efficacy or duration of results of any treatment procedure. (¶¶ I.D., I.E., I.F.)

Alleged Misrepresentations Re: Billing Practices. The complaint further charges that respondents Genetus, George Oprean, and Linda Oprean misrepresented to patients and their insurance companies that all medical tests and laboratory procedures billed by Genetus had been performed, that all patients had been diagnosed and had services performed or ordered by a medical practitioner licensed to do so, and that all claims submitted by Genetus to insurance companies were signed or approved for signature by a physician. (¶ 13) The complaint also charges that respondents Genetus, George Oprean, and Linda Oprean also misrepresented to patients that, in most cases, the costs of their treatment program would be covered by the patients' health insurance. (¶ 15) In fact, according to the complaint, not all the medical tests and laboratory tests billed by Genetus were performed, many patients were diagnosed and had services performed or ordered by Linda Oprean, and many claims were signed by Linda Oprean without a physician's knowledge or permission. (¶ 14) For these reasons, the costs of Genetus' treatment program were not, in most cases, covered by patients' health insurance. (¶ 16) In addition, patients were otherwise responsible for paying for most or all of the amounts billed by Genetus because the amounts Genetus charged bore no reasonable relationship to the costs of certain goods and services and substantially exceeded the amount the insurers had agreed to pay for such items. (¶ 16) The proposed order prohibits all respondents from making the alleged misrepresentations. (¶¶ I.H., I.I.)

Monetary Remedies. The proposed order also prohibits all respondents from taking any action to collect any payments still owing from any customers of Genetus for any of its impotence treatment services. In addition, the proposed order requires Genetus, George Oprean, and Linda Oprean to pay consumer redress in the amount of $250,000, liability for which is suspended based upon the truthfulness and accuracy of financial statements provided to the Commission by all four respondents. If the Commission later determines that any financial statement contained any material misrepresentations or omissions, the entire amount of $250,000 is immediately due and payable.

The purpose of this analysis is to facilitate comment on the proposed consent order. This analysis is not intended to constitute an official interpretation of the agreement or proposed order, or to modify in any way its terms.

Donald S. Clark,

Secretary.

[FR Doc. 95–23796 Filed 9–25–95; 8:45 am]

BILLING CODE 6750–01–M

[File No. 951 0090]

Hoechst AG; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: This consent agreement, accepted subject to final Commission approval, settles alleged violations of federal law prohibiting unfair or deceptive acts and practices and unfair methods of competition arising from the $7.1 billion merger of Hoechst AG and Marion Merrell Dow, Inc. The consent agreement, among other things, would require Hoechst—a pharmaceutical firm—to provide Biovail Corporation International with a letter of access to the toxicology data necessary to secure additional FDA approvals for a hypertension and cardiac drug called Tiazac (diltiazem). It would also require Hoechst to return any confidential information obtained from Biovail; to refrain from using the information; to dismiss a patent infringement lawsuit filed by Marion Merrell Dow regarding Tiazac; to withdraw a citizen petition Marion Merrell Dow filed with the Food and Drug Administration relating to Tiazac; and to agree not to file any subsequent litigation against Biovail regarding diltiazem. In addition, the consent agreement would require Hoechst to divest the rights to either Trental or Beraprost (two drugs intended to treat intermittent claudication, a painful leg cramping condition); to divest the rights to Pentasa (or the generic formulation), which is one of two oral forms of mesalamine used to treat ulcerative colitis and Crohn's Disease; and to divest the rights to Rifadin (or the generic formulation), which is used to treat tuberculosis. The required divestitures would have to be made to Commission approved entities. If they are not completed within nine months of the date on which the Commission accords final approval to the consent agreement, the consent agreement would permit the Commission to appoint a trustee to complete them.

DATES: Comments must be received on or before November 27, 1995.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: William Baer, FTC/H–374, Washington, DC 20580 (202) 326–2932; or Ann Malester, FTC/S–2308, Washington, DC 20580 (202) 326–2682.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and § 2.34 of the Commission's rules of practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's rules of practice (16 CFR 4.9(b)(6)(ii)).

In the Matter of Hoechst AG, a corporation.

