in the research, Development, manufacture, distribution, marketing or sale of any one or more of the Divestiture Products to confirm the identification of the Master Seed and to perform the potency tests of the Divestiture Products, including the reference vaccine for each Divestiture Product for the Territory, which are not conveyed to Acquirer as Divestiture Assets and are retained by Respondent for the conduct of its business outside the Territory.
- KKK. “Supply Cost” means a cost not to exceed the manufacturer’s average direct unit cost of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contact Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.
- LLL. “Territory” means the United States of America and its territories and possessions.
- MMM. “Third Party(ies)” means any private entity other than: (1) the Respondent, or (2) the Acquirer for the affected assets, rights and Divestiture Products.

Decision and Order

NNN. “Wyeth” means Wyeth, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at Five Giralda Farms, Madison, New Jersey 07940-0874.

II.**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Effective Date, Respondent shall assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Assets, absolutely and in good faith, to Wyeth pursuant to and in accordance with the Asset Purchase Agreement (which Agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Wyeth or to reduce any obligations of Respondent under such Agreement), and such Agreement, if it becomes the Remedial Agreement for one or more of the Divestiture Assets, is incorporated by reference into this Order and made a part hereof. If Respondent does not divest the Divestiture Assets to Wyeth within ten (10) days after the Effective Date, the Commission may appoint a Divestiture Trustee to divest the Divestiture Assets;

provided, however, that if Respondent has divested the Divested Assets to Wyeth 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 Wyeth is not an acceptable purchaser of any one or more of the Divestiture Assets, then Respondent shall immediately rescind the transaction with Wyeth, in whole or in part, as directed by the Commission, and shall divest any one or more of the Divestiture Assets within six (6) months from the date the Order becomes final, absolutely and in

Decision and Order

good faith, at no minimum price, to an Acquirer and only in a manner that receives the prior approval of the Commission.

provided further that if Respondent has divested the Divested Assets to Wyeth 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 the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture to Wyeth of any one or more of the Divestiture Assets (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date, Respondent shall secure all consents and waivers from Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to the relevant Acquirer, and/or to permit such Acquirer to continue the research, Development, manufacture, sale, marketing, or distribution of the Divestiture Products;

provided, however, that Respondent may satisfy this requirement by certifying that the relevant Acquirer has obtained fully executed consents and waivers directly with each of the relevant Third Parties.

- C. Respondent shall transfer the Product Manufacturing Technology related to each Divestiture Product to the Acquirer in an organized, comprehensive, complete, useful, timely, and meaningful manner. Respondent shall, *inter alia*:

1. Designate employees of Respondent knowledgeable with respect to Product Manufacturing Technology for each

Decision and Order

Divestiture Product to a committee for the purposes of communicating directly with the Acquirer and the Interim Monitor for the purposes of effecting such transfer;

2. Prepare technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the relevant Divestiture Product, such protocols and acceptance criteria to be subject to the approval of the Acquirer;
3. Prepare and implement 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 Product Manufacturing Technology to the Acquirer;
4. Upon reasonable notice and request from the Acquirer to Respondent, provide in a timely manner, at no greater than Direct Cost, assistance and advice to enable the Acquirer (or the Designee of the Acquirer) to:
 - a. Manufacture the Divestiture Products in the same quality achieved by the Respondent and in commercial quantities;
 - b. Obtain any product approvals necessary for the Acquirer to manufacture, sell, market or distribute the Divestiture Products; and,
 - c. Receive, integrate, and use such Product Manufacturing Technology to achieve the Order's purposes; and,
5. Provide consultation with knowledgeable employees of Respondent and training, at the request of the Acquirer

Decision and Order

and at a facility chosen by the Acquirer, until the Acquirer (or the Designee of the Acquirer) obtains all Divestiture Product approvals to manufacture the Divestiture Products in the same quality achieved by the Respondent and in commercial quantities, and in a manner consistent with the rules and regulations set forth by USDA in the code of Federal Regulations Title 9 and current industry good manufacturing practices for animal health products, independently of Respondent and sufficient to satisfy the Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the Divestiture Products.

