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]

BILLING CODE 4160–01–F

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

availability of a draft guidance for industry entitled ''Cancer Drug and Biological Products—Clinical Data in Marketing Applications.'' The draft guidance document provides recommendations for sponsors designing clinical trials to demonstrate the safety and efficacy of cancer treatments on the collection of data that may be submitted to support marketing claims in new drug applications (NDA's), biologics license applications (BLA's), or applications for supplemental indications.

DATES: Submit written comments on the draft guidance by January 8, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Grant A. Williams, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5740, or Patricia Keegan, Center for Biologics Evaluation and Research (HFM–573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Guidance for Industry: Cancer Drug and Biological Products—Clinical Data in Marketing Applications.'' This draft guidance provides general principles for data collection and submission for sponsors of investigational new drug applications, NDA's, BLA's, or applications for supplemental indications. It is intended to enable sponsors to more effectively create plans to record and report the data from controlled trials that form the clinical basis for approval of anticancer drug and biological products.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on clinical data in marketing applications for cancer drug or biologic products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm.

Dated: October 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–28776 Filed 11–8–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Statement of Mission, Organization, Functions and Delegation of Authority

Part G, of the statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services, as amended at 60 FR 56606, November 9, 1995, and most recently amended at 61 FR 67048, December 19, 1996, is amended to reflect a reorganization of the Office of Public Health (GAB), Indian Health Service (IHS).

The changes are as follows:

Delete the functional statements for the Office of Public Health in their entirety and replace with the following:

Section GAB–00, Office of Public Health, IHS—Mission. The Office of Public Health, IHS defines its mission as a commitment to the well-being and cultural integrity of Indian people through a participatory and consultative process. The goal of the Office of Public Health is to elevate the health status of American Indian and Alaska Native (AI/AN) people to the highest possible level by (1) providing and/or assuring availability; (2) providing increasing opportunities for Indians to manage and operate their own health programs; and (3) serving as an advocate for Indian people.

Section GAB–10, Functions Office of Public Health (OOH) (GAB). (1) Advises and supports the Director, Indian Health Service (IHS), on policy, budget formulation, resource allocation regarding the operation and management of IHS direct, tribal, and urban public health programs, risk management, quality assurance, facilities programs, and self-determination; (2) provides agency-wide leadership and consultation to IHS direct, tribal, and urban public health programs on IHS goals, objectives, policies, standards, and priorities; (3) represents the IHS within the HHS and external organizations for purposes of liaison, professional collaboration, cooperative ventures, and advocacy; (4) manages and provides national leadership and consultation for IHS and Area offices on strategic and tactical planning, program evaluation and assessment, public health and medical services, research agendas, and special public health initiatives for the agency; (5) manages the design, development, and assessment for implementation of resource requirements and resource allocation methodology models for the agency; (6) manages demographic and program databases and performs statistical and epidemiological analyses and consultation; (7) carries out IHS responsibilities as required by the United States Federal Response Plan under Emergency Support Function No. 8; (8) assures agency compliance with the Code of Federal Regulations 45, Part 46, Protection of Human Subjects; and (9) manages and administers the functions related to business office services, contract health care, clinical and community services, preventive services, managed care, hospitals and ambulatory care centers, general public health practices and advocacy, environmental health, realty, facilities construction, facilities operation and