Agreement Containing Consent Order

The Federal Trade Commission (''Commission''), having initiated an investigation of the merger of Hoechst AG (''Hoechst''), through its United States subsidiary, Hoechst Corporation, and Marion Merrell Dow Inc. (''MMD''), and it now appearing that Hoechst, hereinafter sometimes referred to as ''Proposed Respondent,'' is willing to enter into an Agreement Containing Consent Order to (i) divest certain assets, (ii) cease and desist from certain acts, and (iii) provide for certain other relief:

It is hereby agreed by and between Proposed Respondent, by its duly authorized officers and its attorneys, and counsel for the Commission that:

1. Proposed Respondent Hoechst is a corporation organized, existing, and doing business under and by virtue of the laws of Germany, with its principal place of business located at 65926 Frankfurt am Main, Germany.

2. Proposed Respondent admits all the jurisdictional facts set forth in the draft of complaint.

3. Proposed Respondent waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this Agreement; and

(d) Any claim under the Equal Access to Justice Act.

4. This Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Agreement and so notify Proposed Respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This Agreement is for settlement purposes only and does not constitute an admission by Proposed Respondent that the law has been violated as alleged in the draft of complaint, or that the facts as alleged in the draft complaint, other than jurisdictional facts, are true.

6. This Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's rules, the Commission may, without further notice to Proposed Respondent, (1) issue its complaint corresponding in form and substance with the draft of complaint and its decision containing the following Order to divest and to cease and desist in disposition of the proceeding, and (2) make information public with respect thereto. When so entered, the Order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The Order shall become final upon service. Delivery by the United States Postal Service of the complaint and decision containing the agreed-to Order to Proposed Respondent's counsel, William C. Pelster, of Skadden, Arps, Slate, Meagher & Flom, 919 Third Avenue, New York, New York 10022–3897, shall constitute service. Proposed Respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the Order, and no agreement, understanding, representation, or interpretation not contained in the Order or the Agreement may be used to vary or contradict the terms of the Order.

7. Proposed Respondent has read the proposed Complaint and Order contemplated hereby. Proposed Respondent understands that once the Order has been issued, it will be required to file one or more compliance reports showing it has fully complied with the Order. Proposed Respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final. By signing this Agreement, Proposed Respondent represents that the relief contemplated by this Agreement can be accomplished.

Order

I

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

A. ''Respondent'' or ''Hoechst'' means Hoechst AG, its directors, officers, employees, agents and representatives, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled by Hoechst AG; subsidiaries, divisions, groups and affiliates in which Hoechst AG owns more than 25 percent of the voting securities; and the respective directors, officers, employees, agents and representatives, and the respective successors and assigns of each.

B. ''MMD'' means Marion Merrell Dow Inc., its directors, officers, employees, agents and representatives, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled by Marion Merrell Dow Inc.; and the respective directors, officers, employees, agents and representatives, and the respective successors and assigns of each.

C. ''Merger'' means the merger of Hoechst and MMD through the acquisition by Hoechst of the voting securities of MMD pursuant to a Stock Purchase Agreement and an Agreement and Plan of Merger both dated as of May 3, 1995.

D. ''Commission'' means the United States Federal Trade Commission.

E. ''FDA'' means the United States Food and Drug Administration.

F. ''NDA'' means new drug application.

G. ''ANDA'' means abbreviated new drug application.

H. ''Diltiazem'' means any formulation of the compound diltiazem hydrochloride used in the treatment of hypertension or angina.

I. ''Biovail'' means Biovail Corporation International, organized and existing under the laws of Canada and with its offices and principal place of business at 460 Comstock Road, Scarborough, Ontario, Canada, including its successors, licensees and assigns.

J. ''Biovail Diltiazem Products'' means the sustained release and/or extended release diltiazem products that Hoechst was developing with Biovail pursuant to the Rights Agreement that Hoechst and Biovail entered into on June 30, 1993.

K. ''Documents'' means all computer files and written, recorded, and graphic materials of every kind. The term ''documents'' includes electronic correspondence and drafts of documents, originals and all copies of documents, and copies of documents the originals of which are not in the possession, custody or control of the company.

L. ''Non-Public Information'' means any information or documents not in the public domain furnished by Biovail to Hoechst in connection with the Biovail Diltiazem Products. Non-Public Information shall not include information that subsequently becomes public or falls within the public domain through no violation of this Order by Respondent or nor shall it include information that subsequently becomes known to Respondent from a third-party not in breach of a confidential disclosure agreement.

