IN THE MATTER OF

AMERICAN HOME PRODUCTS CORPORATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3557. Complaint, Feb. 14, 1995--Decision, Feb. 14, 1995

This consent order requires, among other things, the New Jersey-based corporation to divest its tetanus and diphtheria vaccine business to a Commission-approved buyer; to license Cyanamid's rotavirus vaccine research to a Commission-approved licensee; and to change a previously established licensing agreement to ensure that it does not obtain certain competitively sensitive information. The consent order also prohibits, for ten years, the respondent from acquiring any interest in any entity engaged in the clinical development, manufacture, or sale of tetanus, diphtheria, or rotavirus vaccines in the United States without prior Commission approval.

Appearances

For the Commission: *Claudia Higgins, Ann Malester* and *Mary Lou Steptoe.*

For the respondent: *Michael Sohn, Arnold & Porter*, Washington, D.C. *Kenneth Logan, Simpson, Thacher & Bartlett*, New York, N.Y. *Kenneth Prince, Sherman & Sterling*, New York, N.Y.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that respondent, American Home Products Corporation ("AHP"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire all of the voting stock of American Cyanamid Company ("Cyanamid"), 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, ("FTC Act"), 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

1. Respondent American Home Products Corporation is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its principal place of business located at Five Giralda Farms, Madison, New Jersey.

II. THE ACQUIRED COMPANY

2. American Cyanamid Company is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Maine, with its principal executive offices located at One Cyanamid Plaza, Wayne, New Jersey.

III. JURISDICTION

3. Respondent is, and at all times relevant 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.

IV. THE ACQUISITION

4. On or about August 17, 1994, AHP and Cyanamid signed an Agreement and Plan of Merger whereby AHP would acquire 100 percent of the voting securities of Cyanamid for approximately $9.7 billion ("Acquisition").

V. THE RELEVANT MARKETS

5. For purposes of this complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are:

(1) The manufacture and sale of combined tetanus and diphtheria vaccine approved by the United States Food and Drug Administration

("FDA") for sale in the United States for adults and children seven years old and older, known as "adult Td";

(2) The manufacture and sale of combined diphtheria and tetanus vaccine approved by the FDA for sale in the United States for children between the ages of two months and seven years, known as "pediatric DT";

(3) The manufacture and sale of tetanus vaccine approved by the FDA for sale in the United States, known as "tetanus toxoid";

(4) The research and development of a vaccine against Rotavirus infection in humans; and

(5) The research, development, production and sale of cytokines for white blood cell and platelet restoration.

6. For purposes of this complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in all the relevant lines of commerce.

VI. STRUCTURES OF THE MARKETS

7. The market for the manufacture and sale of combined tetanus and diphtheria vaccine approved by the FDA for use for adults and children seven years old or older, known as "adult Td," is highly concentrated as measured by the Herfindahl-Hirschmann Index.

8. AHP and Cyanamid are actual competitors in the relevant market for the manufacture and sale of adult Td in the United States.

9. The market for the manufacture and sale of combined diphtheria and tetanus vaccine for children between the ages of two months and seven years, known as "pediatric DT," is highly concentrated as measured by the Herfindahl-Hirschmann Index.

10. AHP and Cyanamid are actual competitors in the relevant market for the manufacture and sale of pediatric DT in the United States.

11. The market for the manufacture and sale of tetanus vaccine, known as "tetanus toxoid," is highly concentrated as measured by the Herfindahl-Hirschmann Index.

12. AHP and Cyanamid are actual competitors in the relevant market for the manufacture and sale of tetanus toxoid in the United States.

13. The research and development market for a Rotavirus vaccine is highly concentrated as measured by the Herfindahl-Hirschmann

Index. As of the date of this complaint, there are only three producers of vaccines with research projects either in clinical development or near clinical development aimed at developing a vaccine against Rotavirus infection in humans.

14. AHP and Cyanamid are actual competitors in the relevant market for the research and development of a Rotavirus vaccine for sale in the United States.

15. The market for research, development, production and marketing of cytokines for white blood cell and platelet restoration is highly concentrated as measured by the Herfindahl-Hirschmann Index. As of the date of this complaint, the only cytokines for the restoration of white blood cells and platelets approved by the FDA for sale in the U.S. are: Granulocyte-Macrophage colony stimulating factor ("GM-CSF") manufactured and sold by Cyanamid and Granulocyte colony stimulating factor ("G-CSF") manufactured and sold by Amgen. Three cytokines for the restoration of white blood cells and platelets are pending FDA approval for sale in the U.S. These are: GM-CSF manufactured by Sandoz, under license from AHP; Interleukin-3 manufactured by Sandoz, under license from AHP; and Pixy321, also identified as rhIL-3/rhGM-CSF S. cerevisiae fusion protein, manufactured by Cyanamid.

