

enter the terms of the order into the automated system for use in issuing income withholding orders. Copies of the income withholding order are made for all necessary parties, and copies are transmitted to the employer/income

withholder by mail or through the OCSE electronic income withholding order (e-IWO) portal.

The Income Withholding for Support form and instructions were updated for consistency and clarity in light of numerous comments suggesting

changes, based on comments received during the 60-day comment period of the 1st **Federal Register** Notice publication.

*Respondents:* State Child Support Agencies and Tribes.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Income Withholding for Support (Form) .....	58	0	0	0
e-IWO Record Layouts .....	58	0	0	0

Estimated Total Annual Burden Hours: 0.

#### Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

#### OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project. Fax: 202-395-6974. Attn: Desk Officer for the Administration for Children and Families.

Dated: September 15, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2010-N-0490]

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** 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 Harmonisation (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, November 6 through 11, 2010, at which discussion of the topics underway and the future of ICH will continue.

**Date and Time:** The public meeting will be held on October 13, 2010, from 2:30 p.m. to 4:30 p.m.

**Location:** The public meeting will be held at the Washington Theater at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

**Contact Person:** All participants must register with Jennifer Haggerty, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, email: [jennifer.haggerty@fda.hhs.gov](mailto:jennifer.haggerty@fda.hhs.gov), or FAX: 301-595-7937.

**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 Jennifer Haggerty (see *Contact Person*) by 5 p.m. e.s.t. on October 11, 2010.

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

**Transcripts:** Please be advised that as soon as a transcript is available, it can be obtained 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 (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, 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>.

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 4 p.m. and 4:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by 5 p.m. e.s.t. on October 11, 2010, 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/ucm225322.htm>.

Dated: September 16, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-23642 Filed 9-21-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0486]

#### Safe Use Initiative; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop entitled "Safe Use Initiative." This public workshop, organized and hosted by FDA's Safe Use Initiative Team, will communicate the status of ongoing activities and the future vision for Safe Use Initiative projects. The workshop will also offer an opportunity for the Safe Use Initiative Team to gather input and perspectives for future directions and develop collaborative, cross-sector safe medication use activities with health care stakeholders.

**DATES:** The public workshop will be held on November 16, 2010, from 8:30 a.m. to 4:45 p.m., and November 17, 2010, from 8:30 a.m. to 12 noon. Suggestions for safe use topics received by October 15, 2010, may become the focus for indepth discussions during the workshop breakout sessions held the afternoon of November 16, 2010 (see section II of this document). Electronic or written comments will be accepted until January 31, 2011 (see section IV of this document).

**ADDRESSES:** The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993-0002.

Submit electronic comments on this document 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.

**FOR FURTHER INFORMATION CONTACT:** Sharon Bakayoko, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1353, Silver Spring, MD 20993-0002, 301-796-7600, [CDERSafeUseInitia@fda.hhs.gov](mailto:CDERSafeUseInitia@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The mission of the Safe Use Initiative is to reduce preventable harm from FDA-regulated medications. The Safe

Use Initiative seeks to create and facilitate public and private collaborations aimed at reduction of preventable harm.

FDA announced the "FDA's Safe Use Initiative—Collaborating to Reduce Preventable Harm From Medications" (the Safe Use Report) on November 5, 2009 (74 FR 57319). The Safe Use Report calls for an open and transparent process with health care stakeholders to identify candidate drug/drug classes or therapeutic areas that could benefit from a collaborative approach to harm reduction.

The first steps in public engagement involved outreach to the health care community—through public meetings, teleconferences, and listening sessions with stakeholder groups (e.g., health care professionals, consumer groups, insurers, and industry). The goals were to inform organizations about the Safe Use Initiative, to obtain feedback about medication safety and preventable medication harm, and to seek opportunities for collaboration. The suggestions that emerged from the safe use outreach activities ranged from preventing a specific drug-related adverse event to broad and overarching themes in health care.

##### II. Scope of the Public Workshop

This public workshop expands the Safe Use Initiative outreach efforts. It will provide a forum to engage the health care community about collaborations, interventions, and metrics for ongoing and future projects to make medications safer.

We are soliciting input in advance of the public workshop about topics for potential safe use collaborations. FDA will consider all topics. However, if submitted by October 15, 2010, some topics may become the focus for more indepth discussions and partnership development during the public workshop. Please submit topic suggestions (identified with the docket number found in brackets in the heading of this document) to the Division of Dockets Management (see **ADDRESSES**). When submitting a topic for consideration, please suggest how it could become a safe use project, e.g., other health care partners who might have an interest in the issue, kinds of interventions to reduce preventable harm, metrics, etc.

##### III. Attendance and Registration to Speak

The FDA Conference Center at the White Oak location is a Federal facility with security procedures. There is no fee to attend the workshop, and attendees who do not wish to make an