M. ''Beraprost'' means the prostaglandin analog(s) licensed by Toray Industries, Inc. to MMD used for the treatment of peripheral arterial disease, including, but not limited to, intermittent claudication.

N. ''Beraprost Assets'' means all of MMD's U.S. assets and rights relating to the research and development, manufacture and sale of Beraprost, that are not part of MMD's physical facilities. ''Beraprost Assets'' include, but are not limited to, all rights to brand or trade name, 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 to use such information), software specific to MMD's Beraprost, inventory sufficient for the Acquirer to complete all safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals, and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

O. ''Trental®'' means the compound pentoxifylline marketed by Hoechst for use in the treatment of vascular disease, including, but not limited to, intermittent claudication.

P ''Trental® Assets'' means all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of Trental®, including the unique physical assets used by Hoechst to manufacture Trental® and all of its brand names and trade names. ''Trental® Assets'' include, but are not limited to, all rights to brand or trade name, 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 to use such information), software specific to Hoechst's Trental®, and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

Q. ''Mesalamine'' means the compound mesalamine used for the treatment of ulcerative colitis and Crohn's disease.

R. ''Mesalamine Assets'' means either (1) all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of mesalamine by Hoechst that are not part of Hoechst's physical facilities and that were not acquired through the Merger; or (2) all of MMD's U.S. assets and rights relating to the research and development, manufacture and sale of mesalamine by MMD, including the unique physical assets used by MMD to manufacture mesalamine and all of its brand names and trade names. ''Mesalamine Assets'' include, but are not limited to, all rights to brand or trade names, 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, information stored on management information systems (and specifications sufficient for the Acquirer to use such information), inventory sufficient for the Acquirer to complete all ongoing safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

S. ''Rifampin'' means the compound rifampin used for the treatment of tuberculosis.

T. ''Rifampin Assets'' means either (1) all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of rifampin by Hoechst that are not part of Hoechst's physical facilities and that were not acquired through the Merger; or (2) MMD's U.S. assets and rights relating to the research and development, manufacture and sale of rifampin by MMD, including the unique physical assets used by MMD to manufacture rifampin and all of its brand names and trade names. ''Rifampin Assets'' include, but are not limited to, all rights to brand or trade names, 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, information stored on management information systems (and specifications sufficient for the Acquirer to use such information), inventory sufficient for the Acquirer to complete all ongoing safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

U. ''Acquirer'' means the entity or entities to whom Hoechst shall divest the assets required to be divested pursuant to this Order.

V. ''Contract Manufacture'' means the manufacture of Trental®, mesalamine or rifampin, as applicable, by Hoechst for sale to an Acquirer in a form acceptable for commercial sale in the United States, in each form of packaging used by Respondent or MMD in the distribution and sale of such product, with information including, but not limited to, the name and identification codes of the Acquirer inscribed on the packaging, and packaged in units specified by the Acquirer, as permitted by the FDA.

W. ''Cost'' means Respondent's or MMD's actual per unit cost of manufacturing the assets to be divested pursuant to this Order.

X. ''Formulation'' means any and all information, including patent, trade secret information, technical assistance and advice, relating to the manufacture of the assets to be divested pursuant to this Order that meet FDA approved specifications therefor.

II

It is further ordered That:

A. Within seven (7) days of the date this Order becomes final:

1. Respondent shall grant to Biovail the right of reference to the pharmacology, toxicology and animal reproductive toxicology data contained in MMD's NDA No. 18–602 for Diltiazem on file with the FDA. Respondent shall make the necessary filings with the FDA authorizing the FDA to refer to the appropriate section(s) of MMD's NDA No. 18–602 for such data (including, but not limited to, pharmacology and toxicology data) in support of Biovail's NDA No. 20–401 for the Biovail Diltiazem Products, including any supplemental NDAs or related NDAs. Provided however, the right of reference granted to Biovail pursuant to this Paragraph does not constitute a general release of the data contained in MMD's NDA No. 18–602, except as it might appear in labelling.

2. Respondent shall withdraw the Citizen Petition(s) that MMD filed with the FDA relating to NDAs under section 505(b)(2) of the Food, Drug and Cosmetics Act, 21 U.S.C. 355(b)(2), including the NDA for the Biovail Diltiazem Products. Respondent shall not file any further Citizen Petition with the FDA relating to the NDA under section 505(b)(2) of the Food, Drug and Cosmetics Act, 21 U.S.C. 355(b)(2), that could have the effect of delaying the approval of the NDA for the Biovail Diltiazem Products.