16. AHP is a potential competitor of Cyanamid in the market for cytokines for white blood cell and platelet restoration.

VII. BARRIERS TO ENTRY

17. Entry into the adult Td, pediatric DT, and tetanus toxoid vaccine markets is difficult and time consuming. Entry into the manufacture and sale of tetanus and diphtheria vaccines is governed by the requirements of the FDA. The minimum time that it would take for a firm to complete FDA requirements to enter into the tetanus and diphtheria vaccine markets would be several years.

18. Entry into the relevant Rotavirus vaccine research and development market is difficult and time consuming, requiring the expenditure of significant resources over a period of many years with no assurance that a viable commercial vaccine will result.

19. Entry into the cytokines for white blood cell and platelet restoration market is difficult and time consuming. FDA regulations create long lead times for the introduction of new drugs; patents create large and often insurmountable barriers to entry.

VIII. EFFECTS OF THE ACQUISITION

20. The effects of the Acquisition if consummated may be substantially to 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, by, among others:

a. Eliminating actual, direct and substantial competition between AHP and Cyanamid in the relevant adult Td, pediatric DT, and tetanus toxoid vaccine markets;

b. Increasing the likelihood that AHP will unilaterally exercise market power in the relevant cytokines for white blood cell and platelet restoration market and the relevant adult Td, pediatric DT, and tetanus toxoid vaccine markets;

c. Creating a dominant firm in the relevant adult Td, pediatric DT, and tetanus toxoid vaccine markets;

d. Eliminating actual, direct competition for research and development between AHP and Cyanamid in the Rotavirus vaccine research and development market and in the cytokines for white blood cell and platelet restoration market;

e. Enhancing the likelihood of collusion or coordinated interaction between or among the remaining firms in each of the relevant markets; and

f. Eliminating potential competition in the relevant Rotavirus vaccine research and development market and cytokines for white blood cell and platelet restoration market.

IX. VIOLATIONS CHARGED

21. The Acquisition described in paragraph four, 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.

22. The Acquisition agreement described in paragraph four constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. 45.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of respondent's proposed acquisition of certain stock of American Cyanamid Company ("Cyanamid") and respondent having been furnished thereafter with a copy of a draft of complaint that the Bureau of Competition presented 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

The respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by respondent of all the jurisdictional facts set forth in the aforesaid draft of the complaint, a statement that the signing of said 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, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that respondent has violated the said Acts, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent American Home Products Corporation ("AHP") is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware, with its principal place of business located at Five Giralda Farms, Madison, New Jersey.

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

ORDER

I. DEFINITIONS

It is ordered, That, as used in this order, the following definitions shall apply:

A. "*AHP*" means American Home Products Corporation, its predecessors, subsidiaries, divisions, groups and affiliates controlled by AHP, and their respective directors, officers, employees, agents and representatives, and their respective successors and assigns.

B. "*Cyanamid*" means American Cyanamid Company.

C. "*Acquirer*" means the entity to whom AHP shall divest AHP's Tetanus and Diphtheria Vaccine Assets pursuant to paragraph II of this order.

D. "*New Acquirer*" means the entity to whom the trustee shall divest AHP's Tetanus and Diphtheria Vaccine Assets pursuant to paragraph IV of this order.

E. "*Rotavirus Licensee*" means the entity to whom AHP shall license Cyanamid's Rotavirus Vaccine Research pursuant to paragraph V of this order.

F. "*Respondent*" means AHP.

G. "*Commission*" means the Federal Trade Commission.

H. "*Acquisition*" means the acquisition by AHP of the common stock of Cyanamid pursuant to a tender offer commenced on August 10, 1994.

