accountability. *Form Number:* CMS–R–48 (OMB#: 0938–328); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 4,991; *Total Annual Responses:* 1,120,817; Total Annual Hours: 9,151,200.57.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on January 8, 2008. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 2, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–21990 Filed 11–8–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0422]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the application for participation in the Medical Device Fellowship Program (MDFP).

DATES: Submit written or electronic comments on the collection of information by January 8, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Application for Participation in the Medical Device Fellowship Program; 5 U.S.C. 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 (OMB Control Number 0910–0551)—Extension

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code, authorize Federal agencies to rate applicants for Federal jobs. Collecting applications for the MDFP will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the agency and lessen the likelihood of applications being misrouted within the agency mail system. It will assist the agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

5 U.S.C. Section/ FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1104, 1302, 3301, 3304, 3320, 3361, 3393, 3394/ Form No. 3608	250	1	250	1	250

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

FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 3 years.

Dated: November 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21971 Filed 11–8–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0430]

Agency Emergency Processing Under Office of Management and Budget Review; Orphan Drug Products; Common European Medicines Evaluation Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is an amendment to OMB control number 0910–0167 and concerns the joint adoption by FDA and the European Medicines Evaluation Agency (EMEA) of the Common EMEA/FDA Application Form for Orphan Medicinal Product Designation (form FDA 3671).

DATES: Fax written comments on the collection of information by November 19, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number ''0910–0167'' and the title, ''Orphan Drug Products; Common EMEA/FDA Application Form for Orphan Medicinal Product Designation.'' Also include the FDA docket number found in brackets in the heading of this document. To obtain a copy of the draft form FDA 3671, please call Mary Grice at 301–827–3666 or submit written requests via fax to 301–827–0017.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13) to enable the agency to jointly announce with EMEA the adoption of the Common EMEA/FDA Application Form for Orphan Medicinal Product Designation at the European Union (EU)-wide Administrative Simplification Workshop on November 28, 2007. The information is essential to the agency's mission of protecting and promoting the public health. The use of the normal clearance procedures would likely result in the prevention or disruption of this collection of information.

With respect to the collection of information, FDA invites comments on these topics: (1) The clarity and ease of use of this proposed common application form; (2) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (3) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility, and clarity of the information to be collected; and (5) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology.

Orphan Drug Products; Common EMEA/FDA Application Form for Orphan Medicinal Product Designation—(OMB Congrol Number 0910–0167)—Amendment

This common application form is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from both the European Commission and FDA by reducing the burden of preparing separate applications to meet the regulatory requirements in each jurisdiction. It highlights the regulatory cooperation between the United States and EU mandated by the Transatlantic Economic Council (TEC). The TEC mandate involves: Removal of barriers to transatlantic commerce; rationalizing, reforming, and, where appropriate, reducing regulations to empower the private sector; achieving more effective, systematic, and transparent regulatory cooperation to reduce costs associated with regulation to consumers and producers; removing unnecessary differences between jurisdictional regulations in order to foster economic integration; reinforcing the existing transatlantic dialogue structures in regulatory cooperation, both by intensifying our sector-by-sector United States-EU regulatory cooperation and our dialogue between OMB and the European Commission services on methodological issues.

At present, when seeking orphan designation of the same drug for the diagnosis, treatment, or prevention of the same rare disease or condition in the United States and in the European Community, a sponsor must submit a designation request to FDA (in accordance with section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)) and a separate designation application to EMEA (in accordance with Regulation (EC) No. 141/2000 of December 16, 1999, and Commission Regulation (EC) No. 847/2000). In most cases, the two documents are formatted differently to meet regulatory demands, but the required core information elements are similar with the exception of some unique regulatory requirements exclusive to each jurisdiction. Therefore, FDA and EMEA believe that a common application form will help reduce the sponsor's regulatory burden and costs to produce and submit a differently-formatted request/application. In addition, a common application form may also streamline the administrative and substantive regulatory review processes, and aid in information exchange between the agencies. In accordance with the Confidentiality Arrangements concluded on September 12, 2003, between the European Commission, EMEA, and FDA,[1] FDA and EMEA have agreed in principle to adopt a template for the common application form as proposed in form FDA 3671.

Any sponsor seeking orphan designation of the same drug for the same disease or condition from both FDA and EMEA may use this common application form for regulatory filing purposes. A sponsor may also use this common application form when seeking designation only from FDA. This

[1]See ''Confidentiality Arrangements Concluded Between the EU (EC and EMEA) and the US FDA/DHHS Implementation Plan for Medicinal Products for Human Use'' at *http://www.fda.gov/oia/arrangements0904.html*.