3. Respondent shall file a stipulation of dismissal with prejudice to MMD of all litigation currently pending in the United States between or among MMD, Hoechst, and Biovail, including, but not limited to, *Marion Merrell Dow Inc., Carderm Capital L.P. and Elan plc* v. *Hoechst-Roussel Pharmaceuticals, Inc.*, No. 93–5074 (D.N.J), and shall not institute or cause any other person to institute any patent infringement action against Biovail relating to the Biovail Diltiazem Products.

4. Respondent shall return to Biovail all documents relating to the research, development, FDA approval, patenting, manufacture, marketing, or sale of the Biovail Diltiazem Products.

B. Respondent shall not use any Non-Public Information relating to the Biovail Diltiazem Products and shall not provide, disclose or otherwise make available to MMD any Non-Public Information relating to the Biovail Diltiazem Products.

C. The purpose of this Paragraph II is to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

III

It is further ordered That:

A. Respondent shall divest, absolutely and in good faith, within nine (9) months of the date this Order becomes final, either the Beraprost Assets or Trental® Assets.

B. Respondent shall divest the Beraprost Assets or Trental® Assets only to an Acquirer 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 the Beraprost Assets or Trental® Assets is to ensure continued competition between Trental® and Beraprost, in the same manner in which Trental® and Beraprost would compete absent the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

C. The time period for divestiture pursuant to this Paragraph III of this Order shall be tolled if and when Respondent:

1. Provides to the Commission objective evidence, including, but not limited to, results of clinical trials, indicating that, based on a compound's medical profile, and through no fault of Respondent, the Beraprost Assets are not viable or marketable; and

2. Petitions the Commission to modify this Order, pursuant to section 5(b) of the FTC Act and § 2.51 of the Commission's rules of practice, based on the circumstances described in Paragraph III.C.1 of this Order.

This tolling of the time period for divestiture shall end when the Commission rules on Respondent's petition to modify this Order.

IV

It is further ordered That:

A. Respondent shall divest, absolutely and in good faith, within nine (9) months of the date this Order becomes final, the Mesalamine Assets.

B. Respondent shall divest the Mesalamine Assets only to an Acquirer 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 the Mesalamine Assets is to ensure continued competition between Hoechst's mesalamine and MMD's mesalamine, in the same manner in which these compounds would compete absent the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

V

It is further ordered That:

A. Respondent shall divest, absolutely and in good faith, within nine (9) months of the date this Order becomes final, the Rifampin Assets.

B. Respondent shall divest the Rifampin Assets only to an Acquirer 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 the Rifampin Assets is to ensure continued competition between Hoechst's rifampin and MMD's rifampin, in the same manner in which these compounds would compete absent the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

VI

It is further ordered That:

A. Upon reasonable notice and request from the Acquirer(s) to Hoechst, Hoechst shall provide information, technical assistance and advice to the Acquirer(s) with respect to any assets divested pursuant to this Order such that the Acquirer(s) will be capable of continuing all applicable research, development and manufacturing. Such assistance shall include reasonable consultation with knowledgeable employees of Hoechst and training at the Acquirer's facility for a period of time sufficient to satisfy the Acquirer's management that its personnel are adequately knowledgeable about the assets divested pursuant to this Order. However, Respondent shall not be required to continue providing such assistance for more than twelve (12) months after divestiture of such assets. Respondent may require reimbursement from the Acquirer(s) for all of its own direct costs incurred in providing the services required by this Subparagraph. Direct costs, as used in this Subparagraph, means all actual costs incurred exclusive of overhead costs. If an Acquirer hires any of Respondent's officers, directors, agents, or employees whose work relates to a divested asset being acquired by the Acquirer, Respondent shall waive any confidentiality or non-competition employment rights relating to assets divested pursuant to this Order that Respondent has against such employee.

B. Pending divestiture of the assets to be divested pursuant to this Order, Respondent shall:

1. Take such actions as are necessary to prevent the destruction, removal, wasting, deterioration or impairment of the assets to be divested pursuant to this Order, except for ordinary wear and tear; and

2. Maintain research and development of the assets required to be divested by this Order, at the levels planned by either Hoechst or MMD for such assets as of June 1, 1995.