I. "*AHP's Tetanus and Diphtheria Vaccine Assets*" means AHP's assets relating to the manufacture and sale of AHP's Tetanus and Diphtheria Vaccines that are not part of AHP's physical facilities or other tangible assets. "AHP's Tetanus and Diphtheria Vaccine Assets" include but are not limited to all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, customer lists, information stored on management information systems and specifications sufficient for the Acquirer or the New Acquirer, as applicable, to use such information, software used solely in connection with AHP's Tetanus and Diphtheria Vaccines and all data, materials and information relating to United States Food and Drug Administration

("FDA") approvals for Tetanus and Diphtheria Vaccines. "AHP's Tetanus and Diphtheria Vaccine Assets" do not include any manufacturing assets of AHP or any assets acquired by AHP from American Cyanamid as a result of the Acquisition or AHP's Vaccine Filling and Packaging Assets.

J. "*AHP's Vaccine Filling and Packaging Assets*" means a non-exclusive license to all patents, trade secrets, technology and know-how relating to filling vials, syringes or other forms of filling or packaging used by AHP for Tetanus and Diphtheria Vaccines at any time up to and including the date of the Acquisition, including but not limited to the Tubex® filling system. "AHP's Vaccine Filling and Packaging Assets" do not include any manufacturing assets of AHP or any assets acquired by AHP from American Cyanamid as a result of the Acquisition.

K. "*Tetanus and Diphtheria Vaccines*" means vaccines used to create and maintain antitoxin levels in human beings to prevent tetanus and/or diphtheria, including tetanus toxoid vaccine, tetanus-diphtheria toxoids vaccine (adult) and diphtheria-tetanus toxoids vaccine (pediatric), approved by the FDA for sale in the United States.

L. "*Contract Manufacture*" means the manufacture of Tetanus and Diphtheria Vaccines by AHP for sale to the Acquirer or the New Acquirer, as applicable, in Finished Packaged Form, in annual volumes not to exceed: Tetanus Toxoid (fluid) 1,000,000 doses; Tetanus Toxoid (adsorbed) 3,000,000 doses; diphtheria-tetanus toxoids vaccine (pediatric) 1,000,000 doses; and tetanus-diphtheria toxoids vaccine (adult) 13,000,000 doses.

M. "*Finished Packaged Form*" means packaged in a form acceptable for commercial sale in the United States, in each form of packaging, or substantially similar thereto (including Tubex® & prefilled syringes) as that used by AHP (any time up to and including the date of the Acquisition) in the distribution and sale of AHP's Tetanus and Diphtheria Vaccines, with information including but not limited to the name and identification codes of the Acquirer or the New Acquirer, as applicable, inscribed on the packaging of the Tetanus and Diphtheria Vaccines, and packaged in units specified by the Acquirer or the New Acquirer, as applicable, as permitted by AHP's existing FDA approvals.

N. "*Cost*" means AHP's actual per unit cost of manufacturing AHP's Tetanus and Diphtheria Vaccines, which may be adjusted once

annually to reflect any increases in AHP's actual cost, provided, however, that for any year, the total rate of such adjustment with respect to all components of cost other than material and labor shall not exceed the rate of increase in the Consumer Price Index for such year.

O. "*Formulation*" means any and all information, including both patent and trade secret information, technical assistance and advice, relating to the manufacture of Tetanus and Diphtheria Vaccines that meet United States Food and Drug Administration approved specifications therefor.

P. "*Cyanamid's Rotavirus Vaccine Research*" means:

(1) All of the patents and patent applications that Cyanamid holds, has an option to hold or is licensed to practice under and that are directed to the development of a vaccine to protect humans against rotavirus disease;

(2) All of the know-how that Cyanamid received from licensors or developed itself that is directed to the development of a vaccine to protect humans against rotavirus disease;

(3) All of the biochemical materials, including, but not limited to, reagents, cell lines, monoclonal antibodies, bacculovirus stocks and rotavirus stocks that are directed to the development of a vaccine to protect humans against rotavirus disease; and

(4) All documentation, written materials, and other relevant data that are directed to the development of a vaccine to protect humans against rotavirus disease;

As of the date of the licensing pursuant to paragraph V or VI of this order, which can be licensed to the Rotavirus Licensee including, but not limited to, those items enumerated in the Confidential Appendix A.

II. TETANUS AND DIPHTHERIA VACCINES DIVESTITURE PROVISIONS

It is further ordered, That:

A. Within four (4) months of the date this order becomes final, AHP shall divest, absolutely and in good faith, AHP's Tetanus and Diphtheria Vaccine Assets and consummate an agreement that

includes the provisions required by paragraph II.C of this order, with an Acquirer or a New Acquirer, as applicable, (hereinafter "Divestiture Agreement").