- D. Respondent shall include in any Remedial Agreement related to the Divested Assets the following provisions:
1. At the option of the Acquirer, Respondent shall Contract Manufacture and deliver to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of any one or more of the Divestiture Products at Respondent's Supply Cost, for a period of time sufficient to allow the Acquirer (or the Designee of the Acquirer) to obtain any Agency or Government Entity approvals necessary to manufacture the Divestiture Products.
 2. After Respondent commences delivery of any one or more of the Divestiture Products to the Acquirer pursuant to a Remedial Agreement to Contract Manufacture any one or more of the Divestiture Products, Respondent will make inventory of any one or more of the Divestiture Products available for sale or resale in the Territory only to the Acquirer.
 3. Respondent shall make representations and warranties to the Acquirer that the Divestiture Products supplied through Contract Manufacture pursuant to the Remedial Agreement meet any Agency or Government Entity

Decision and Order

specifications. 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 Divestiture Products supplied to the Acquirer pursuant to the Remedial Agreement by the Respondent to meet any Agency or Government Entity specifications. This obligation shall be contingent upon the Acquirer giving Respondent prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondent under this Order; *provided, however*, Respondent may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with the Respondent's responsibilities to supply the Divestiture Products in the manner required by this Order; *provided further, however*, this obligation shall not require Respondent to be liable for any negligent act, omission or willful misconduct of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondent to the Acquirer.

4. Respondent shall make representations and warranties to the Acquirer that Respondent will hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondent to deliver any one or more of the Divestiture Products in a timely manner as required by the Remedial Agreement unless Respondent can demonstrate that its failure was entirely beyond the control of the Respondent and in no part the result of negligence or willful misconduct by Respondent

Decision and Order

5. During the term of the Contract Manufacture between Respondent and the Acquirer, upon request of the Acquirer or Interim Monitor (if applicable), Respondent shall make available to the Acquirer or the Interim Monitor all records that relate to the manufacture of the Divestiture Products for the Territory that are generated or created after the Closing Date
 6. Upon reasonable notice and request from the Acquirer to the Respondent, Respondent shall provide in a timely manner at no greater than Direct Cost:
 - a. assistance and advice to enable the Acquirer (or the Designee of the Acquirer) to obtain all necessary permits and approvals from any Agency or Government Entity to manufacture and sell the Divestiture Products in the Territory;
 - b. assistance to the Acquirer (or the Designee of the Acquirer) to manufacture the Divestiture Products in substantially the same manner and quality employed or achieved by Respondent in the Territory; and
 - c. consultation with knowledgeable employees of Respondent and training, at the request of the Acquirer and at a facility chosen by the Acquirer, until the Acquirer (or the Designee of the Acquirer) obtains all Agency or Government Entity approvals necessary to manufacture the Divestiture Products independently of the Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the Divestiture Products.
- E. Respondent shall:

Decision and Order

1. Submit to the Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products;
2. Deliver such Confidential Information as follows:
 - a. In good faith;
 - b. As soon as practicable, avoiding delays in transmission of the respective information; and,
 - c. In a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. Pending complete delivery of all such Confidential Business Information to the Acquirer, provide the Acquirer and the Interim Monitor 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 the relevant Divestiture Products in the Territory that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. Not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Divestiture Products in the Territory other than as necessary to comply with the following:
 - a. The requirements of this Order;
 - b. Respondent's obligations to the Acquirer under the terms of the Remedial Agreement related to Divestiture Products; or

Decision and Order

- c. Applicable Law;
 - 5. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Acquirer or other persons specifically authorized by the Acquirer to receive such information, and only if authorized to do so by Acquirer; and,
 - 6. Not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products in the Territory to the employees associated with business related to those Retained Products that are approved by any Agencies for the same or similar indications or purposes as the Divestiture Products.
- F. At the Acquirer's option and upon written notice to Respondent from the Acquirer, delivered at Closing:
- 1. Respondent shall provide the Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees during the Employee Access Period.
 - 2. Respondent shall provide any Proposed Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees in connection with the divestiture of the Divestiture Assets; *provided, however*, that any such employment contracts entered into prior to the Closing Date shall be contingent upon the Commission's approval of the Asset Purchase Agreement and the other Remedial Agreements.
 - 3. Not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee

Decision and Order

Information or (2) ten (10) days after the relevant Closing Date, Respondent shall provide the Acquirer or the Proposed Acquirer the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information related to the Divestiture Product Core Employees within the time provided herein shall extend the Employee Access Period with respect to that employee in an amount equal to the delay or seven (7) days, whichever is greater.

