Services (HHS) National Breastfeeding Awareness Campaign.

A sample of pregnant women will be drawn from a commercial consumer opinion panel for a longitudinal study in which almost all data will be collected by mailed questionnaires. The sample design was chosen to maximize the response rate, which is critical for the success of a longitudinal study. Almost all of the sample will be members of the consumer opinion panel from which the sample will be drawn, while a few will be household members but not the panel member. All participants will be asked to complete one questionnaire during pregnancy, a short telephone interview shortly after delivery, a neonatal questionnaire sent a few weeks after the birth, and nine postnatal questionnaires sent approximately monthly from infant age 2 to 12 months. The postnatal questionnaires consist of various combinations of nine modules, some of which will be sent at each data collection, while others will be sent only some of the time. Seven of the questionnaires will take about 25 minutes to complete, and the other two will take about 15 minutes.

A subset of the sample will be asked to complete a modified Diet History Questionnaire (from National Institutes of Health, National Cancer Institute) during pregnancy and again when the infants are about 3 months old. Pregnant women who reside in a panel member's home but are not themselves the panel member will be sent a short additional questionnaire to collect basic demographic information.

The expected sample size is about 3,500 pregnant women, of whom about 2,250 are expected to complete questionnaires in the later infant ages. The sample will be well distributed throughout the United States. Only women who give birth to a full-term, healthy, singleton infant will be included in the study. An estimated 12 percent of the original 3,500 women will be ineligible for the study by these criteria. Many of the questions are identical to ones asked in a previous Infant Feeding Practices Study conducted by the FDA in 1993 to 1994. Use of the same questions in both time periods will enable comparison between the two data collections. Because the previous data are a decade old, and research suggests that significant changes in infant feeding issues have occurred in the past ten years, it is likely that consumer attitudes and practices have changed since the first data collection. FDA needs current information to support consumer education programs and to describe the policy context of current issues related to infant feeding. In addition, HHS and its agencies need data to evaluate various outreach efforts about child and maternal nutrition.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED REPORTING BURDEN[1]

Questionnaire	No. of Respondents	Frequency per Response	Total Responses	Hours per Response	Total Hours
Prenatal	3,500	1	3,500	.25	875
Prenatal diet history questionnaire	900	1	900	1.00	900
Demographic questionnaire	140	1	140	.17	24
Birth screener	2,772	1	2,772	.07	194
Neonatal questionnaire	2,494	1	2,494	.25	624
Postnatal diet history questionnaire	900	1	900	1.00	900
Postnatal questionnaires A	2,250	7	15,750	.42	6,615
Postnatal questionnaires B	2,250	2	4500	.25	1,125
Total					11,257

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

The burden estimate is based on FDA's experience with the 1993 to 1994 survey mentioned in the previous paragraph and information available for the diet history questionnaire.

Dated: April 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8995 Filed 4–20–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0525]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Hazard Analysis and Critical Control Point; Procedures for the Safe and Sanitary Processing and Importing of Juice

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 May 21, 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 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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice (OMB Control Number 0910–0466)—Extension

These regulations mandate the application of HACCP procedures to fruit and vegetable juice processing. HACCP is a preventative system of hazard control that can be used by all food processors to ensure the safety of their products to consumers. A HACCP system of preventive controls is the most effective and efficient way to ensure that these food products are safe. FDA's mandate to ensure the safety of the nation's food supply is derived principally from the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced and held under sanitary conditions, and are not misbranded or deceptively packaged; under 21 U.S.C. 371, the act authorizes the agency to issue regulations for its efficient enforcement. The agency also has authority under the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another other State. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety. Through these regulations, FDA is implementing its authority under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)).

In the **Federal Register** of December 8, 2003 (68 FR 68400), FDA asked for public comment on the information collection. FDA received one comment. The comment stated that the agency had underestimated the annual recordkeeping burden of the regulation. The comment identified the following three sources of underestimated burden:

1. The comment stated that we underestimated the burden of validation required of importers in 21 CFR 120.14. We estimated the burden to be 4 hours, whereas the comment said that validation requires 30 to 40 hours per importer.

2. The comment stated that we underestimated the time required to document the monitoring of critical control points (21 CFR 120.8(b)(7)). We estimated 36 seconds; the comment said that 2 to 3 minutes is a better estimate.

3. The comment stated that we underestimated the number of times per week that processors verify records in accordance with 21 CFR 120.11. We estimated once per week but, according to the comment, many processors verify records more often. The comment said that some processors verify records daily.

We have considered the three points raised in the comment. We will revise the estimated burden in response to the first point, but we find that the other two points do not require a revision of the estimated burden. The following are our detailed responses:

1. Part of the difference between our estimated burden under 21 CFR 120.14 and the estimate in the comment is that we computed burden per foreign source (308 entities) while the comment computes burden per importer (120 entities). Our burden per importer for validation is about 10 hours per year, which is still less than the comment's estimate but by a smaller order of magnitude. If foreign processors deal with multiple importers, the comment's estimate of 30 to 40 hours per importer is plausible. We therefore adjust the last line in the table in response to the comment. The hours per record change from 4 to 12 (column 5 of the table), and the total burden changes from 1,232 to 3,696 hours (column 6 of the table). This total burden corresponds to a burden of about 30 hours per importer.

2. The comment on documenting the monitoring of critical control points reflects some confusion about our calculation as presented in the burden table. Our estimate of 0.6 minutes per record is an average based on our overall estimate of the amount of additional recordkeeping time per hour required by the rule (on average an additional 3 minutes per hour). Some records will require more time to keep and others less. The comment may be correct that some records may take at least 2 to 3 minutes to make. However, the comment does not purport, and FDA does not believe, that all records will require that amount of time. Furthermore, many firms are already voluntarily performing a significant amount of the activities required to keep the records required by the rule to maintain good quality control to protect their brand value. Our estimate of the recordkeeping burden attributable to this rule is only for those additional activities that firms have not been doing prior to the rule, but undertake to comply with the rule.

3. The verification burden under 21 CFR 120.11 is based on the number of records that need to be verified. We say that each record must be verified within a week, so verification can be done weekly. But the burden is the same if verification is done twice a week or daily because the number of records to be verified is the same. So the burden would not change if we assumed more frequent verification.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Sections	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
120.6(c) and 120.12(a)(1) and (b)	1,875	365	684,375	0.1	68,438
120.7, 120.10(a), and 120.12(a)(2), (b), and (c)	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) and 120.12(a)(4)(ii) and (b)	1,840	12	22,080	0.1	2,208

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Sections	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
120.11(a)(1)(iv), 120.11 (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) and 120.14(c) and (d)	308	1	308	12	3,696
Total hours					360,930

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

Table 1 provides a breakdown of the total estimated annual recordkeeping burden. The estimates in this table have been reviewed by the agency's HACCP experts, who have practical experience in observing various processing operations and related recordkeeping activities.

The burden estimates in table 1 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: April 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8996 Filed 4–20–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0329]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 26, 2004 (69 FR 3586), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0454. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 14, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–9072 Filed 4–20–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0327]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 26, 2004 (69 FR 3587), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned