independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 2, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 13, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–16885 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M-0199]

Bayer Corp.; Premarket Approval of Technicon Immuno 1® CEA Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Bayer Corp., 511 Benedict Ave., Tarrytown, NY, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Immuno 1 CEA Assay. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of January 30, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 2, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On September 29, 1994, Miles, Inc., Tarrytown, NY 10591, submitted to CDRH an application for premarket approval of Immuno 1® CEA Assay. The device is an in vitro diagnostic device intended to quantitatively measure carcinoembryonic antigen (CEA) in human serum on the Technicon Immuno 1® system. Measurements of CEA aid in the management of cancer patients by monitoring CEA concentrations. This diagnostic method is not intended for use on any other system.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this committee.

On January 30, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 2, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 9, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–16972 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

Product and Establishment License Applications, Refusal to File; Meeting of Oversight Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's) and establishment license applications (ELA's). CBER's RTF oversight committee examines all RTF decisions that occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

DATES: The meeting will be held in July 1996.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–5), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee meetings continue CBER's effort to promote the timely, efficient, and consistent review of PLA's and ELA's.

FDA regulations on filing PLA's and ELA's are found in 21 CFR 601.2(a) and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3) (see 57 FR 17950, April 28, 1992).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings, ordinarily, will be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all confidential commercial information omitted, 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 meeting, at a cost of 10 cents per page. If, following the committee's review, an RTF decision changes, the appropriate division will notify the sponsor.

Dated: June 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–16971 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[R–48]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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:* Hospital Conditions of Participation—42 CFR Part 482; *Form No.:* HCFA–R–48; *Use:* Hospitals seeking to participate in the Medicare and Medicaid programs must meet the Conditions of Participation (COP) for Hospitals, 42 CFR Part 482. The information collection requirements contained in this package are needed to implement the Medicare and Medicaid COP for hospitals. *Frequency:* Annually; *Affected Public:* Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 1,500; *Total Annual Responses:* 1,500; *Total Annual Hours Requested:* 53,522.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address:

OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503

Date: June 26, 1996

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–16897 Filed 7–2–96; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Request for Nominations to the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration, DHHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill retiring members vacancies of the Council on Graduate Medical Education (COGME).

DATES: Nominations must be received by close-of-business on Friday, July 26, 1996.

ADDRESSES: Nominations and the curricula vitae of nominees should be sent to Enrique S. Fernandez, M.D., M.S. Ed., Executive Secretary, Council on Graduate Medical Education, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 9A–27, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Enrique S. Fernandez, M.D., M.S.Ed., at the above address, or phone (301) 443–6190.

SUPPLEMENTARY INFORMATION: HRSA is requesting nominations under the authorities that established the Council on Graduate Medical Education, September 30, 1986, in accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463).

COGME was authorized by Congress in 1986 to provide an ongoing assessment of physician workforce trends and to recommend appropriate Federal and private sector efforts to address identified needs. Legislation calls for COGME to serve in an advisory capacity to the Secretary of the Department of Health and Human Services (DHHS), the Senate Committee on Labor and Human Resources, and the