DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Federal Child Support Portal Registration.

OMB No.: 0970–0370.

Description: The federal Office of Child Support Enforcement, Division of Federal Systems, maintains the Child Support Portal, which contains a variety of child support applications to help enforce state child support cases. To securely access the child support applications, authorized users must register to use the Child Support Services Portal. Information collected from the registration form is used to authenticate and authorized users.

The federal Child Support Portal Registration information collection activities are authorized by 42 U.S.C. 653(m)(2), which requires the Secretary to establish and implement safeguards to restrict access to confidential information in the Federal Parent Locator Service to authorized persons, and to restrict use of such information to authorized purposes.

Respondents: Employers, Financial Institutions, Insurers, and State Agencies

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Registration Screens	183	1	0.15	27.45

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained an comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and, (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–08397 Filed 4–10–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1082]

Preparation for International Conference on Harmonization Steering Committee and Expert Working Group Meetings in Fukuoka, Japan; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a regional public meeting entitled ''Preparation for ICH Steering Committee and Expert Working Group Meetings in Fukuoka, Japan'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Fukuoka, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Fukuoka, Japan, scheduled on June 6 through 11, 2015, at which the discussion of the topics underway and ICH reforms will continue.

DATES: The public meeting will be held on May 15, 2015, from 1 p.m. to 4 p.m. Registration to attend the meeting and requests for oral presentations must be received by May 11, 2015. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room (Rm. 1503 A), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit either electronic or written comments by June 14, 2015. Submit electronic comments to *http://www.regulations.gov.* Submit written comments 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: Tracy Porter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1173, Silver Spring, MD 20993, 301–796–7789, FAX: 301–847–8443, email: *tracy.porter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. Members of the ICH Steering Committee include the European Union; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; Swissmedic; and the World Health Organization (as an Observer). The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

II. Meeting Attendance and Participation

A. Registration

If you wish to attend the meeting, visit *https://www.eventbrite.com/e/international-conference-on-harmonization-regional-public-meeting-tickets-16183519342.* Please register for the meeting by May 11, 2015. Seating may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meetings will be based on space availability.

If you need special accommodations because of a disability, please contact Tracy Porter (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 3:30 p.m. and 4 p.m. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Tracy Porter (see **FOR FURTHER INFORMATION CONTACT**) by May 11, 2015, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm439475.htm.*

III. Comments

Interested persons may submit either electronic or written comments to the public docket (see **ADDRESSES**) by June 14, 2015. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Transcripts

Please be advised that as soon as a meeting transcript is available, FDA will post it at *http://www.fda.gov/Drugs/NewsEvents/ucm439475.htm.*

Dated: April 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0363]

Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of the guidance entitled ''Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions.'' This guidance outlines FDA's new, voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions and that are subject to premarket approval (PMA) applications or de novo classifications. FDA believes that the Expedited Access Pathway (EAP) program will help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standard of reasonable assurance of safety and effectiveness for premarket approval, consistent with the Agency's mission to protect and promote public health. The document also discusses how the EAP program approaches the balance of premarket and postmarket data collection and incorporates a benefit-risk framework. The EAP program will become effective April 15, 2015.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or