

*Estimated Total Annual Burden Hours:* 1,155

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 and 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. E-mail address: [grjohnson@acf.hhs.gov](mailto:grjohnson@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.

Dated: September 16, 2005.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 05-19012 Filed 9-22-05; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Improper Payments Information Survey for the CCDF Program.

*OMB No.:* New Collection.

*Description:* This survey for the Child Care and Development Fund (CCDF) program will request that States Voluntarily provide information including how they define improper payments in their State, the process used to identify such payments and what actions are taken in the State to reduce or eliminate improper payments. HHS/ACF intends to establish a repository for the State submissions, which will be available to all States for viewing on an HHS/ACF Web site. This Web site will provide information that will help States improve their program integrity systems so that improper payments in the program can be reduced.

*Respondents:* The 50 States of the United States, the District of Columbia, and the Territories of Guam, Puerto Rico and the Virgin Islands.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Improper Payments Information Survey for the CCDF Program .....	54	1	24	1,296

*Estimated Total Annual Burden Hours:* 1,296 hours.

*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: [grjohnson@acf.hhs.gov](mailto:grjohnson@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 received 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, Attn: Desk Officer for ACF, E-mail address: [Katherine\\_T.\\_Astrich@omb.eop.gov](mailto:Katherine_T._Astrich@omb.eop.gov).

Dated: September 16, 2005.

**Robert Sargin,**

*Reports Clearance Officer.*

[FR Doc. 05-19013 Filed 9-22-05; 8:45am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 2005N-0363]**

**Preparation for International Conference on Harmonization Meetings in Chicago, Illinois; Public Meeting**

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

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH meetings in Chicago, Illinois" to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Chicago, IL. 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 Groups meetings in Chicago, IL, November 7 through 10, 2005, at which discussion of the topics underway and the future of ICH will continue.

*Date and Time:* The meeting will be held on October 20, 2005, from 1:30 p.m. to 4 p.m.

*Location:* The meeting will be held at 5600 Fishers Lane, 3rd Fl., Maryland Conference Room, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 1:25 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to the Maryland Conference Room.

*Contact:* Sema Hashemi, Office of the Commissioner (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3050, FAX: 301-480-0716, e-mail: [Sema.Hashemi@fda.hhs.gov](mailto:Sema.Hashemi@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 by October 14, 2005. If you need special accommodations due to a disability, please contact Sema Hashemi at least 7 days in advance.

**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. Oral presentations from the public 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 by October 14, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail 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 October 7, 2005, via the Internet at [http://www.fda.gov/cder/meeting/ICH/ICH\\_fall2005.htm](http://www.fda.gov/cder/meeting/ICH/ICH_fall2005.htm).

**Transcripts:** Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: September 16, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-19017 Filed 9-22-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0375]

#### Stakeholder Meeting on the Implementation of A New Direction for the Food and Drug Administration's Radiological Health Program; Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public meeting: A New Direction for FDA's Radiological Health Program. The topics of discussion are the agency's activities to implement its radiological health program (the program).

**DATES:** The public meeting will be held on October 31 and November 1, 2005, from 8:30 a.m. to 5 p.m. The agency is requiring registration by October 17, 2005.

All parties wishing to make a presentation or to speak on an issue specific to the topics of the meeting

should indicate their intent, the topics to be addressed, and provide an abstract of their comments to be presented by October 17, 2005. FDA will limit the time for presentations to the public comment periods; the number of parties requesting to participate will determine the amount of time allotted to each presentation.

**ADDRESSES:** The public meeting will be held at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Submit written requests to make an oral presentation to Kaye Chesemore (see **FOR FURTHER INFORMATION CONTACT**). Include your name, title, firm or organization name (if representing such), address, telephone, and fax number with your request. All requests and presentation materials should include the docket number found in brackets in the heading of this document. Submit all requests for suggestions and recommendations to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Kaye Chesemore, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3309, FAX: 301-594-3306, e-mail: [kfc@cdrh.fda.gov](mailto:kfc@cdrh.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In May 2004, FDA's Center for Devices and Radiological Health (CDRH) began an effort to examine how the program could best adapt to current public health needs. This effort culminated in a report that outlines key elements of the program and states how the new direction will impact the most pressing public health problems in the radiological health area. A copy of the report is available on CDRH's Web site at <http://www.fda.gov/cdrh/radhlth/initiative.html>.

The agency has determined that it must shift the focus of resources to the products and procedures with the highest risks to the public, including those that affect the greatest number of people or present the potential for the greatest harm.

The benefits that FDA expects from this focus are that the new program will:

- (1) Align CDRH efforts with current and evolving public health needs,
- (2) Expand focus on patient and consumer protection,
- (3) Allow for a more targeted approach to FDA's programs and activities,