

programs as required by 412(e) of the Immigration and Naturalization Act. We also calculate state-by-state Refugee Cash Assistance and Refugee Medical

Assistance utilization rates for use in formulating program initiatives, priorities, standards, budget requests, and assistance policies. The Office of

Refugee Resettlement regulations require that this form be completed in order to participate in the program.
Respondents: States.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR-6	48	4	3.875	744

Estimated Total Annual Burden Hours: 744 hours.

Additional Information: The Administration for Children and Families (ACF) is requesting that OMB grant a 180-day approval for this information collection under procedures for emergency processing by March 5, 2004. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the ACF Reports Clearance Officer, Robert Sargis at (202) 690-7275. In addition, a request may be made by sending an e-mail request to: rsargis@acf.hhs.gov.

Comments and questions about the information collection described above should be directed to the following address by March 5, 2004: Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, Washington, DC. E-mail address: katherine_t_astrich@omb.eop.gov.

Dated: February 26, 2004.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0508]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 2, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

Focus Groups as Used by the Food and Drug Administration—(OMB Control Number 0910-0497)—Extension

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups provide an important role in gathering information because they allow for a more in depth understanding of consumers' attitudes, beliefs, motivations, and feelings than quantitative studies.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

FDA estimates the burden for completing the forms for this collection of information in table 1 of this document. The total annual estimated burden imposed by this collection of information is 2,830 hours annually.

Annually, FDA projects about 28 focus group studies using 186 focus groups lasting an average of 1.78 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

In the **Federal Register** of November 24, 2003 (68 FR 65938), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (includes screening)	Total Hours
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication)	10	100	9	1.58	1,422
Center for Devices and Radiological	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves)	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (e.g., food safety, nutrition, dietary supplements, consumer education)	8	40	9	1.58	569
Center for Veterinary Medicine	Varies (e.g., animal nutrition, supplements, labeling of animal Rx)	5	25	9	2.08	468
Total		28	186		1.78	2,830

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0333]

Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document related to the processing of juice entitled "Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition." The guidance document supports and complements FDA's regulation that requires a processor of juice to evaluate its operations using Hazard Analysis Critical Control Point

(HACCP) principles and, if necessary, to develop and implement HACCP systems for its operations. The guidance represents FDA's views on potential hazards in juice products and recommends how to control such hazards, and is designed to assist juice processors in the development of their HACCP plans.

DATES: You may submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-

305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2022, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 12, 2002 (67 FR 57829), FDA announced the availability of a draft guidance document entitled "Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition." Under FDA's HACCP regulations in part 120 (21 CFR part 120), juice processors are required to evaluate their operations using HACCP principles and, if necessary, to develop and implement HACCP systems for their operations. Under § 120.9, juice products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)), if a processor fails to have and implement a HACCP plan when one is necessary, or otherwise fails to meet any of the requirements of the regulations. The primary purpose of the guidance is to help processors of juice products evaluate the likelihood that a food safety hazard may occur in their product, and to guide them in the preparation of appropriate HACCP plans for those