Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Focus Groups as Used by the Food and Drug Administration—(OMB Control Number 0910–0497)

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more indepth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

FDA estimates the burden for completing the forms for this collection of information in table 1 of this document .

The total annual estimated burden imposed by this collection of information is 2,830 hours annually.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (includes screening)	Total Hours
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication	10	100	9	1.58	1,422
Center for Devices and Radiological Health	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (e.g., food safety, nutrition, dietary supplements, consumer education)	8	40	9	1.58	569
Center for Veterinary Medicine	Varies (e.g., animal nutrition, supplements, labeling of animal Rx)	5	25	9	2.08	468
Total		28	186		1.78	2,830

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

Annually, FDA projects about 28 focus group studies using 186 focus groups lasting an average of 1.78 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29197 Filed 11–21–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0512]

Guidance for Industry and Food and Drug Administration Staff; User Fees and Refunds for Premarket Approval Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''User Fees and Refunds for Premarket Approval Applications.'' This guidance outlines the types of premarket approval applications (PMAs), including supplements and other submissions, that are subject to user fees as well as those that do not have an associated fee. The guidance also identifies industry and FDA actions on these submissions that may result in a partial refund of the fee. The guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''User Fees and Refunds for Premarket Approval Applications'' 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 two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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:

Regarding device issues: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

Regarding biologics issues: Sayah Nedjar, Center for Biologics Evaluation and Research (HFM–380), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3524.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), amends the Federal Food, Drug, and Cosmetic Act to allow FDA to collect user fees for certain premarket reviews. The new law also permits partial refunds under certain circumstances, such as in the case of a non-filing decision for a PMA. In other cases, the statute permits a refund but stipulates that it is to be in an amount determined by the level of effort expended by the agency during its review of the application. The guidance outlines the user fees due with certain PMAs, the refunds set by statute, and FDA's plan for determining the amount of the fee to be refunded when the exact amount is not prescribed by the new law.

FDA is making this guidance document immediately available because prior public participation was not feasible. MDUFMA's user fee provisions were effective immediately, and it is essential for the agency to provide guidance to its stakeholders on the user fee program as quickly as possible. Although it was not feasible to obtain comments before issuing the guidance, in accordance with this agency's GGP procedures, FDA will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on user fees and refunds for PMAs. 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

To receive a copy of ''User Fees and Refunds for Premarket Approval Applications'' by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1224) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. 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 guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the user fee forms (OMB control number 0910–0511), which expires on August 31, 2006, and the regulations governing administrative practices and procedures (21 CFR part 10, OMB control number 0910–0192).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this guidance. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* 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: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29196 Filed 11–21–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed information collection. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), this notice seeks comments concerning the end-of-course evaluation form used to evaluate the National Fire Academy's (NFA) resident and regional delivery courses.

SUPPLEMENTARY INFORMATION: The NFA is mandated under the Fire Prevention and Control Act of 1974, Public Law 93–498, to provide training and education to the Nation's fire service and emergency service personnel. To maintain the quality of these programs, it is necessary to evaluate them on an ongoing basis. The National Fire Academy Course Evaluation Form provides one means of maintaining quality assurance for NFA resident and regional courses. This form is used for on-campus courses delivered at the NFA facility, located in Emmitsburg, Maryland, and for NFA regional courses, which are identical to the NFA resident courses, but offered in selected regions to students unable to travel to NFA for the resident offering of the course.

Collection of Information

Title: National Fire Academy Course Evaluation Form.

Type of Information Collection: Revision of a currently approved collection.

OMB Number: 1660–0032.

Form Number: FEMA Form 95–20, National Fire Academy Course Evaluation Form.

Abstract: The National Fire Academy Course Evaluation Form is used to evaluate the effectiveness of all resident and regional delivery courses. The form is primarily used to assess the effectiveness of course materials, instructor delivery and physical location. The demographic information is used in developing needs assessments and identifying the student population's representation.

Affected Public: Individuals participating in NFA on-campus or regional courses.

Estimated Total Annual Burden Hours: 1,450.

Estimated Number of Respondents: 5,800.

Estimated Hour Burden Per Response: 15 minutes.

Frequency of Response: On occasion.

Estimated Cost: The annualized cost to respondents is minimal. Respondents utilize the hour burden at the end of each course to complete the written evaluation form, therefore, a cost estimate is not included.

Comments: Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. Comments should be received within 60 days of the date of this notice.

ADDRESSES: Interested persons should submit written comments to Muriel B. Anderson, Branch Chief, Records Management Branch, Information Resources Management Division, Information Technology Services Directorate, Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security, 500 C Street, SW., Room 316, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Contact Terry Gladhill, Program Analyst, National Fire Academy at (301) 447–1239 for additional information. You may contact Ms. Anderson for copies of the proposed collection of information at facsimile number (202) 646–3347 or e-mail address: *Information.Collections@fema.gov.*

Dated: November 13, 2003.

Edward W. Kernan,

Division Director, Information Resources Management Division, Information Technology Services Directorate.

[FR Doc. 03–29290 Filed 11–21–03; 8:45 am]

BILLING CODE 9110–17–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency has submitted the following proposed information collection to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

Title: FEMA's Excess Federal Real Property Program Application.

Type of Information Collection: New.

Abstract: GSA provides announcements to FEMA, and to State and local governments, concerning available Federal surplus real property for emergency management response use purposes including fire and rescue services. An applicant must notify the disposal agency such as GSA Regional and Headquarters offices, or the Department of Defense (DOD) Base Realignment Closure (BRAC) offices, and FEMA Regional and Headquarters offices of its intent to acquire the property. The notification should occur within 20 days after notification of property availability. States, the District of Columbia, any territory or possession of the United States, or any political subdivision or instrumentality thereof, may apply for the transfer or conveyance of surplus real property for emergency management response use purposes. An applicant must formally submit a completed FEMA Excess Federal Real Property Program application including supporting