C. Hoechst shall maintain the physical assets, if any exist, necessary to manufacture Trental®, Beraprost, mesalamine and rifampin, until Respondent's obligations pursuant to Paragraphs III, IV, V, VI and VII of this Order have been fulfilled. The maintenance of physical assets described in this subparagraph shall not exceed two (2) years following divestitures pursuant to Paragraphs III, IV and V of this Order.

D. Respondent shall obtain from each Acquirer a certification of the Acquirer's good faith intention to obtain in an expeditious manner all necessary FDA approvals to manufacture and sell in the United States the assets to be divested pursuant to this Order and a commitment by the Acquirer to use reasonable diligence to continue to research and develop the assets to be divested pursuant to this Order for sale in the United States.

VII

It is further ordered That:

A. If Respondent fulfills its obligations pursuant to this Order by divesting assets relating to a product for which the FDA has issued either approval of a NDA or an ANDA (hereinafter Divested Product), Respondent shall execute an Agreement (hereinafter Divestiture Agreement) with the Acquirer of such Divested Product.

B. Each Divestiture Agreement shall include the following and Respondent shall commit to satisfy the following:

1. Respondent shall Contract Manufacture and deliver to the Acquirer in a timely manner the requirements of the Acquirer for the Divested Product at Respondent's or MMD's Cost for a period not to exceed five (5) years from the date the Divestiture Agreement is approved, or six (6) months after the date the Acquirer obtains all necessary FDA approvals to manufacture the Divested Product for sale in the United States, whichever is earlier.

2. Respondent shall commence delivery of the Divested Product to the Acquirer within two (2) months from the date the Commission approves the Acquirer and the Divestiture Agreement.

3. After Respondent commences delivery of the Divested Product to the Acquirer pursuant to Paragraph VII.B.2 of this Order, all inventory of the Divested Product produced by Respondent for the U.S. market at the facility that produced such Divested Product, regardless of the date of its

production, may be sold by Respondent only to the Acquirer.

4. Respondent shall make representations and warranties to the Acquirer that the Divested Product Contract Manufactured by Respondent for the Acquirer meets the FDA approved specifications therefor and is not adulterated or misbranded within the meaning of the Food, Drug and Cosmetic Act, 21 U.S.C. 321, *et seq.* 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 Divested Product Contract Manufactured by Respondent to meet FDA specifications. This obligation shall be contingent upon the Acquirer giving Respondent prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting Respondent 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 Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondent to the Acquirer.

5. During the term of Contract Manufacturing, upon reasonable request by the Acquirer, Respondent shall make available to the trustee appointed pursuant to Paragraph VIII.A. of this Order all records kept in the normal course of business that relate to the cost of manufacturing the Divested Product.

VIII

It is further ordered That:

A. Within forty-five (45) days of the date this Order becomes final, the Commission shall appoint a trustee to ensure that Respondent expeditiously performs its responsibilities required by this Order. Respondent shall consent to the following terms and conditions regarding the trustee's powers, duties, authorities, and responsibilities under this Paragraph:

1. The Commission shall select the trustee, 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 any proposed trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed trustee, Respondent shall be deemed to have consented to the selection of the proposed trustee.

2. Within ten (10) days after the appointment of the trustee, Respondent 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 this Order, including the rights and powers necessary to divest assets, if the trustee is so directed by the Commission. As part of the trustee agreement, the trustee shall execute confidentiality agreement(s) with Respondent.

3. The trustee shall serve until either (a) the Acquirer(s) has filed a complete application with the FDA for approval to manufacture and sell a product(s) based on the Trental® Assets or the Beraprost Assets, the Rifampin Assets and the Mesalamine Assets, as applicable; (b) the trustee determines that the Acquirer(s) has abandoned its efforts to obtain FDA approval to manufacture and sell a product(s) based upon the Trental® Assets or the Beraprost Assets, the Rifampin Assets and the Mesalamine Assets, as applicable; or (c) the trustee determines that the Acquirer(s) has failed to exercise reasonable diligence in research and development toward obtaining FDA approval to manufacture and sell a product(s) based upon the Trental® Assets or the Beraprost Assets, the Rifampin Assets and the Mesalamine Assets, as applicable, which lack of diligence will have been certified to and accepted by the Commission, whichever comes first. The trustee's service shall continue for no more than two (2) years following divestiture of the Trental® Assets or the Beraprost Assets, the Rifampin Assets and the Mesalamine Assets, as applicable.

