the pilot protocols will be included in the ClinicalTrials.gov data bank, the estimated annual burden for the first year will be reduced by the number of protocols included in the pilot.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN [1]

	New Protocols	Protocol Changes	New Investigators	Total Annual Responses	Hours per Response	Total Hours
CDER	200	400	600	1,200	5.6	6,720
CBER	50	100	150	300	5.6	1,680
Total						8,400

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

Dated: November 6, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–28851 Filed 11–8–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1441]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by December 11, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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.

Infant Formula Requirements (OMB Control Number 0910–0256)—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the act (21 U.S.C. 350a) requires manufacturers of infant formula to: (1) Establish and adhere to quality control procedures, (2) notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and (3) keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately. In a document published in the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1 and 2 of this document. The document included revised burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.

In the **Federal Register** of August 18, 2000 (65 FR 50539), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Federal Food, Drug, and Cosmetic Act (the Act) or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 412(d) of the act	4	7	28	10	280
106.120(b)	4	0.25	1	4	4
107.10(a) and 107.20	4	7	28	8	224
107.50(b)(3) and (b)(4)	3	4	12	4	48
107.50(e)(2)	3	0.33	1	4	4
Total					560

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
106.100	4	10	40	4,000	16,000
107.50(c)(3)	3	10	30	3,000	9,000
Total					25,000

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

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. The figures for hours per response are based on estimates from experienced persons in the agency and in industry.

Dated: November 6, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–28852 Filed 11–8–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Health Reengineering; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), is announcing a public workshop intended to gather information regarding its radiological health programs. The topic to be discussed is reengineering of electronic product radiation control processes with attention to prioritization, information exchange on new technology and public health issues, standards, and product testing.

Date and Time: The public workshop will be held on November 15 and 16, 2000, 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Holiday Inn, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Joanne Barron, Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4654, FAX 301–594–4672, e-mail: jxb@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION: At the workshop, FDA would like to hear whether certain radiological health programs and processes would benefit from changes and, if so, which changes would be most effective. The purpose of reengineering the radiological health processes is to make the best use of FDA expertise and resources in performing activities that best fulfill FDA's role in radiation protection. While reengineering provides opportunities to shift priorities, FDA also would like to establish partnerships with others who have a role in radiation protection from electronic products.

During the past 2 years, FDA obtained comments from stakeholders on improvements needed in the radiological health program. Comments received suggested four areas for improvement: (1) Prioritization, (2) information exchange, (3) standards, and (4) product testing. Several FDA teams considered the ideas and now would like public participation in revising the processes. CDRH must prioritize the use of limited resources to effectively and efficiently address these public health concerns. To that end, FDA issues recommendations and guidance and develops and enforces regulatory performance standards for radiation-emitting electronic products to minimize exposures to unnecessary radiation. FDA develops test methods and tests electronic products to ensure conformance to standards, identify nationwide exposure trends, and provide a basis for analyzing new technologies. FDA and stakeholders need information on product emissions, exposures, use, and health effects as a basis for decisions and actions. CDRH expects this public workshop to benefit the radiological health reengineering effort by developing practical solutions to the following questions:

1. How should CDRH choose and implement specific radiological health activities and set priorities?

2. How can CDRH optimize and improve the development/administration of electronic product radiation standards, recommendations, and guidances?

3. How can CDRH optimize and improve the evaluation of radiation emissions and exposures from electronic products?

4. How can CDRH better communicate and network with partners (States, other Federal agencies, industry, health professionals, standards organizations, etc.) regarding its radiological health program?

FDA will conduct concurrent breakout sessions on each of the four topics during this public workshop.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, fax number, and e-mail address), and written material and requests to make oral presentations to Diarra Hall at Laurel Consulting Group, 14504 Greenview Dr., suite 500, Laurel, MD 20708, 301–490–5500, FAX 301–490–7260 by November 13, 2000; or complete the registration form that is available at http://www.fda.gov/cdrh/reenging/radhlth/index.html.

If you need special accommodations due to a disability, please contact Diarra Hall in advance.

Transcripts: Transcripts of the public workshop 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 public workshop at a cost of 10 cents per page.

Dated: November 2, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–28694 Filed 11–8–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1562]

Draft Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the