from providing, discussing, exchanging, circulating or otherwise furnishing competitive information about such business to or with any person whose employment or agency involves the Cordis Neuroscience Business.

Any violation of the Consent Agreement or the Agreement to Hold Separate, incorporated by reference as part of the Consent Order, may subject Johnson & Johnson to civil penalties and other relief as provided by law.

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 from Johnson & Johnson under which Johnson & Johnson would divest the Cordis Neuroscience Business, which includes Cordis' neurological shunt product line.

The proposed consent 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 again 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.

Johnson & Johnson, a New Jersey based corporation, has proposed to acquire Cordis Corporation, a Florida based corporation, in a stock for stock exchange worth $1.8 billion.

The proposed complaint alleges that the proposed merger, 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, in the market for neurological shunts. Neurological shunts are medical devices used to treat hydrocephalus, a brain disorder that primarily afflicts young children. The merger will substantially increase concentration in the already highly concentrated U.S. shunt market: two firms will control over 85% of the market. Anticompetitive effects, such as increased prices and decreased services, are likely to result. In addition, timely entry by other companies, both in the United States and overseas, is unlikely to defeat these anticompetitive effects. Entry cannot occur in a timely fashion because of the difficulty of developing competitive neurological shunt designs, establishing manufacturing facilities, organizing a sales and service network, receiving Food and Drug Administration approval, and gaining physician acceptance in the market.

The proposed consent order would remedy the alleged violation by replacing the lost competition that would result from the merger. It provides that Johnson & Johnson shall divest the Cordis Neuroscience Business within twelve (12) months of the date the proposed order becomes final. The Cordis Neuroscience Business is a single operational unit that sells neurological shunts, intracranial pressure drainage systems and neuroendoscopy equipment. Significant synergies between the products manufactured and sold by the Business exist, and Cordis' shunts are sold as part of the broader product line. Therefore, a divestiture of the whole business is necessary to maintain competition in the shunt market. The proposed order requires Cordis Neuroscience Business to take all the steps necessary to assure the viability, marketability, and competitiveness of the Cordis Neuroscience Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Cordis Neuroscience Business.

If Johnson & Johnson is unable to divest the Cordis Neuroscience Business within twelve (12) months, then a trustee may be appointed by the Commission to divest the Cordis Neuroscience Business within an additional twelve (12) month period. If, at the end of that twelve (12) month period, the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the time period for divestiture can be extended up to two (2) times by the court.

A Hold Separate Agreement signed by Johnson & Johnson provides that, during the time period from the date the Hold Separate is accepted until the divestiture of the Cordis Neuroscience Business is completed, the Cordis Neuroscience Business shall be held separate and operated independently of Johnson & Johnson.

Under the provisions of the order, Johnson & Johnson 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 this order becomes final, and every sixty (60) days thereafter until Johnson & Johnson has completely divested its interest in the Cordis Neuroscience Business.

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.

[FR Doc. 95–31558 Filed 12–29–95; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95E–0301]

Determination of Regulatory Review Period for Purposes of Patent Extension; PREVACID®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PREVACID® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the

Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product PREVACID® (lansoprazole). PREVACID® is indicated for short-term treatment (up to 4 weeks) for healing and symptom relief of active duodenal ulcer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PREVACID® (U.S. Patent No. 4,628,098) from Hiroshi Akimoto, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 25, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PREVACID® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PREVACID® is 2,870 days. Of this time, 2,328 days occurred during the testing phase of the regulatory review period, while 542 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: July 3, 1987. FDA has verified the applicants's claim that the date that the investigational new drug application (IND) became effective was July 3, 1987.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: November 15, 1993. The applicant claims November 12, 1993, as the date the new drug application (NDA) for PREVACID® (NDA 20–406) was initially submitted. However, FDA records indicate that the applicant submitted NDA 20–406 on November 12, 1993, and FDA received the NDA on November 15, 1993, which is considered to be the NDA initially submitted date.

3. *The date the application was approved*: May 10, 1995. FDA has verified the applicant's claim that NDA 20–406 was approved on May 10, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,706 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 4, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 1, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–31557 Filed 12–29–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0303]

Determination of Regulatory Review Period for Purposes of Patent Extension; ADENOSCAN®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ADENOSCAN® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ADENOSCAN® (adenosine). ADENOSCAN® is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ADENOSCAN® (U.S. Patent No. 5,070,877) from Medco Research, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 25, 1995, FDA advised the Patent and Trademark Office that this