4. The trustee shall have full and complete access to the personnel, books, records, facilities and technical information related to the Trental® Assets or the Beraprost Assets, the Rifampin Assets and the Mesalamine Assets, 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 research and development of and the cost of manufacturing Trental® or Beraprost, mesalamine and rifampin. Respondent shall develop such financial or other information as the trustee may request and shall cooperate with the trustee. Respondent shall take no action to interfere with or impede the trustee's accomplishment of his or her responsibilities pursuant to this Order.

5. The 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 may set. The trustee shall have authority to employ, at the cost and expense of Respondent, 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.

6. 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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

7. 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 VIII.A. of this Order.

8. 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 accomplish the requirements of this Order.

9. The trustee shall report in writing to Respondent and the Commission every one hundred and eighty (180) days concerning the trustee's obligations pursuant to this Paragraph VIII.

B. Respondent shall comply with all reasonable directives of the trustee regarding Respondent's obligations to comply with this Order.

C. The trustee may require Respondent to manufacture Beraprost for use by the Acquirer in conducting clinical trials or other actions as required by the FDA if:

1. the Acquirer has depleted its inventory of Beraprost acquired pursuant to the divestiture;

2. the Acquirer has a need to conduct further trials or studies prior to submission of an application to the FDA to manufacture and sell a product based on the Beraprost Assets; and

3. despite good faith efforts to establish its own manufacturing capability for Beraprost, the Acquirer has not succeeded in doing so as of the time Beraprost is needed for such

clinical trials or other actions as required by the FDA.

The trustee shall determine reasonable compensation for Respondent, based upon the costs of manufacture for such production.

IX

It is further ordered That:

A. If Respondent has not divested, absolutely and in good faith and with the Commission's prior approval, (1) either the Trental® Assets or the Beraprost Assets; (2) the Mesalamine Assets; and (3) the Rifampin Assets, within the time required by Paragraphs III.A., IV.A., and V.A. of this Order, the Commission may direct the trustee appointed pursuant to Paragraph VIII of this Order to accomplish any divestiture required pursuant to this Order. Neither the decision of the Commission to direct the trustee nor the decision of the Commission not to direct the trustee to divest the assets required to be divested shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to section 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondent to comply with this Order. Respondent shall consent to the following terms and conditions regarding the trustee's powers, duties, authorities, and responsibilities under this Paragraph:

B. If the trustee is directed under Subparagraph A. of this Paragraph to divest any assets, Respondent shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:

1. The Commission shall extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include divesting any assets required to be divested by this Order that have not been divested.

2. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest any assets required to be divested pursuant to this Order that have not been divested.

3. Within ten (10) days after the extension of the trustee's authority and responsibilities, Respondent shall amend the existing trust agreement in a manner that, subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestitures required by this Order.

4. The trustee shall have twelve (12) months from the date the Commission approves the extension of the trustee's authorities and responsibilities as described in Paragraph IX.B.3 to accomplish the divestiture(s), which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve month period, the trustee has submitted a plan of divestiture(s) or believes that divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court; provided, however, the Commission may extend this period only two (2) times.

5. The trustee shall have full and complete access to the personnel, books, records, facilities and technical information related to the assets to be divested by the trustee, 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 research and development of, and the cost of manufacturing, Trental®, Beraprost, mesalamine and rifampin. Respondent shall develop such financial or other information as the trustee may request and shall cooperate with the trustee. Respondent shall take no action to interfere with or impede the 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 trustee, by the court.

6. The trustee shall use his or her 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 at no minimum price; to assure that Respondent enters into Divestiture Agreement(s) that comply with the provisions of Paragraph VII; to assure that Respondent and the Acquirer(s) comply with the remaining provisions of this Order. The divestitures and the Divestiture Agreement(s) shall be made in the manner set forth in Paragraphs III, IV, V, VI and VII of this Order; provided, however, that if the trustee receives bona fide offers from more than one acquiring entity for any of the assets to be divested pursuant to this Order, and if the Commission determines to approve more than one such acquiring entity for any of the assets to be divested pursuant to this Order, the trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission.

