ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Schering-Plough Corporation, File No. 071 0132

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 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 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 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.

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, 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 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.