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:

Human Blood and Blood Components Intended for Transfusion or for Further Manufacture'' dated January 2000 that was announced in the **Federal Register** of January 3, 2000 (65 FR 134).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on reporting changes to an approved application for human blood and blood components that are intended for transfusion or for further manufacture. 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 requirement of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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 either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: June 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–19683 Filed 8–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Healthy Schools, Healthy Communities User/Visit Surveys

The Bureau of Primary Health Care of HRSA is planning to conduct User/Visit Surveys of the Healthy Schools, Healthy Communities (HSHC) Program. The purpose of these surveys is to obtain nationally representative data about the patients of HSHC health centers and the services provided to them. The study consists of two parts. One is the User Survey, which involves interviewing HSHC patients or their parents about the patients' health and health care. The second is the Visit Survey, in which patient visit data will be collected from medical records in order to find out what health services are being used by patients. The data collected will provide policymakers with a better understanding of the services students are receiving at HSHC health centers and how well these centers are meeting the needs of students. The surveys will provide new information about health care received in HSHC settings.

Data from the surveys will provide quantitative information on the population served by the HSHC program, specifically: (a) Sociodemographic characteristics, (b) health care access and utilization, (c) health status and morbidity, (d) health care experiences and risk behaviors, (e) content of medical encounters, (f) preventive care (g) and patient satisfaction. These surveys will provide data useful to the program and will enable HRSA to provide data required by Congress under the Government Performance and Results Act of 1993.

The estimated burden on respondents is as follows:

Respondents	Number of Respondents	Hours per Respondent	Total Hour Burden
Adolescent Users of HSHC Clinics	750	.5	375
Guardians (Proxies) of Users of HSHC Clinics	750	.5	375
Medical Records Copied by Health Center Personnel	*1500	.25	385
Total	1500		1,135

*Medical records.