7. The 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 may set. The trustee shall have authority to employ, at the cost and expense of Respondent, 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 monies derived from the sale and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondent. The trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee's divesting the assets to be divested.

8. 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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

9. 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 VIII.A. of this Order.

10. The Commission or, in the case of a court-appointed trustee, the court 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 accomplish the divestitures required by this Order.

11. The trustee shall report in writing to Respondent and the Commission every sixty (60) days concerning the trustee's efforts to accomplish the divestiture(s) required by this Order.

12. If a divestiture application filed pursuant to Paragraph III.A. is pending before the Commission, and Respondent petitions the Commission to modify this Order based on the conditions in Paragraph III.C., then the Commission shall not approve the divestiture application until it rules on the petition to modify.

X

It is further ordered That, for the purpose of determining or securing compliance with this Order, Respondent shall permit any duly authorized representatives of the Commission:

A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondent, relating to any matters contained in this Order; and

B. Upon five (5) days' notice to Respondent, and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondent, who may have counsel present regarding such matters.

XI

It is further ordered That, within sixty (60) days after the date this Order becomes final and every sixty days (60) days thereafter until Respondent has fully complied with the provisions of Paragraphs II, III, IV, V, VI and VII of this Order, 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 include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraphs II, III, IV, V, VI and VII of this Order, including a description of all substantive contacts or negotiations for accomplishing the divestiture and the identity of all parties contacted. Respondent shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

XII

It is further ordered That Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent such as dissolution, assignment, sale resulting in the emergence of a successor, or the creation or dissolution of subsidiaries, or any other change that may affect compliance obligations arising out of this Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an agreement containing a proposed Consent Order (''Order'') from Hoechst AG (''Hoechst''), which remedies the anticompetitive effects of Hoechst's merger with Marion Merrell Dow Inc. (''MMD''). The proposed order requires Hoechst to divest assets and undertake certain actions to restore competition in four separate markets: (1) Once-a-day diltiazem, (2) drugs for the treatment of intermittent claudication, (3) oral dosage forms of mesalamine, and $4) rifampin.

The proposed Order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed Order.

On June 28, 1995, Hoechst merged with Marion Merrell Dow, which was formerly 71% owned by The Dow Chemical Company. Hoechst was permitted to complete the merger prior to the conclusion of the Commission's investigation under the terms of a Hold Separate Agreement, which provided that Marion Merrell Dow would be operated separately from Hoechst until the conclusion of the investigation. As a further condition to the Commission allowing Hoechst to consummate the merger, Hoechst agreed to accept the terms of the proposed Order if after the conclusion of its investigation, the Commission determined that the proposed Order was necessary.

The proposed complaint alleges that the merger violates 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 four markets in the United States: (1) The research, development, manufacture and sale of once-a-day diltiazem; (2) the research, development, manufacture and sale of drugs for the treatment of intermittent claudication; (3) the research, development, manufacture and sale of oral dosage forms of mesalamine; and (4) the research, development, manufacture and sale of rifampin.

The proposed Order would remedy the alleged violations. First, in the market for once-a-day diltiazem the proposed Order facilitates effective competition in the once-a-day diltiazem market. MMD markets the leading once-a-day diltiazem product, Cardizem® CD, which is used to treat hypertension and angina. In 1993, Hoechst and MMD began the negotiations that culminated in the merger of the two companies. At the same time, Hoechst and Biovail Corporation International (''Biovail'') were developing, Tiazac®, a once-a-day diltiazem product intended to compete directly with MMD's Cardizem® CD. The Hoechst-MMD merger negotiations affected Hoechst's incentives to develop Tiazac® as an independent competitor to Cardizem® CD, delaying and impeding entry of Tiazac® into the market. Just before the merger was announced, Hoechst returned its rights to Tiazac®. However, this purported ''fix-it-first'' failed to remedy the anticompetitive effects resulting from the merger.

Under the proposed Order, Hoechst is required, within seven days of the date the Order becomes final, to provide Biovail with a letter of access to the toxicology data necessary to secure additional Food and Drug Administration (''FDA'') approvals for Tiazac®. In addition, the proposed Order requires Hoechst to return any confidential information obtained from Biovail in the course of their relationship, to refrain from using this information, to dismiss a patent infringement lawsuit filed by MMD relating to Tiazac®, and to withdraw a Citizen Petition filed with the FDA by MMD relating to Tiazac®. These provisions will remedy the loss of competition that resulted from the merger.