4. During the Divestiture Product Core Employee Access Period, Respondent shall not interfere with the hiring or employing by the Acquirer of any Divestiture Product Core Employees, and shall remove any impediments within the control of Respondent that may deter any Divestiture Product Core Employee from accepting employment with the Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Acquirer. In addition, Respondent shall not make any counteroffer to a Divestiture Product Core Employee who receives a written offer of employment from the Acquirer;

provided, however, that these requirements shall not prohibit the Respondent from making offers of employment to or employing any Divestiture Product Core Employee during the Divestiture Product Core Employee Access Period where the Acquirer has notified the Respondent in writing that the Acquirer does not intend to make an offer of employment to that employee;

provided further, that if the Respondent notifies the Acquirer in writing of its desire to make an offer of

Decision and Order

employment to a particular Divestiture Product Core Employee and the Acquirer does not make an offer of employment to that employee within twenty (20) days of the date the Acquirer receives such notice, the Respondent may make an offer of employment to that employee.

5. Respondent shall provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions until the Closing Date. Such incentives shall include a continuation of all employee benefits offered by Respondent until the Closing Date has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that nothing in these requirements or in this Order requires or shall be construed to require the Respondent to terminate the employment of any employee.

6. For a period of one (1) year from the Closing Date, Respondent shall not:
 - (a) directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer with any amount of responsibility related to the Divestiture Products ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer; *provided, however*, a violation of this provision will not occur by any of the following actions: (i) Respondent advertises for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees, or (ii) a Divestiture Product Employee contacts Respondent on his or her own initiative

Decision and Order

without any direct or indirect solicitation or encouragement from the Respondent; or

- (b) hire any Divestiture Product Employee; *provided, however,* Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or who independently applies for employment with the Respondent, as long as such employee was not solicited in violation of the non-solicitation requirements contained herein.

- G. Respondent shall require, as a condition of continued employment post-divestiture, that each Divestiture Product Core Employee sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to Divestiture Products strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).
- H. Not later than thirty (30) days after the Effective Date, Respondent shall provide written notification of the restrictions on the use of the Confidential Business Information related to Divestiture Products by Respondent's personnel to all of Respondent's employees who (i) are or were involved in the research, Development, manufacturing, distribution, sale or marketing of any one or more of the Divestiture Products; (ii) are directly involved in the research, Development, manufacture, distribution, sale or marketing of Retained Products that are approved by any Agencies for the same or similar indications or purposes as the Divestiture Products; and/or (iii) may have Confidential Business Information related to the Divestiture Products. Such notification shall be in substantially the form set forth

Decision and Order

in the Employee Notification attached to this Order as non-public Appendix II. Respondent shall give such notification by email with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondent shall provide a copy of such notification to the Acquirer. Respondent shall maintain complete records of all such agreements at Respondent's corporate headquarters and shall provide an officer's certification to the Commission, stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- I. Upon reasonable notice and request by the Acquirer, Respondent shall make available to the Acquirer, at no greater than Direct Cost, such personnel, assistance and training as the Acquirer might reasonably need to transfer the Divestiture Assets, and shall continue providing until the Acquirer (or the Designee of the Acquirer) is fully validated, qualified, and approved by all Agencies, and able to manufacture the Divestiture Products independently of the Respondent.
- J. Pending divestiture of the Divestiture Assets, Respondent shall take such actions as are necessary to maintain the viability and marketability of the Divestiture Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.
- K. Respondent shall maintain manufacturing facilities for production of the Divestiture Products that are ready, validated, qualified and approved by the Agency and Government Entities, and fully capable of producing Divestiture Products for the Territory until the Acquirer (or the Designee of the Acquirer) is fully validated, qualified

Decision and Order

and approved by the Agency and Government Entities and able to manufacture Divestiture Products for the Territory independently of Respondent; *provided, however*, the Commission may eliminate, or limit the duration of, the Respondent's obligation under this provision should the Commission determine that the Acquirer is not using commercially reasonable best efforts to secure the Agency and Government Entities approvals necessary to manufacture Divestiture Products for the Territory independently of Respondent.

III.**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order. Notwithstanding any paragraph, section, or other provision of the Remedial Agreement, any failure to meet any condition precedent to closing (whether waived or not) without the prior approval of the Commission shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to a Divestiture Product, a specific reference to this Order, the remedial purposes thereof, and the provisions to reflect the full scope and breadth of Respondent's obligations to the Acquirer pursuant to this Order.
- D. Respondent shall include in each Remedial Agreement a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure from Agencies all approvals necessary to manufacture, or to have

Decision and Order

manufactured by Third Parties, in commercial quantities, each Divestiture Product, and to have any such manufacture to be independent of Respondent, as soon as reasonably practicable.

