manufacturers of similar or related devices can easily be identified.

The likely respondents to this information collection are domestic and foreign device establishments who must register and submit a device list to FDA, e.g., establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

In the **Federal Register** of February 5, 2008 (73 FR 6731), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.31(e)	200	1	200	.50	100

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
807.31(a through d)	16,200	4	64,800	.50	32,400

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

The annual respondent reporting burden for device establishment registrations and listing is estimated to be 100 hours and the annual respondent recordkeeping burden is estimated to be 32,400 hours. The estimates cited in tables 1 and 2 of this document are based primarily on the annual FDA accomplishment report, which includes actual FDA registration and listing data derived for fiscal year (FY) 2006. These estimates are also based on FDA estimates of FY 2006 data from current systems and conversations with industry and trade association representatives. FDA anticipates reviewing annually, 200 historical files.

Dated: April 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9374 Filed 4–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0222] (formerly Docket No. 2008N–0007)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs; Common European Medicines Agency/ Food and Drug Administration Application Form for Orphan Medicinal Product Designation (Form FDA 3671)

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 review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 30, 2008.

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. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Orphan Drugs; Common European Medicines Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation (Form FDA 3671)—(OMB Control Number 0910–0167)—Extension

Sections 525 and 526 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa and 360dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and sets forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the non-clinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable

expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the applications under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

The information requested from respondents represents, for the most part, an accounting of information already in the possession of the applicant. It is estimated, based on frequency of requests over the past 5 years, that 171 persons or organizations per year will request orphan-drug designation and none will request formal recommendations on design of preclinical or clinical studies.

The Common EMEA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671) 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 (US) and the European Union (EU) mandated by the Transatlantic Economic Council (TEC). The TEC mandate involves the following: (1) Removal of barriers to transatlantic commerce; (2) rationalizing, reforming, and, where appropriate, reducing regulations to empower the private sector; (3) achieving more effective, systematic, and transparent regulatory cooperation to reduce costs associated with regulation to consumers and producers; (4) removing unnecessary differences between jurisdictional regulations to foster economic integration; and (5) reinforcing the existing transatlantic dialogue structures in regulatory cooperation, both by intensifying our sector-by-sector US-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 US and in the European Community, a sponsor must submit a designation request to FDA (in accordance with section 526 of the act) 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 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/Department of Health and Human Services (DHHS),[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 common application form is intended to complement, not to supersede, the relevant regulatory frameworks currently in effect. The sponsor must comply with all applicable regulatory requirements in each jurisdiction in which it seeks designation when using this common application form.

To use the common application form, the sponsor must provide the required information in each applicable section as instructed in the explanatory notes. Certain information elements are identified in the form as required exclusively by either FDA or EMEA regulations, and as such they must be included only in the application to that jurisdiction. Where additional explanations and/or supportive documents are necessary, the sponsor should sequentially append them at the end of the common application form in the order they appear in the form. The sponsor must also complete the declaration and signature page. For FDA, the completed common application form and required appended documents must be submitted to the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. For EMEA, the completed documents must be submitted to European Medicines Agency, 7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom.

FDA estimates the reporting burden of this common application form as follows. Between January 2000 and May 2006, FDA and EMEA received 226 comparable orphan designation requests/applications of the same drugs for the same diseases or conditions, or an average of 35 per year. With the ease of a common application form, FDA anticipates the number of such requests/applications may increase over time. Therefore, generally there is one request/application per respondent and, at the extreme, all respondent are US-based, FDA believes up to 40 such respondents may use the common application form each year. The respondents will be primarily pharmaceutical companies or other for-profit organizations. For applications submitted exclusively to FDA, we do not believe the new form will result in any increased burden on the respondents and therefore we estimate no additional burden for those respondents. FDA believes the information required for the EMEA submission, for the most part, is very similar to that in the FDA submission, which is already in the respondents' possession. The respondents, however, may have to search existing data sources or gather additional needed data, such as on the prevalence or the availability of alternative methods of diagnosis, prevention, and treatment of the rare disease or condition of interest in the European Community, to complete the EMEA submission. FDA estimates that it will take an additional 32 hours—16 hours of professional time and 16 hours of support time—to compile information required for the EMEA submission. Hence, the estimated total annual human resource hours, at most, would be 1,280 hours for the EMEA submission.