B. Respondent shall divest AHP's Tetanus and Diphtheria Vaccine Assets only to and consummate a Divestiture Agreement only with an Acquirer or New Acquirer, as applicable, that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission. The purpose of the divestiture of AHP's Tetanus and Diphtheria Vaccine Assets and the Divestiture Agreement is to ensure the continuation of AHP's Tetanus and Diphtheria Vaccine Assets as an ongoing, independent operation, engaged in the same business in which AHP's Tetanus and Diphtheria Vaccine Assets are presently engaged, and to remedy the lessening of competition resulting from the proposed Acquisition as alleged in the Commission's complaint.

C. The Divestiture Agreement shall include the following and AHP shall commit to satisfy the following:

1. AHP shall Contract Manufacture and deliver to the Acquirer or the New Acquirer, as applicable, in a timely manner the requirements of the Acquirer or the New Acquirer, as applicable, for Tetanus and Diphtheria Vaccines at AHP's Cost for a period not to exceed five (5) years from the date the Divestiture Agreement (or the New Acquirer's Divestiture Agreement, as applicable) is approved, or six (6) months after the date the Acquirer or the New Acquirer, as applicable, obtains all necessary FDA approvals to manufacture Tetanus and Diphtheria Vaccines for sale in the United States, whichever is earlier; provided, however, that the five (5) year period shall be extended for a period not to exceed twenty-four (24) months if the trustee submits to the Commission the certification provided for in subparagraph II.C.10 of this order.

2. AHP shall commence delivery of Tetanus and Diphtheria Vaccines to the Acquirer or the New Acquirer, as applicable, within two (2) months from the date the Commission approves the Acquirer and the Divestiture Agreement (or the New Acquirer and its Divestiture Agreement).

3. After AHP commences delivery of Tetanus and Diphtheria Vaccine to the Acquirer or the New Acquirer, as applicable, pursuant to subparagraph II.C.2 of this order, all inventory of Tetanus and Diphtheria Vaccines produced by AHP at its facility located at

Marietta, Pennsylvania, regardless of the date of its production, may be sold by AHP only to the Acquirer or the New Acquirer, as applicable.

4. AHP shall make representations and warranties to the Acquirer or the New Acquirer, as applicable, that the Tetanus and Diphtheria Vaccines contract manufactured by AHP for the Acquirer or the New Acquirer, as applicable, meet the United States Food and Drug Administration approved specifications therefor and are not adulterated or misbranded within the meaning of the Food, Drug and Cosmetic Act, 21 U.S.C. 321, *et seq.* AHP shall agree to indemnify, defend and hold the Acquirer or the New Acquirer, as applicable, harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Tetanus and Diphtheria Vaccines contract manufactured by AHP to meet FDA specifications. This obligation shall be contingent upon the Acquirer or the New Acquirer, as applicable, giving AHP prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting AHP to assume the sole control of all phases of the defense and/or settlement of such claim, including the selection of counsel. This obligation shall not require AHP to be liable for any negligent act or omission of the Acquirer or the New Acquirer, as applicable, or for any representations and warranties, express or implied, made by the Acquirer or the New Acquirer, as applicable, that exceed the representations and warranties made by AHP to the Acquirer or the New Acquirer, as applicable.

5. During the term of contract manufacturing, upon reasonable request by the Acquirer or the New Acquirer, as applicable, AHP shall make available to the Acquirer or the New Acquirer, as applicable, all records kept in the normal course of business that relate to the cost of manufacturing Tetanus and Diphtheria Vaccines at its Marietta, Pennsylvania facility.

6. Upon reasonable notice and request from the Acquirer or the New Acquirer, as applicable, AHP shall provide information, technical assistance and advice sufficient to assist the Acquirer or the New Acquirer, as applicable, in obtaining all necessary FDA approvals to manufacture Tetanus and Diphtheria Vaccines for sale in the United States. Upon reasonable notice and request from the Acquirer or the New Acquirer, as applicable, AHP shall also provide consultation with knowledgeable employees of AHP and training at the Acquirer's facility or the New Acquirer's facility, as applicable,

for a period of time, not to exceed one (1) year, sufficient to satisfy the Acquirer's management or the New Acquirer's management, as applicable, that its personnel are adequately trained in the manufacture of Tetanus and Diphtheria Vaccines for sale in the United States. Respondent may require reimbursement from the Acquirer or the New Acquirer, as applicable, for all its direct out-of-pocket expenses incurred in providing the services required by this subparagraph II.C.6.