- E. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

IV.

IT IS FURTHER ORDERED that the purpose of the divestiture of the Divestiture Assets, the transfer of the Product Manufacturing Technology related to the Divestiture Products, and the related obligations imposed on the Respondent by this Order, is:

- A. To ensure the continued use of the Divestiture Assets in the research, Development, and manufacture of each of the Divestiture Products for the Territory;
- B. To provide for the future use of the Divestiture Assets in the distribution, sale and marketing of each of the Divestiture Products in the Territory;
- C. To create a viable and effective competitor, who is independent of the Respondent, in the research, Development, manufacture, distribution, sale, and marketing of each of the Divestiture Products in the Territory; and,
- D. To remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

V.

IT IS FURTHER ORDERED that:

Decision and Order

Respondent shall assure that, in any instance wherein counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to the Acquirer or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the Acquirer, that Respondent's counsel does so only in order to do the following:

- A. Comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any Government Entity, or any taxation requirements; or,
- B. Defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or assets and businesses associated with those Products; *provided, however*, that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided, however, that pursuant to this Paragraph V, Respondent shall: (1) 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, (2) uses its best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication;

provided further, however, that Respondent may continue to use that portion of those documents retained by Respondent that does not relate to the Divestiture Products.

Decision and Order

VI.**IT IS FURTHER ORDERED** that:

- A. Dr. David A. Espeseth of Espeseth Consulting shall serve as the monitor (“Interim Monitor”) to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order and the Remedial Agreements. In lieu of or as a replacement to Dr. Espeseth, the Commission may appoint one or more Interim Monitors to assure Respondent’s compliance with the requirements of the Order and the related Remedial Agreements.
- B. If Dr. Espeseth fails to serve, or if a new Interim Monitor must be selected, the Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent’s compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

Decision and Order

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 later of:
 - a. the completion by Respondent of the divestiture of all relevant assets required to be divested pursuant to this Order in a manner that fully satisfies the requirements of the Order and notification by the Acquirer to the Interim Monitor that it is fully capable of producing the relevant Product acquired pursuant to a Remedial Agreement independently of Respondent; or
 - b. the completion by Respondent of the last obligation under the Order pertaining to the Interim Monitor's service.

provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Order.
4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books,

Decision and Order

documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the Divestiture Assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Order.

5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the

Decision and Order

Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent obligations under the Order or the Remedial Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report confidentially in writing to the Commission concerning performance by Respondent of its obligations under the Order.

8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
 9. 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 or non-disclosure agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- E. If the Commission determines that the Interim Monitor has ceased to act, failed to act diligently, or for other good cause, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- F. 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.

Decision and Order

- G. 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.

VII.**IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee or trustees (“Divestiture Trustee(s)”) to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant 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

Decision and Order

divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the 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-year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed

Decision and Order

Divestiture Trustee, by the court; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable best 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. Each 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 entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; *provided, further, however*, that Respondent shall select such entity within

Decision and Order

five (5) days after receiving notification of the Commission's approval.

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

Decision and Order

from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. In the event that the Divestiture Trustee determines that he or she is unable to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, Development, manufacture, distribution, marketing, promotion, sale, or after-sales support of the relevant Product, the Divestiture Trustee may assign, grant, license, divest, transfer, deliver or otherwise convey such additional assets of the Poultry Business of Respondent and effect such arrangements as are necessary to satisfy the requirements of this Order.
8. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by this Order.
9. 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.
10. 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*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

Decision and Order

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

VIII.**IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondent has fully complied with Paragraph II (including the performance of all obligations under any Remedial Agreements), Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, including a description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all parties contacted. Respondent shall include in its reports

Decision and Order

copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- B. One (1) year after the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, 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 this Order.

IX.

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 of or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

X.

IT IS FURTHER ORDERED that, for the purpose 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 Respondent made to its principal United States office or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

Decision and Order

- A. Access, during business office hours of 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 Respondent at the request of the authorized representative of the Commission and at the expense of Respondent; and,
- B. To interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

XI.

IT IS FURTHER ORDERED that this Order will terminate on December 28, 2017.

By the Commission.

