

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|---------------------------|
| Performance measure reporting form (for private sector affected public) | 103 | 2 | 0.8 | 165 |
| Performance measure reporting form (for State, local, and tribal government affected public) | 15 | 2 | 0.8 | 30 |
| Estimated Total Annual Burden Hours | | | | 195 |

In compliance with the requirements of Section 506(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 and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a 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 2 through 7, 2012, at which discussion of the topics underway and the future of ICH will continue.

DATES: *Date and Time:* The public meeting will be held on May 14, 2012, from 2 p.m. to 4 p.m.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Information regarding visitor parking and transportation may be accessed at: <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>; under the heading "Public Meetings at the White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: All participants must register with Kimberly Franklin, Office of the Commissioner, Food and Drug

Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, FAX: 301-595-7937, email: *Kimberly.Franklin@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations to the contact person (see *Contact Person*) by May 9, 2012.

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 10 minutes. Those desiring to make oral presentations should notify the contact person (see *Contact Person*) by May 9, 2012, 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.

If you need special accommodations due to a disability, please contact Kimberly Franklin (see *Contact Person*) at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: 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. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area, and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

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**.)

The agenda for the public meeting will be made available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm291624.htm>.

Dated: March 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-5857 Filed 3-9-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 9, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: (301) 847-8533, email: AAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 203214, tofacitinib tablets, Pfizer Inc., for the

treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 25, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 17, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 18, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on