In the **Federal Register** of January 15, 2008 (73 FR 2504), FDA published a 60-

[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*.

day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section and FDA Form	Annual No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
316.10, 316.12, and 316.14	5	1	5	130	650
316.20, 316.21, and 316.26	171	2.0	342	130	44,460
316.20, 316.21, and 316.26 Form FDA 3671	40	1	40	32	1,280
316.22	30	1	30	2	60
316.27	25	1	25	4	100
316.30	500	1	500	2	1,000
316.36	1	1	1	15	15
Total					47,565

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

Dated: April 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9467 Filed 4–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Towards an Artificial Pancreas: A Food and Drug Administration, National Institutes of Health, Juvenile Diabetes Research Foundation Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the National Institutes of Health (NIH) and the Juvenile Diabetes Research Foundation (JDRF), is holding a public workshop focused upon the state of the art in the research and development of an artificial pancreas. The public workshop entitled ''Towards an Artificial Pancreas: A Food and Drug Administration, National Institutes of Health, and Juvenile Diabetes Research Foundation Workshop'' will provide a public forum for discussing the progress and remaining challenges in the development of closed-loop systems designed to regulate glycemic control, as an aid in the management of diabetes mellitus. It is intended to provide stakeholders with information that will accelerate the development of an artificial pancreas.

DATES: The public workshop will be held on July 21, 2008, from 7:55 a.m. to 6 p.m., and on July 22, 2008, from 8 a.m. to 12:45 p.m. Registration is available until 5 p.m. on June 20, 2008 (See **REGISTRATION TO ATTEND THE PUBLIC WORKSHOP**).

ADDRESSES: The public workshop will be held at the Lister Hill Auditorium on the NIH Campus (*http://www.nih.gov/science/campus/index.html*) located at 9000 Rockville Pike, Bethesda, MD 20892.

Parking on the NIH campus is limited. Attendees are encouraged to take public transportation. There is limited parking available at the Natcher Building. See *http://www.nih.gov/about/directions.htm* for more information.

FOR FURTHER INFORMATION CONTACT: Arleen Pinkos, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville, MD 20850, 240–276–0702, FAX 240–276–0651, e-mail: *arleen.pinkos@fda.hhs.gov*.

REGISTRATION TO ATTEND THE PUBLIC WORKSHOP: Those interested in attending the public workshop may register online at *http://www.blsmeetings.net/artificialpancreas08/reg.cfm*. There is no registration fee to attend the meeting; however, all participants must submit a registration form. Space is limited, so please submit your registration early to reserve a space. Registration will be accepted through June 20, 2008; however, onsite registration will be permitted on a space-available basis.

Persons without Internet access may call Akia Richardson at 301–313–0244 ext. 49, by June 20, 2008, to register for onsite attendance.

If you need special accommodations due to a disability, please contact L'Tonya Frazier at 301–594–4453 at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

The artificial pancreas is one of FDA's Critical Path Initiatives, a program dedicated to accelerating the availability of much needed medical products. The Interagency Artificial Pancreas Working Group, a group of multi-disciplined scientists and clinicians from FDA and NIH, was established to support this initiative. The goals of the Artificial Pancreas Initiative are twofold: to provide infrastructure for narrowing the gap between basic biomedical knowledge and clinical application of novel technologies, and to cross-fertilize and partner with stakeholders in order to identify and overcome the clinical and scientific challenges to the development of an artificial pancreas. Through collaborative efforts, such as this workshop, the group strives to develop innovative strategies to achieve their goals.

II. Agenda

World renowned experts will present information on topics that are instrumental to the development of an artificial pancreas, and each session will be followed by roundtable discussions. Session topics will include:

- State of the art design of closed-loop glycemic control systems
- Results of recently conducted clinical trials
- Clinical trial design, including how to define successes and failures of closed-loop systems