issues related to toxicological testing methods, will provide an update on its activities. The Science Board Subcommittee on FDA Research will present a report to the board on a strategy for optimizing the quality and mission relevance of agency research programs.

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. March 14, 1997, 12:30 p.m., National Institutes of Health, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open committee discussion, 12:30 p.m. to 2 p.m.; open public hearing, 2 p.m. to 3 p.m., unless public participation does not last that long; Nancy T. Cherry or Denise A. Royster, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person by March 1, 1997, 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 required to make their comments.

Open committee discussion. The committee will discuss the influenza virus vaccine's formulation for 1997 and 1998.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 12, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–4305 Filed 2–18–97; 11:00 am]

BILLING CODE 4160–01–F

[Docket No. 97N–0042]

Review of the Adverse Event Reporting System for Postmarketing Surveillance; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to provide the pharmaceutical industry and other interested persons with information on the plans, progress, and technical specifications developed under the reengineering of the Center for Drug Evaluation and Research's (CDER's) postmarketing surveillance program. The primary focus of the meeting will be the electronic submission of adverse drug reaction (ADR) reports under the new adverse event reporting system (AERS), which is currently under development as a major component of the reengineering effort.

DATES: The public meeting will be held on Monday, March 17, 1997, from 9:30 a.m. to 5 p.m. There is no registration fee for the meeting. Because space is limited, interested persons are encouraged to register by March 7, 1997.

ADDRESSES: The public meeting will held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852. Persons interested in attending should fax their registration to Robert Nelson at 301–480–2825. The facsimile should include the participant's name and title; organization name, if any; address; and telephone and fax numbers.

Three weeks prior to the public meeting, a copy of the meeting agenda will be available through CDER's Fax-on-Demand, 301–827–0577 or 800–342–

2722, under the index ''AERS Public Meeting,'' document No. 0510. Information about the meeting will be available via Internet using the World Wide Web (WWW). To connect to the CDER home page, type http://www.fda.gov/cder and go to the ''What's Happening'' section. Also available on the CDER home page is a link to the new AERS home page, which contains a brief summary of the materials that will be discussed at the meeting. Information distributed at the public meeting will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 10 business days after the meeting at a cost of 10 cents per page.

The agenda will be placed on display, under the docket number found in brackets in the heading of this document, at the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert C. Nelson, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–700), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3206.

SUPPLEMENTARY INFORMATION: The primary purpose of FDA's postmarketing surveillance program is to identify potentially serious drug safety problems, focusing especially on newly marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provides, for the first time, the opportunity to collect information on rare, latent, and long-term effects. Reports are obtained from a variety of sources, including patients, treating physicians, foreign regulatory agencies, and clinical investigators. Over 75 percent of the ADR reports that FDA receives are routed from health care practitioners through pharmaceutical companies. The remainder of the reports come directly to FDA through the agency's MedWatch program.

FDA's computerized spontaneous reporting system (SRS) contains 1.4 million ADR reports for human drugs and therapeutic biologics. FDA plans to replace SRS with AERS by September 1997. All SRS historical data will be migrated to AERS. AERS will enable FDA to receive reports from pharmaceutical companies by electronic submission, transmitted data base to data base through standardized pathways. The technical specifications of the AERS computerized system will be described at the public meeting and made available to participants, especially as they relate to the electronic submission of expedited and periodic ADR reports.

FDA has participated in the development of several guidelines by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that relate to the submission of ADR reports under the AERS system: ''Clinical Safety Data Management: Definitions and Standards for Expedited Reporting'' (E2A); ''Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports'' (E2B); and ''Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' (E2C). In addition, two other guidelines are currently under development by ICH: ''Medical Terminology (MEDDRA)'' (M1) and ''Electronic Standards for the Transfer of Regulatory Information (ESTRI)'' (M2).

At the public meeting, FDA will explain how it intends to incorporate these recommended standards into the requirements for the electronic submission of ADR reports under AERS. The meeting will include a general discussion of CDER's plans to propose revisions to its postmarketing ADR reporting regulations. The goals of this rulemaking are to implement the recommendations in the ICH guidelines and to enhance the quality of ADR reports received by the agency. The agency hopes to familiarize the pharmaceutical industry with the procedures for the electronic submission of ADR reports under AERS so that they are prepared to comply with any revised regulations that may issue as a result of the rulemaking initiative.

Additional information on the technical specifications of the AERS system will be placed on display, as they are available in final form, at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4161 Filed 2–19–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Form # HCFA–P–15A]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHSS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, thus causing the disruption of this collection of information, which is essential to the agency's mission of ensuring that beneficiary needs are evaluated and implemented, to the extent possible, in a cost-effective manner. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result if normal clearance procedures are followed. Without this information, HCFA would not be able to properly determine the services needed by beneficiaries or the most cost efficient manner to meet beneficiary needs, possibly resulting in the denial of beneficiary warranted services and a loss of program dollars.

HCFA is requesting that OMB provide a 24-hour review and a 180-day approval. During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.5.

1. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Medicare Current Beneficiary Survey (MCBS) Round 18; *Form No.:* HCFA–P–15A; *Use:* The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons for Medicare. The survey provides a comprehensive source of information on beneficiary characteristics, needs, and satisfaction with Medicare-related activities. The proposed MCBS revisions will focus on the evaluation of beneficiary informational needs. This information will enable HCFA to better coordinate and integrate its current communication objectives effectively and efficiently; *Frequency:* On occasion; *Affected Public:* Individuals and households; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 16,000.