III. Reporting/Disclosure

The reporting burden can be broken out by certain sections of the PMA regulation: (1) § 814.15—Research conducted outside the United States, (2) § 814.20—Application, and (3) § 814.37—PMA amendments and resubmitted PMA's.

The bulk of the burden is due to the previous three requirements. Included in these three requirements are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA's estimate of the hours per response (837.28) was derived through FDA's experience and consultation with industry and trade associations. Included in these three requirements are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates, based on the 1985 study, that these requirements account for the bulk of the burden identified by manufacturers.

IV. § 814.39—PMA Supplements

Clearance for this information collection, included within a proposed rule, has already been sought by FDA in an earlier document (63 FR 20558).

V. § 814.82—Postapproval Requirements

Postapproval requirements concern approved PMA's for devices that were not reclassified and require an annual report. In the last decade (1988 to 1997), the range of PMA's which fit this category averaged approximately 37 per year (70 percent of the 52 annual submissions). Most approved PMA's have been subject to some restriction. Approximately half of the average submitted PMA's (26) require associated postapproval information (i.e., clinical trials or additional preclinical information) that is labor-intensive to compile and complete, and the other PMA's require minimal information. Based on its experience and on consultation with industry, FDA estimates that preparation of reports and information required by this section requires 4,983 hours (134.68 hours per respondent).

VI. § 814.84—Reports

Postapproval requirements described in § 814.82 require a periodic report. FDA has determined respondents meeting the criteria of § 814.84 will submit reports on an annual basis. As stated previously, the range of PMA's fitting this category averaged approximately 37 per year. These reports have minimal information requirements. FDA estimates that respondents will construct their report and meet their requirements in approximately 10 hours. This estimate is based on FDA's experience and on consultation with industry. FDA estimates that the periodic reporting required by this section will take 370 hours.

VII. Recordkeeping

The recordkeeping burden in this section involves the maintenance of records to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These requirements are to be performed only by those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMA's are eventually approved and close to 100 percent of those have original clinical trial data. Therefore, about 37 PMA's a year (52 annual submissions times 70 percent) would be subject to these requirements. Also, because the requirements apply to all active PMA's, all holders of active PMA applications must maintain these records. PMA's have been required since 1976, so there are around 814 active PMA's that could be subject to these requirements (22 years x 37 per year). Each study has approximately 200 subjects, and, at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 16.7 hours. The aggregate burden for all 814 holders of approved original PMA's, therefore, is 13,594 hours.

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practice/quality systems regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

Respondents to this information collection are persons filing an application with the Secretary of Health and Human Services for approval of a class III medical device. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments).

Dated: January 20, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1852 Filed 1–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Formation of a Subcommittee to the Food and Drug Administration Science Board

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee to the Food and Drug Administration (Science Board). The subcommittee has been established to address scientific issues related to the research programs conducted by the FDA's Center for Food Safety and Applied Nutrition (CFSAN). The subcommittee's findings will be presented to the Science Board for full public discussion at a future meeting.

FOR FURTHER INFORMATION CONTACT: Anita O'Connor, Office of Science (HF–32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3312.

SUPPLEMENTARY INFORMATION: FDA is announcing the formation of a subcommittee of the Science Board to the Food and Drug Administration (Science Board). The subcommittee has been established to address issues related to the scientific quality, mission relevance, and scientific management and leadership of the research programs conducted by CFSAN. The subcommittee will hold its meeting(s) over the next 3 months to: (1) Collect information on CFSAN's research programs, (2) conduct an external peer review of CFSAN research for quality and relevance, and (3) assess CFSAN's programmatic prioritization. The subcommittee's findings will be presented to the Science Board for full public discussion at a future meeting which will be announced in the **Federal Register** prior to the meeting. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app. 2)).

Dated: January 20, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–1793 Filed 1–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0784]

Determination of Regulatory Review Period for Purposes of Patent Extension; Viagra™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Viagra™ 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 Viagra™ (sildenafil citrate). Viagra™ is indicated for the treatment of erectile dysfunction. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Viagra™ (U.S. Patent No. 5,250,534) from Pfizer, 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 December 10, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Viagra™ 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 Viagra™ is 1,176 days. Of this time, 996 days occurred during the testing phase of the regulatory review period, while 180 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: January 8, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 8, 1995.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 29, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Viagra™ (NDA 20–895) was initially submitted on September 29, 1997.

3. *The date the application was approved*: March 27, 1998. FDA has verified the applicant's claim that NDA 20–895 was approved on March 27, 1998.

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 283 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 29, 1999, 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 26, 1999, 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: January 18, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–1796 Filed 1–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0757]

Determination of Regulatory Review Period for Purposes of Patent Extension; Xeloda™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Xeloda™ 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.