

respondents to provide contact data for possible longer-term follow-up.

*Respondents:* JSA study participants and program staff.

### Annual Burden Estimates

#### EXTENSION OF PREVIOUSLY APPROVED INFORMATION COLLECTIONS

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Baseline Information Form .....	6,400	3,200	1	.2	640
Implementation Study Site Visits .....	600	300	1	1	300
JSA Staff Survey .....	440	220	1	.33	73

#### PROPOSED NEW INFORMATION COLLECTIONS

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
6 Month Follow-Up Survey .....	6,400	3,200	1	.333	1,066
Contact Update Form .....	6,400	3,200	11	.033	1,162

*Estimated Total Annual Burden Hours:* 3,241.

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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@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.

**Karl Koerper,**

*Reports Clearance Officer.*

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Preparation for International Cooperation on Cosmetics Regulation

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

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA or we) is announcing a public meeting entitled "International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR-9 Meeting." The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR-9 meeting that will be held November 4-6, 2015, in Brussels, Belgium.

**Date and Time:** The public meeting will be held on September 10, 2015, from 2 p.m. to 4 p.m.

**Location:** This meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Wiley Auditorium (first floor), College Park, MD 20740.

**Contact Person:** Maria Rossana (Rosemary) Cook, Office of Cosmetics and Colors, Food and Drug Administration, 4300 River Rd., College Park, MD 20740, email: [maria.cook@fda.hhs.gov](mailto:maria.cook@fda.hhs.gov), or FAX: 301-436-2975.

**Registration and Requests for Oral Presentations:** Send registration information (including your name, title, firm name, address, telephone number, fax number, and email address), written material, and requests to make an oral

presentation, to the contact person by August 27, 2015.

If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook by September 3, 2015.

**SUPPLEMENTARY INFORMATION:** You may present proposals for future ICCR agenda items, data, information, or views, orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by August 27, 2015, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate amount of time you need to make your presentation.

**Transcripts:** As soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20850. 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 the Division of Freedom of Information, (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

**The Purpose of the Multilateral Framework on the ICCR:** The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, Canada, and Brazil. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: Health Canada; the European Commission Directorate-General for Internal Market, Industry, Entrepreneurship, and Subject Matter Experts; the Ministry of Health, Labor, and Welfare of Japan; the Brazilian Health Surveillance Agency; and FDA. All decisions made by consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

**Agenda:** We will make the agenda for the public meeting available on the Internet at <http://www.fda.gov/Cosmetics/InternationalActivities/ICCR/default.htm>. Depending on the number of requests for oral presentations, we intend to have an agenda available by September 3, 2015. We may use the information that you provide to us during the public meeting to help us prepare for the November 4–6, 2015, ICCR–9 meeting.

Dated: July 9, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS–0990–0279–60D]

### Agency Information Collection Activities; Proposed Collection; Public Comment Request

**AGENCY:** Office of the Assistant Secretary for Health, HHS.

#### **ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990–0279, which expires on August 31, 2015. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before September 14, 2015.

**ADDRESSES:** Submit your comments to [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or by calling (202) 690–6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690–6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier 0990–0279 for reference.

**Information Collection Request Title:** Institutional Review Board Form—OMB No. 0990–0279, Assistant Secretary for Health, Office for Human Research Protections.

**Abstract:** Section 491(a) of Public Law 99–158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (e.g., a grant, contract, or cooperative agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to ensure protection of the rights and welfare of the human research subjects. IRBs are boards, committees, or groups formally designated by an entity to review,

approve, and have continuing oversight of research involving human subjects.

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990–0279, Institutional Review Board (IRB) Registration Form. This form was modified in 2009 to be consistent with IRB registration requirements, 45 CFR part 46, subpart E and 21 CFR 56.106 that were adopted in July 2009 OHRP and FDA, respectively.

**Need and Proposed Use of the Information:** The information collected through the Institutional Review Board registration collection requirements is the minimum necessary to satisfy the registration requirements of Section 491 (a) of the Public Health Service Act, 45 CFR part 46, subpart E and 21 CFR 56.106.

**Likely Respondents:** Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's regulations, IRBs in the United States that review clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and, IRBs in the United States that review clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

**Burden Statement:** The burden estimates for the IRB registration form include those approved by OMB in March 2015 under Control Number 0990–0263, the Assurance Identification/IRB Certification/Declaration of Exemption form (former Optional Form 310). Those burden estimates are not included as part of the burden estimate presented below.

#### ESTIMATED ANNUALIZED BURDEN TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration 0990–0279 .....	5,900	2	1	11,800
	500	2	1	1,000
Total .....	.....	.....	.....	12,800