6. Acute bacterial exacerbation of chronic bronchitis,
7. Secondary bacterial infection of acute bronchitis,
8. Acute otitis media,
9. Acute uncomplicated gonorrhea,
10. Acute sinusitus,
11. Complicated urinary tract infections and pyelonephritis,
12. Bacterial prostatitis,
13. Early Lyme disease,
14. Empiric therapy of febrile neutropenia,
15. Vulvovaginal candidiasis,
16. Streptococcal pharyngitis and tonsillitis,
17. Bacterial meningitis, and
18. Bacterial vaginosis.

Key aspects of these draft guidances will be discussed in a July 1998 advisory committee meeting. After the meeting, ODE IV will work toward finalizing these guidances.

The next step will involve developing draft guidance documents for the following proposed indications:
1. Nongonoccocal urethritis/cervicitis,
2. Endocarditis,
3. Uncomplicated intra-abdominal infections,
4. Complicated intra-abdominal infections,
5. Gynecologic infections (except sexually transmitted disease and pelvic inflammatory disease),
6. Pelvic inflammatory disease,
7. Osteomyelitis (acute and chronic),
8. Acute bacterial arthritis, and
9. Helicobacter pylori infections.

Once developed, the agency expects that it will release the guidances in draft for review and comment, with key elements discussed before the advisory committee.

ODE IV also is considering developing guidance during the next few years for the following agents:
1. Agents to treat opportunistic infections related to AIDS;
2. Antimycobacterial agents;
3. Antifungal agents;
4. Antiparasitic agents;
5. Immunologic/transplant agents;
6. Antiviral agents;
7. Dermatologic surgical scrubs, etc.;
8. Agents to treat sepsis/septic shock; and
9. Agents used in surgical prophylaxis.

As with the other guidances, it is expected that these guidances will first be issued in draft for review and comment and discussed before the advisory committee.

III. Comments

ODE IV is seeking suggestions and recommendations for future guidance development. Interested persons may submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19319 Filed 7–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0358]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Flowmax™ 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 Flowmax™ (tamsulosin hydrochloride). Flowmax™ is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Flowmax™ (U.S. Patent No. 4,703,063) from Yamanouchi Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Flowmax™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Flowmax™ is 3,529 days. Of this time, 3,163 days occurred during the testing phase of the regulatory review period, 366 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*: August 19, 1987. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on on August 19, 1987.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: April 15, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Flowmax™ (NDA 20–579) was initially submitted on April 15, 1996.

3. *The date the application was approved*: April 15, 1997. FDA has verified the applicant's claim that NDA 20–579 was approved on April 15, 1997.

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 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 21, 1998, 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 January 19, 1998, 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: June 26, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–19379 Filed 7–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98N–0473, 98P–0275, 98P–0215, 98P–0216, and 98P–0338]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of petitions requesting exemption from the premarket notification requirements for certain class II devices. FDA is publishing this notice in order to obtain comments on these petitions in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments by August 20, 1998.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination