

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

21 CFR Sections	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
120.10(c) and 120.12(a)(4)(ii) and (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d)	308	1	308	4	1,232
Total					358,466

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

Table 1 of this document provides a breakdown of the total estimated annual recordkeeping burden. FDA bases this hour burden estimate on its experience with the application of HACCP principles in food processing.

The burden estimates in table 1 of this document are based on an estimate of the total number of juice manufacturing plants (i.e., 2,300) affected by the regulations. Included in this total are 850 plants currently identified in FDA's official establishment inventory plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers. The total burden hours are derived by estimating the number of plants affected by each portion of this final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers were obtained from the agency's final regulatory impact analysis prepared for these regulations.

Moreover, these estimates assume that every processor will prepare sanitary standard operating procedures and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under these regulations.

Dated: July 19, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Clinical Center; Submission for OMB Review; Comment Request Customer and Other Partners Satisfaction Surveys

**SUMMARY:** In compliance with the requirement of Section 3507(A)(1)(D) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Clinical Center (CC) of the National Institutes of Health, (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 9, 2007 (Volume 72, page 26400–26401) and allowed 60-days for public comments. One comment regarding resources required to conduct surveys was received during the 60-day comment period. The purpose of this notice is to provide an additional 30 days for public comment.

5 CFR 1320.5 Respondents to this request for information collection should not respond unless the request displays a currently valid OMB control number.

**Proposed Collection:** Title: Generic Clearance for Satisfaction Surveys of Customer and Other Partners. **Type of Information Collection Request:** Reinstatement (OMB Control Number: 0925–0458). **Need and Use of Information Collection:** The information collected in these surveys will be used by Clinical Center personnel: (1) To evaluate the satisfaction of various Clinical Center customers and other partners with Clinical Center services; (2) to assist with the design of

modifications of these services, based on customer input; (3) to develop new services, based on customer need; and 4) to evaluate the satisfaction of various Clinical Center customers and other partners with implemented service modifications. These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline the Clinical Center's operations. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected by telephone from customers. Information gathered from these surveys of Clinical Center customers and other partners will be presented to, and used directly by, Clinical Center management to enhance the services and operations of our organization. **Frequency of Response:** The participants will respond yearly. **Affected public:** Individuals and households, businesses and other for profit, small businesses and organizations. **Types of respondents:** These surveys are designed to assess the satisfaction of the Clinical Center's major internal and external customers with the services provided. These customers include, but are not limited to, the following groups of individuals: Clinical Center patients, family members of Clinical Center patients, visitors to the Clinical Center, National Institutes of Health investigators, NIH intramural collaborators, private physicians or organizations who refer patients to the Clinical Center, volunteers, vendors and collaborating commercial enterprises, small

businesses, regulators, and other organizations. The annual reporting burden is as follows:

## FY 2007

Customer	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Clinical Center Patients .....	5000	1	.5	2500
Family Members of Patients .....	2000	1	.5	1000
Visitors to the Clinical Center .....	1000	1	.17	170
Clinical Center Employees .....	2500	1	.25	625
NIH Investigators .....	2000	1	.25	625
NIH Intramural Collaborators .....	2000	1	.17	340
Vendors and Collaborating Commercial Enterprises .....	2500	1	.33	833
Professionals and Organizations Referring Patients .....	2000	1	.33	833
Regulators .....	30	1	.33	10
Volunteers .....	275	1	.5	138
<b>Total .....</b>	<b>19,305</b>	<b>.....</b>	<b>.....</b>	<b>7074</b>

Estimated costs to the respondents consists of their time; time is estimated using a rate of \$10.00 per hour for patients and the public; \$30.00 for vendors, regulators, organizations and \$55.00 for health care professionals. The estimated annual costs to respondents for FY 2007 for which the generic clearance is requested is \$159,250. Estimated Capital Costs are \$7,000. Estimated Operating and Maintenance costs are \$73,000.

**Requests for Comments:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Clinical Center and the agency, including whether the information shall have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection

plans and instruments, contact: Dr. David K. Henderson, Deputy Director for Clinical Care, National Institutes of Health Clinical Center, Building 10, Room 6-1480, 10 Center Drive, Bethesda, Maryland 20892, or call non-toll free: 301-496-3515, or e-mail your request or comments, including your address to: [dkh@nih.gov](mailto:dkh@nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: July 18, 2007.

**David K. Henderson,**

*Deputy Director for Clinical Care, CC, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; Comment Request; NICHD Research Partner Satisfaction Surveys

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**Proposed Collection: Title:** NICHD Research Partner Satisfaction Surveys.  
**Type of Information Collection Request:** RENEWAL of OMB Clearance 0925-0532. **Need and Use of Information**

**Collection:** Executive Order 12862 directs agencies that provide significant services directly to the public to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. With this submission, the National Institute of Child Health and Human Development (NICHD), Office of Science Policy, Analysis and Communication (OSPAC), seeks to obtain OMB's generic approval to conduct customer satisfaction surveys surrounding its research programs and activities.

The NICHD was founded in 1963. Its mission is to ensure, through research, the birth of healthy infants and the opportunity for each to reach full potential in adulthood, unimpaired by physical or mental disabilities. The NICHD conducts and supports research on the many factors that protect and enhance the processes of human growth and development. The developmental focus of the NICHD means that its research portfolio is unusually broad. NICHD programs include research on infant mortality, birth defects, learning disorders, developmental disabilities, vaccine development, and demographic and behavioral sciences, among others.

In addition to supporting laboratory research, clinical trials, and epidemiological studies that explore health processes, the NICHD disseminates information that emanates from its research programs to its customers, or those who are partners with the Institute. This includes scientists, practitioners, other health professionals, and the public.

Survey information will augment the NICHD's on-going efforts to assess their research funding mechanisms, activities, and programs, as well as the information products that are used to disseminate research findings. Primary