7. AHP shall offer an option for a non-exclusive license of AHP's Vaccine Filling and Packaging Assets to the Acquirer or the New Acquirer, as applicable, which option shall be exercisable within one (1) year from the date the Commission approves the Divestiture Agreement and the Acquirer or New Acquirer, as applicable. The license granted pursuant to this subparagraph: (a) may prohibit any sublicensing by the Acquirer or New Acquirer, as applicable, except as part of a sale of all of the Tetanus and Diphtheria Vaccines assets of the Acquirer or New Acquirer, as applicable, if such sale occurs after the Acquirer or the New Acquirer, as applicable, has obtained all necessary FDA approvals to manufacture tetanus and diphtheria vaccines for sale in the United States; (b) shall terminate if the Acquirer or New Acquirer, as applicable, ceases to produce or sell Tetanus and Diphtheria Vaccines in the United States, unless the license is transferred to a new entity pursuant to paragraph II.C.7 (a); and (c) may prohibit the Acquirer or the New Acquirer, as applicable, from using AHP's Vaccine Filling and Packaging Assets for any purpose other than for filling and packaging products manufactured or sold by the Acquirer or the New Acquirer, as applicable.

8. The Divestiture Agreement shall require the Acquirer or the New Acquirer, as applicable, to submit to the Commission within sixty (60) days of the approval by the Commission of the Divestiture Agreement with the Acquirer or the New Acquirer, as applicable, a certification attesting to the good faith intention of the Acquirer or the New Acquirer, as applicable, and including an actual plan by the Acquirer or the New Acquirer, as applicable, to obtain in an expeditious manner all necessary FDA approvals to manufacture Tetanus and Diphtheria Vaccines for sale in the United States.

9. The Divestiture Agreement shall require the Acquirer or the New Acquirer, as applicable, to submit to the trustee appointed pursuant to paragraph III of this order, periodic verified written reports setting forth in detail the efforts of the Acquirer or the New

Acquirer, as applicable, to sell contract manufactured Tetanus and Diphtheria Vaccines in the United States and to obtain all FDA approvals necessary to manufacture its own Tetanus and Diphtheria Vaccines for sale in the United States. The Divestiture Agreement shall require the first such report to be submitted 60 days from the date the Divestiture Agreement is approved by the Commission and every 90 days thereafter until all necessary FDA approvals are obtained by the Acquirer or the New Acquirer, as applicable, to manufacture Tetanus and Diphtheria Vaccines for sale in the United States. The Divestiture Agreement shall also require the Acquirer or the New Acquirer, as applicable, to report to the Commission and the trustee at least thirty (30) days prior to its ceasing the sale of contract manufactured Tetanus and Diphtheria Vaccines in the United States for any time period exceeding sixty (60) days or abandoning its efforts to obtain all necessary FDA approvals to manufacture its own Tetanus and Diphtheria Vaccines for sale in the United States.

10. The Divestiture Agreement shall provide that the Commission may terminate the Divestiture Agreement if the Acquirer or the New Acquirer, as applicable: (1) voluntarily ceases for sixty (60) days or more the sale of Tetanus and Diphtheria Vaccines in the United States prior to obtaining all necessary FDA approvals to manufacture Tetanus and Diphtheria Vaccines for sale in the United States; (2) abandons its efforts to obtain all necessary FDA approvals to manufacture Tetanus and Diphtheria Vaccines for sale in the United States; or (3) fails to obtain all necessary FDA approvals of its own to manufacture Tetanus and Diphtheria Vaccines for sale in the United States within five (5) years from the date the Commission approves the Divestiture Agreement with the Acquirer or the New Acquirer, as applicable; provided, however, that the five (5) year period may be extended for a period not to exceed twenty-four (24) months if the trustee certifies to the Commission that the Acquirer or the New Acquirer, as applicable, made good faith efforts to obtain all necessary FDA approvals for manufacturing Tetanus and Diphtheria Vaccines for sale in the United States and that such FDA approvals appear likely to be obtained within such extended time period.

11. The Divestiture Agreement shall provide that, if the Divestiture Agreement is terminated, the AHP Tetanus and Diphtheria Vaccine Assets shall be divested by the trustee to a New Acquirer pursuant to the provisions of paragraph IV of this order.

