TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
13,500	1	13,500	13	175,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's mailing lists were used to estimate the number of medical device manufacturers who would be subject to this collection. FDA estimates that it will take manufacturers an average of 13 hours to collect, prepare, and submit the requested information. These estimates include allowance for variance in the number of devices to be reported by a manufacturer.

Dated: May 5, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11734 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1069]

Changes in the Procedures for Providing Public Notice of the Availability of Completed Environmental Assessments and Findings of No Significant Impact

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing changes in the procedures used for providing public notice of the availability of completed environmental assessments (EA's) and findings of no significant impact (FONSI's) for new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplemental applications.

EFFECTIVE DATE: May 10, 1999.

ADDRESSES: Copies of EA's and FONSI's are available on the Internet at ''http://www.fda.gov.cder/foi/index.htm'' or may be requested by writing the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5633.

SUPPLEMENTARY INFORMATION: Under the National Environmental Policy Act of 1969 (NEPA), Congress declared that it will be the continuing policy of the Federal Government to ''use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans.'' (See 42 U.S.C. 4331(a).) NEPA requires all Federal agencies to include in every recommendation or report for major Federal actions significantly affecting the quality of the human environment a detailed statement assessing the environmental impact of, and alternatives to, the proposed action and to make available to the public such statements. (See 42 U.S.C. 4332 and 40 CFR 1506.6.)

FDA regulations in part 25 (21 CFR part 25) govern compliance with NEPA, as implemented by the regulations of the Council on Environmental Quality (CEQ) in 40 CFR part 1500. Under FDA regulations, actions to approve NDA's, ANDA's, and supplements to existing approvals ordinarily require the preparation of an EA. (See § 25.20(l).)

In accordance with FDA regulations, FDA must make completed EA's and FONSI's for NDA's, ANDA's, and supplements available to the public upon request in accordance with the procedures in 40 CFR 1506.6. (See § 25.51(b)(2).) The regulations at 40 CFR 1506.6 require that certain environmental documents be made available to the public under the provisions of the Freedom of Information Act (5 U.S.C. 552) and that these documents be made available to the public without charge, to the extent practicable. (See 40 CFR 1506.6(f).) This is the procedure used by CDER to provide completed EA's and FONSI's for NDA's, ANDA's, and supplements for human drugs to the public when they are requested.

Although not required by regulation, CDER has also periodically published notices in the **Federal Register** (57 FR 18887, 61 FR 49470, 62 FR 22960, 63 FR 27300) that provide a listing of EA's and FONSI's that are available for NDA's, ANDA's, and supplements. FDA is announcing that CDER will no longer publish such notices, because the environmental documents are now available on the Internet.

In 1996, FDA established the Center for Drug Evaluation and Research (CDER) Freedom of Information Office Electronic Reading Room, which can be accessed through the Internet at ''http://www.fda.gov.cder/foi/index.htm''. The electronic reading room provides a listing of applications approved by CDER and electronic copies of agency documents used to support the approval of the applications under the heading ''Drug Approval Packages.'' The agency documents include an EA and FONSI for each application unless the action was categorically excluded from the requirement to prepare an EA. (See § 25.31.)

Publication of a notice in the **Federal Register** announcing the availability of completed EA's and FONSI's for NDA's, ANDA's, and supplements duplicates the information available through the CDER Freedom of Information Office Electronic Reading Room. Therefore, to promote efficient operations, FDA will discontinue publication of such **Federal Register** notices, effective immediately.

Dated: April 30, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11583 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0611]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Femara® 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 Femara® (letrozole). Femara® is indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Femara® (U.S. Patent No. 4,978,672) from Novartis Corp., 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 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Femara® 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 Femara® is 2,160 days. Of this time, 1,794 days occurred during the testing phase of the regulatory review period, while 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 28, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 28, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: July 25, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Femara® (NDA 20–726) was initially submitted on July 25, 1996.

3. *The date the application was approved*: July 25, 1997. FDA has verified the applicant's claim that NDA 20–726 was approved on July 25, 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 1,232 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 9, 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 November 8, 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: April 29, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–11584 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0487]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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