Decision and Order

Nonpublic Appendix I

Asset Purchase Agreement

[Redacted From Public Record Version
But Incorporated By Reference]

Nonpublic Appendix II

Notice of Divestiture and Requirement for Confidentiality

[Redacted From Public Record Version
But Incorporated By Reference]

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Schering-Plough Corporation (“Schering-Plough”), which is designed to remedy the anticompetitive effects of its acquisition of Organon BioSciences N.V. (“Organon BioSciences”) from Akzo-Nobel N.V. (“Akzo-Nobel”). Under the terms of the proposed Consent Agreement, Schering-Plough would be required to divest to Wyeth: (1) the Schering-Plough rights and assets necessary to develop, manufacture, and market live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry; (2) the rights and assets necessary to develop, manufacture, and market live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry; and (3) the rights and assets necessary to develop, manufacture, and market live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* (“MG”) in poultry.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to the terms of a Letter of Intent dated March 12, 2007, Schering-Plough proposes to acquire from Akzo Nobel 100 percent of the outstanding shares of Organon BioSciences voting stock. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade

Analysis to Aid Public Comment

Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for the manufacture and sale of the following poultry vaccines: (1) live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry; (2) live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry; and (3) live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry. The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

The Products and Structure of the Markets

The markets for the Georgia 98 strain of infectious bronchitis, fowl cholera, and live MG vaccines are highly concentrated, with Schering-Plough and Intervet accounting for significant market shares in each of these markets. The proposed acquisition would create a monopolist in the live Georgia 98 vaccine market and would give Schering-Plough shares of approximately eighty-five percent and seventy-two percent in the markets for live fowl cholera and live MG vaccines, respectively.

The Georgia 98 strain of infectious bronchitis is a highly contagious respiratory disease in poultry spread by contact with infected respiratory discharge and feces. Live Georgia 98 vaccines are the only vaccines that can effectively prevent and treat the Georgia 98 strain of infectious bronchitis virus. Other infectious bronchitis virus vaccine strains, administered either individually or in multiple-antigen combination vaccines, do not provide adequate protection against the Georgia 98 serotype to act as a sufficient alternative to the live Georgia 98 vaccines. The relevant market for the manufacture, distribution, and sale of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry in the United States is highly concentrated. Respondent Schering-Plough and Organon BioSciences are the only suppliers of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious

Analysis to Aid Public Comment

bronchitis virus in poultry in the United States. Schering-Plough's Avimune IB98 product is the market leader with an estimated seventy-nine percent market share, while Intervet competes with its MILDVAC GA-98 product, selling the remaining twenty-one percent in the United States. The acquisition would create a monopoly by combining the only two companies with products on the market.

Live fowl cholera vaccines prevent an infectious bacterial disease in poultry caused by a common pathogenic bacterium, *Pasteurella multocida*. The relevant market for the manufacture, distribution, and sale of live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry in the United States is highly concentrated. Respondent Schering-Plough and Organon BioSciences are two of only three suppliers of live fowl cholera vaccines, and the only providers of a PM-1 strain of the vaccine. Organon BioSciences is the market leader with its CHOLERVAC-PM-1 product, accounting for approximately fifty-three percent of the live fowl cholera vaccines sold in the United States. Schering-Plough is the second leading supplier with its PM-ONEVAC-C and M-NINEVAX products, accounting for thirty-two percent of sales in the market. Together, Schering-Plough and Organon BioSciences account for approximately eighty-five percent of the sales in this highly concentrated market. Accordingly, the Acquisition would significantly increase the concentration levels in the United States in the market for live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry.

MG is a respiratory disease that is transmitted laterally between chickens or through infected eggs. The relevant market for the manufacture, distribution, and sale of live *Mycoplasma gallisepticum* vaccines in the United States is highly concentrated. Respondent Schering-Plough and Organon BioSciences are the two leading suppliers of live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States. Akzo

Analysis to Aid Public Comment

Nobel is the market leader with its MYCOVAC-L product, while Schering Plough competes with its F-VAX MG. Together, they account for over seventy-two percent of the sales in this highly concentrated market. Accordingly, the Acquisition would significantly increase the concentration levels in the United States in the market for live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry.

Entry

Entry into any relevant line of commerce would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Acquisition. Entry into any of these markets would require overcoming three major obstacles: lengthy development periods, USDA approval requirements, and customer acceptance. As a result, new entry into any of these markets sufficient to achieve a significant market impact within two years is unlikely.