Second, in the market for drugs for the treatment of intermittent claudication, Hoechst markets Trental®, the only drug currently approved by the FDA for the treatment of this disease, which is painful leg cramping as a result of arteriosclerosis. MMD was developing Beraprost, one of only a few drugs in development for the treatment of intermittent claudication. Thus, the merger eliminates significant potential competition between Trental® and Beraprost. The proposed Order would remedy the alleged violation by requiring Hoechst to divest either Trental® or Beraprost. Hoechst must accomplish the divestiture to a Commission-approved acquirer within nine months.

Third, in the market for oral dosage forms of mesalamine, MMD markets Pentasa®, one of two oral forms of mesalamine available for the treatment of the gastrointestinal diseases of ulcerative colitis and Crohn's Disease. Hoechst was one of only a few firms developing a generic formulation of mesalamine. Therefore, the merger eliminates significant potential competition between these two products. The proposed Order requires Hoechst, within nine months, to divest either Pentasa® or the generic formulation in development to a Commission-approved acquirer.

Fourth, in the market for rifampin, which is used to treat tuberculosis, MMD markets Rifadin®. Hoechst was one of only a few firms developing a generic formulation of rifampin. Thus, the merger eliminates significant potential competition between these two products. The proposed Order requires Hoechst, within nine months, to divest either Rifadin® or the generic formulation of rifampin in development, to a Commission-approved acquirer.

The proposed Order also provides for the appointment of a trustee to assure that Hoechst appropriately completes the required divestitures. If Hoechst fails to divest any of the products within nine months, then the trustee's authority may be extended to include responsibility for accomplishing the required divestitures. The Order also requires Hoechst to provide technical assistance and advice to assist the purchaser(s) in obtaining FDA approval to manufacture and sell the divested products.

Under the provisions of the Order, Hoechst is also required to provide to the Commission a report of compliance with the divestiture provisions of the Order within sixty (60) days following the date the Order becomes final, and every sixty (60) days thereafter until Hoechst has completed the required divestitures. The Order also requires Hoechst to notify the Commission at least thirty (30) days prior to any change in the structure of Hoechst resulting in the emergence of a successor.

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

Donald S. Clark,

Secretary.

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BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Arthritis Advisory Committee

Date, time, and place. October 11, 1995, 8 a.m., Holiday Inn—Gaithersburg, Whetstone Ballroom, Two Montgomery Village Ave., Gaithersburg, MD, and October 12, 1995, 8:30 a.m., Holiday Inn—Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open committee discussion, October 11, 1995, 8 a.m. to 1 p.m.; open public hearing, 1 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 5 p.m.; open committee discussion, October 12, 1995, 8:30 a.m. to 9:30 a.m.; open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 4:30 p.m.; Isaac F. Roubein or Kathleen Reedy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Arthritis Advisory Committee, code 12532.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before September 29, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On October 11, 1995, the committee will consider issues presented in a citizen petition submitted by the Health Research Group of Public Citizen (Docket No. 94P–0458/CP1). The petition requests that FDA remove from the market drug products containing piroxicam, a nonsteroidal anti-inflammatory drug (NSAID), stating that the drug presents a significantly higher risk of gastropathy than other drugs in its class. The committee will examine safety data for the drug and advise FDA on whether piroxicam should be withdrawn from the market, whether changes in the drugs' labeling should be made, or whether no action need be taken. On October 12, 1995, the committee will examine the adequacy of the current gastropathy warnings in labeling for the class of NSAID's.

Food Advisory Committee

Date, time, and place. October 11 and 12, 1995, 9 a.m., Disabled American Veterans, Denvel D. Adams National Service and Legislative Headquarters, 807 Maine Ave. SW., Washington, DC. Seating for this meeting is limited. If you plan to attend, please call a contact person listed below to reserve a seat.

Type of meeting and contact person. Open committee discussion, October 11, 1995, 9 a.m. to 4 p.m.; open public hearing, October 12, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 4 p.m.; Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4727, or Catherine M. DeRoever, Advisory Committee Staff (HFS–22), 202–205–4251, FAX 202–205–4970, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Food Advisory Committee, code 10564.

General function of the committee. The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in