ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ROZEREM 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 human drug product 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 Director 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 ROZEREM (ramelteon). ROZEREM is indicated for the treatment of insomnia characterized by difficulty with sleep onset. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ROZEREM (U.S. Patent No. 6,034,239) from Takeda 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 February 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ROZEREM 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 ROZEREM is 2,224 days. Of this time, 1,920 days occurred during the testing phase of the regulatory review period, while 304 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 (the act) (21 U.S.C. 355(i)) became effective*: June 22, 1999. The applicant claims May 5, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 22, 1999, when the applicant was notified that the IND studies were allowed to proceed after being on clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: September 22, 2004. FDA has verified the applicant's claim that the new drug application (NDA) for Rozerem (NDA 21–782) was initially submitted on September 22, 2004.

3. *The date the application was approved*: July 22, 2005. FDA has verified the applicant's claim that NDA 21–782 was approved on July 22, 2005.

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 808 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 18, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 18, 2006. 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 Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–9509 Filed 6–16–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0063]

Guidance for Industry and Food and Drug Administration Staff; the Review and Inspection of Premarket Approval Application Manufacturing Information and Operations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations.'' One of the performance goals, referenced in a letter that accompanied the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) legislation, includes a commitment to improve FDA's scheduling and timeliness of preapproval inspections. This draft guidance document is intended to assist manufacturers in preparing for FDA's review of their premarket approval application (PMA) manufacturing section and in the coordination of the

preapproval inspection of the manufacturing operations described in the PMA or PMA supplement. This draft guidance document does not address premarket notification (510(k)) submissions because a premarket inspection is not ordinarily conducted for 510(k) submissions. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by September 18, 2006.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0100.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA (Public Law 107–250) was signed into law. Among other things, MDUFMA authorized the collection of user fees to improve the performance and predictability of FDA's review of certain marketing applications, including PMAs. FDA, in consultation with the industry, agreed to dedicate user fees to help the agency meet various performance goals as outlined in a letter from the Secretary of Health and Human Services to Congress that accompanied the user fee legislation. One such goal included a commitment to ''improve the scheduling and timeliness of preapproval inspections.'' User fees collected under MDUFMA will be used to help to cover the costs associated with FDA's review of the PMA manufacturing section information and inspection of the manufacturing facility. FDA will monitor its good manufacturing practice preapproval inspection program and include this information in its annual performance report to Congress.

This draft guidance provides information on the administrative process that FDA intends to follow in its review of the quality system regulation (21 CFR part 820) information included in the manufacturing section of a PMA submission and the inspection of the manufacturing facility. The administrative process outlined in this draft guidance for the review of the PMA manufacturing section and the conduct of any related preapproval inspection should facilitate FDA's timely review of the application and improve the agency's coordination of the preapproval inspection with the applicant.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. To receive ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1566 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) . The collections of information addressed in 21 CFR part 814 have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–9505 Filed 6–16–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4800–FA–22]

Announcement of Funding Awards for Fiscal Year 2003; Community Development Work Study Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of funding awards for the Fiscal Year 2003 Community