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]

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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]

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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