Effects

The markets for the Georgia 98 strain of infectious bronchitis, fowl cholera, and MG live vaccines are highly concentrated, with Schering-Plough and Intervet accounting for substantial shares of sales in each of these markets. The proposed acquisition would create a monopolist in the live Georgia 98 vaccine market and would give Schering-Plough shares of approximately eighty-five percent and seventy-two percent in the markets for live fowl cholera vaccine and live MG vaccines, respectively.

The competitive concerns can be characterized as unilateral in nature. Schering-Plough and Organon BioSciences are each other's closest competitors in all of the relevant markets. Consumers have benefitted from the price competition between Schering-Plough and Organon BioSciences. If unremedied, the proposed acquisition would likely cause higher prices and reduce incentives to improve service or product quality, resulting in significant harm to consumers in the U.S. markets for these vaccines.

Analysis to Aid Public Comment

The Consent Agreement

The proposed Consent Agreement remedies the competitive harm caused by the proposed transaction. Pursuant to the Consent Agreement, Schering-Plough must divest or license all of the assets relating to Schering-Plough's live vaccine for the Georgia 98 strain of infectious bronchitis (Avimune IB98), Intervet's live fowl cholera vaccine (CHOLERVAC-PM-1) and Schering-Plough's live MG vaccine (F VAX-MG) ("the assets to be divested"), to the Fort Dodge division of Wyeth, within ten days after the date Schering-Plough acquires Organon BioSciences. The assets to be divested include research and development, customer, supplier and manufacturing contracts and any intellectual property including existing licenses, but excluding trademarks. Fort Dodge plans to bring all manufacturing of the three vaccines in-house to its own manufacturing facilities and to add the three to its own portfolio of poultry vaccines. While Fort Dodge undertakes the process of obtaining USDA regulatory approvals and bringing vaccine production in-house, Schering-Plough will provide Fort Dodge with the vaccines pursuant to a supply and transition services agreement with a term of two years, and an option to extend it another year, individually for each of the three vaccines, if required.

The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

Wyeth, headquartered in Madison, New Jersey, is a global leader in pharmaceuticals, consumer health care products and animal health care products. In 2006, it had net sales of \$20 billion. Wyeth's Fort Dodge Animal Health division offers a broad range of biological and pharmaceutical products for the companion animal, equine,

Analysis to Aid Public Comment

livestock, swine and poultry industries. Significantly, Wyeth already has an established poultry vaccine line comprised of internally developed vaccines as well as several vaccines that it has acquired and transferred to its manufacturing facilities. Fort Dodge has its own distribution network and an experienced sales force with existing relationships with major poultry producers. The three vaccines being divested to Fort Dodge are all established products that have been on the market for at least two years. Fort Dodge has its own manufacturing facilities with excess capacity and intends to bring the manufacturing of all of the products it is acquiring from Schering-Plough in-house. For these reasons, Wyeth is a strong buyer that appears well positioned to replace the competition lost by the acquisition.

If the Commission determines that Wyeth is not an acceptable acquirer of the assets to be divested, the parties must unwind the sale and divest the Products within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Schering-Plough to provide transitional services to enable the Commission-approved acquirer to obtain all of the necessary approvals from the USDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Schering-Plough and Akzo-Nobel.

The Commission has appointed Dr. David A. Espeseth to oversee the implementation of the Order as the Interim Monitor Trustee. Dr. Espeseth retired in 1998 from a career at the USDA, where his last position was as Special Assistant to the Deputy Administrator of Veterinary Services and where he spent the majority of his 37 years regulating veterinary biologic products (vaccines). Today, he is a consultant to animal health companies, assisting with regulatory issues before the USDA and technology

Analysis to Aid Public Comment

transfers. Dr. Espeseth's strengths are his strong regulatory background, his experience overseeing technology transfers, and experience resolving disputes between companies and the USDA.

Dr. Espeseth is an excellent candidate to handle the expected duties and responsibilities of the Interim Monitor Trustee in this matter. He has the requisite capability and applicable knowledge to ensure the proper transfer of the divested assets, oversee the transfer of the relevant technology, monitor the critical manufacturing and supply activities of the Respondent, ensure the Respondent's compliance with the Order and related agreements, respond to Commission needs, and perform other related services as may be required. Accordingly, the Commission has appointed Dr. Espeseth as the Interim Monitor Trustee.

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

INTERLOCUTORY, MODIFYING,
VACATING, AND MISCELLANEOUS
ORDERS
