Date and Time: The meeting will be held on June 7, 2001, 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, or by e-mail at 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: The committee will discuss single patient use of nonapproved oncology drugs and biologics. This is a continuation of the discussion started at the December 13 and 14, 2000, meeting.

Procedure: The meeting is open to the public from 8 a.m. to 1 p.m. 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 May 31, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 31, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Background materials for this meeting will be posted at the Oncologic Drugs Advisory Committee dockets Web site at www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2001 and scroll down to the Oncologic Drugs Advisory Committee meetings.) The slides and transcripts from the meeting will be posted at this same Web site about 3 weeks after the meeting.

Closed Committee Deliberations: The meeting will be closed from 1 p.m. to 5:30 p.m. to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

FDA regrets that it was unable to publish this notice 15 days prior to the May 23, 2001, Oncologic Drugs Advisory Committee meeting. Because there agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Dated: May 22, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–13368 Filed 5–23–01; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0087]

Guidance for Industry on IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' This guidance provides recommendations to industry on formal meetings between sponsors of investigational new drug applications (INDs) and the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) on chemistry, manufacturing, and controls (CMC) information.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to 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 20852–1488, FAX 1–888–CBER–FAX or 301–827–3844. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Stephen K. Moore, Center for Drug Evaluation and Research (HFD–501), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430;

or

Robert A. Yetter, Center for Biologics and Research (HFM–10), Food and Drug Administration, Bldg. N29B, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' This guidance covers three kinds of meetings held at specific times between sponsors and the agency where CMC issues are discussed: (1) Pre-IND, (2) end-of-phase 2, and (3) pre-new drug application or prebiologics license application. These meetings are used to address questions and scientific issues that arise during the course of clinical investigations, aid in the resolution of problems, and facilitate evaluation of the drug. The meetings often coincide with critical points in the drug development and/or regulatory process. This guidance is intended to assist in making these meetings more efficient and effective by providing information on the: (1) Purpose, (2) meeting request, (3) information package, (4) format, and (5) focus of the meeting.

In the **Federal Register** of February 4, 2000 (65 FR 5645), FDA announced the availability of a draft version of this guidance. The February 4, 2000, guidance gave interested persons an opportunity to submit comments through May 4, 2000. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, the guidance is clearer and more concise than the draft version.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on IND meetings for human drugs and biologics; chemistry, manufacturing, and controls information. 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, at any time, submit written comments on the 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 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 either http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/ohrms/dockets/default.htm, or http://www.fda.gov/cber/guidelines.htm.

Dated: May 17, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–13249 Filed 5–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–216]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Procedures for Advisory Opinions Concerning Physician Referrals and Supporting Regulations in 42 CFR 411.370 through 411.389; *Form No.:* HCFA–R–216 (OMB# 0938–0714); *Use:* Section 4314 of Public Law 105–33, in establishing section 1877(g)(6) of the Act, requires the Department to provide advisory opinions to the public regarding whether a physician's referrals for certain designated health services are prohibited under the other provisions in section 1877 of the Act. These regulations provide the procedures under which members of the public may request advisory opinions from HCFA. Because all requests for advisory opinions are purely voluntary, respondents will only be required to provide information to us that is relevant to their individual requests.; *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions, Business or other for-profit, and Individuals and Households; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 2,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan,HCFA–R–216, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 17, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–13207 Filed 5–24–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–224]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Collection of Managed Care Data Using the Uniform Institutional Providers Form (HCFA–1450/UB–92) and Supporting Statute section 1853(a)(3) of the Balanced budget Act of 1997; *Form No.:* HCFA–R–224 (OMB No. 0938–0711); *Use:* Section 1853(a)(3) of the Balanced Budget Act (BBA) requires Medicare+Choice organizations, as well as eligible organizations with risk-sharing contracts under section 1876, to submit encounter data. Data regarding inpatient hospital services are required for periods beginning on or after July 1, 1997. These data may be collected starting January 1, 1998. Other data (as the Secretary deems necessary) may be required beginning July 1, 1998.

The BBA also requires the Secretary to implement a risk adjustment methodology that accounts for variation in per capita costs based on health status. This payment method must be implemented no later than January 1, 2000. The encounter data are necessary to implement a risk adjustment methodology.

HCFA continues to require hospital inpatient encounter data from Medicare+Choice organizations to