D. While the obligations imposed by paragraphs II, III or IV of this order are in effect, respondent shall take such actions as are necessary: (1) to maintain all necessary FDA approvals to manufacture AHP's Tetanus and Diphtheria Vaccines for sale in the United States; (2) to maintain the viability and marketability of AHP's Tetanus and Diphtheria Vaccine Assets as well as all tangible assets, including manufacturing facilities, needed to contract manufacture and sell Tetanus and Diphtheria Vaccines; and (3) to prevent the destruction, removal, wasting, deterioration or impairment of any of AHP's Tetanus and Diphtheria Vaccine Assets or tangible assets including manufacturing facilities needed to contract manufacture and sell Tetanus and Diphtheria Vaccines except for ordinary wear and tear.

III. TETANUS AND DIPHTHERIA VACCINES
TRUSTEE AUDITOR PROVISIONS

It is further ordered, That:

A. Within thirty (30) days of the date this order becomes final, the Commission shall appoint a trustee to ensure that AHP and the Acquirer or the New Acquirer, as applicable, expeditiously perform their respective responsibilities as required by the Divestiture Agreement approved by the Commission and by paragraph II of this order. AHP shall consent to the following terms and conditions regarding the trustee's powers, duties, authorities, and responsibilities:

1. The Commission shall select the trustee, subject to the consent of AHP, which consent shall not be unreasonably withheld. If AHP has not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after notice by the staff of the Commission to AHP of the identity of any proposed trustee, AHP shall be deemed to have consented to the selection of the proposed trustee.

2. The trustee shall have the power and authority to assure respondent's compliance with the terms of paragraph II of this order and with the Divestiture Agreement with the Acquirer or the New Acquirer, as applicable.

3. Within ten (10) days after appointment of the trustee, AHP shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the trustee all the rights and powers necessary to permit the trustee to assure respondent's compliance with the terms of paragraph II of this order and with the Divestiture Agreement with the Acquirer or the New Acquirer, as applicable.

4. The trustee shall serve until such time as the Acquirer or the New Acquirer, as applicable, has received all necessary FDA approvals to manufacture Tetanus and Diphtheria Vaccines for sale in the United States, or for fifteen years, whichever is shorter.

5. The trustee shall have full and complete access to the personnel, books, records, facilities and technical information related to the manufacture of AHP's Tetanus and Diphtheria Vaccines, or to any other relevant information, as the trustee may reasonably request, including but not limited to all records kept in the normal course of business that relate to the cost of manufacturing Tetanus and Diphtheria Vaccines. Respondent shall cooperate with any reasonable request of the trustee. Respondent shall take no action to interfere with or impede the trustee's ability to assure respondent's compliance with paragraph II of this order and the Divestiture Agreement with the Acquirer or the New Acquirer, as applicable.

6. The trustee shall serve, without bond or other security, at the cost and expense of AHP, on such reasonable and customary terms and conditions as the Commission may set. The trustee shall have authority to employ, at the cost and expense of AHP, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all expenses incurred. The Commission shall approve the account of the trustee, including fees for his or her services.

7. Respondent shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other 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 liabilities, losses, damages, claims, or expenses result from the misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

8. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in paragraph III of this order.

9. The Commission may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of paragraph II of this order and the Divestiture Agreement with the Acquirer or the New Acquirer, as applicable.

10. The trustee shall evaluate reports submitted to it by the Acquirer or the New Acquirer, as applicable, with respect to the efforts of the Acquirer or the New Acquirer, as applicable, to obtain all necessary FDA approvals to manufacture Tetanus and Diphtheria Vaccines for sale in the United States and shall report in writing to the Commission every six months concerning compliance by the respondent and the Acquirer or the New Acquirer, as applicable, with the provisions of paragraph II of this order and the efforts of the Acquirer or the New Acquirer, as applicable, to receive all necessary FDA approvals to manufacture Tetanus and Diphtheria Vaccines for sale in the United States.

B. Respondent shall comply with all reasonable directives of the trustee regarding:

1. Respondent's obligations to contract manufacture and deliver the Acquirer's requirements or the New Acquirer's requirements, as applicable, for Tetanus and Diphtheria Vaccines, pursuant to paragraphs II.C.1 and II.C.2 of this order;

2. Respondent's obligations to provide representations and warranties regarding Tetanus and Diphtheria Vaccines, pursuant to paragraph II.C.4 of this order; and

3. Respondent's obligations to provide information, technical assistance and advice, pursuant to paragraph II.C.6 of this order.

C. If the Commission terminates the Divestiture Agreement pursuant to paragraph II.C.10, the Commission may direct the trustee to seek a New Acquirer, as provided for in paragraph IV of this order.