''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Health and Diet Survey

The authority for FDA to collect the information derives from the authority of the Commissioner of Food and Drugs, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)). The Health and Diet Survey will provide FDA information about consumers' knowledge, perceptions, attitudes, and practices related to dietary supplements and food. A nationally representative sample of 2,000 adults in the 48 contiguous States and the District of Columbia will be selected at random and interviewed by telephone. Participation will be voluntary. The survey will collect information about: (1) Prevalence, experience, and purposes of use of dietary supplements; (2) knowledge of health benefits, health risks, and regulation of dietary supplements; (3) sources of dietary supplement information; (4) perceptions of dietary supplement labels; (5) replacement and combination use of supplements and drugs; (6) adverse experience with dietary supplements; (7) children's and teenagers' use of dietary supplements; (8) knowledge of diet-health relationships; (9) dietary management practices; and (10) use of food labels.

Some of the questions to be asked (items 8 through 10 listed in the previous paragraph) replicate the ones asked in the 1995 Health and Diet Survey. Responses to these questions will help FDA identify and measure any changes in consumer knowledge, perceptions, attitudes, and practices with regard to diet, health, and use of food labels. The information will also help the agency evaluate the effectiveness of the Nutrition Labeling and Education Act of 1990 in promoting the public health.

The agency will use the other questions in the proposed survey to enhance its understanding of consumer knowledge, perceptions, attitudes, and practices regarding dietary supplements. Subsequent to the enactment of the Dietary Supplement Health and Education Act of 1994, the consumption of dietary supplements in the United States has been increasing. FDA needs current, timely, and policy-relevant consumer information to help it identify needs for and develop consumer education programs and regulatory policies to ensure safe and appropriately labeled supplement products. The survey will help the agency measure prevalence and distribution of consumer knowledge, perceptions, attitudes, and practices. This information can be used to understand and describe the consumer environment that is the intended target of labeling and education initiatives.

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

TABLE1.— ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive interview	9	1	9	1.5	13.5
Pretest	9	1	9	0.5	4.5
Screener	4,200	1	4,200	0.02	84
Survey	2,000	1	2,000	0.5	1,000
Total					1,102

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

These estimates are based on FDA's experience with previous consumer surveys. Prior to the administration of the survey, the agency plans to conduct a series of nine cognitive interviews and a series of nine pretests to ensure the quality of the survey. Cognitive interviews will help the agency understand respondent comprehension of the meanings of questions and words, and how respondents answer questions. Pretests will help the agency examine and reduce problems in the administration of the final questionnaire. The agency will use a screener to select an eligible adult respondent in each household to participate in the survey.

Dated: August 1, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–19626 Filed 8–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 10, 2001, from 8:30 a.m. to 5:30 p.m., and September 11, 2001, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 10, 2001, the committee will discuss: (1) Clinical trial designs for first-line hormonal treatment of metastatic breast cancer; and (2) new drug application (NDA) 21–236, IntraDose® (cisplatin/epinephrine) Injectable Gel, Matrix Pharmaceutical, Inc., indicated for the treatment of recurrent or refractory squamous cell carcinoma of the head and neck in patients who are not considered curable with surgery or radiotherapy. On September 11, 2001, the committee will discuss: (1) Biologics license application (BLA) 125019, Zevalin™ (ibritumomab tiuxetan), IDEC Pharmaceuticals Corp., indicated for the treatment of patients with relapsed or refractory low grade, follicular or CD20+ transformed B cell non-Hodgkins lymphoma (NHL) and rituximab refractory follicular NHL; and (2) supplemental NDA 20–637/S016, Gliadel® Wafer (carmustine), Guilford Pharmaceuticals, Inc., indicated for use as a treatment to significantly prolong survival and maintain overall function (as measured by preservation of Karnovsky Perfomance Status) and neurological function in patients with malignant glioma undergoing primary and/or recurrent surgical resection.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 31, 2001. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and 1:30 p.m. and 1:45 p.m. on September 10, 2001, and between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:15 p.m. on September 11, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentation should notify the contact person before August 31, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and address of proposed participants, and an indication of the approximate time requested to make their presentation. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by August 31, 2001, to address issues specific to the topic before the committee.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 31, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–19625 Filed 8–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5046]

''Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture'' dated July 2001. The guidance document provides information about reporting changes to licensed biological products including labeling, production processes, quality controls, equipment, and facilities that have been documented in approved license applications. The guidance document is intended to assist biological product manufacturers in identifying the kinds of changes to be reported, the category into which the change is to be placed, and the time to report the change to FDA.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 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 mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or 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 guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture'' dated July 2001. CBER developed the guidance in response to public comments on the ''Guidance for Industry: Changes to an Approved Application: Biological Products'' dated July 1997 and public comments on the CBER Biologics Workshop on the Biologics License Application (BLA), December 2, 1997. The guidance applies to the manufacture of all licensed Whole Blood, blood components, Source Plasma, and Source Leukocytes. The guidance is intended to assist biological product manufacturers in identifying the kinds of changes to be reported, the category into which the change is to be placed, and the time to report the change to FDA.

This guidance replaces the recommendations for the products mentioned above in the ''Guidance for Industry: Changes to an Approved Application: Biological Products'' dated July 1997 and revises and finalizes the draft guidance entitled ''Guidance for Industry: Changes to an Approved Application: Biological Products: