human drug product had undergone a regulatory review period and that the approval of ADENOSCAN® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ADENOSCAN® is 2,688 days. Of this time, 768 days occurred during the testing phase of the regulatory review period, while 1,920 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: January 9, 1988. The applicant claims December 10, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 9, 1988, which was 30 days after FDA receipt of the IND on December 10, 1987.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: February 14, 1990. The applicant claims February 9, 1990, as the date the new drug application (NDA) for ADENOSCAN® (NDA 20–059) was initially submitted. However, while FDA records indicate that the applicant submitted NDA 20–059 on February 9, 1990, FDA received the NDA on February 14, 1990, which is considered to be the date the NDA was initially submitted.

3. *The date the human drug was approved*: May 18, 1995. FDA has verified the applicant's claim that NDA–059 was approved on May 18, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 159 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 4, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 1, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–31555 Filed 12–29–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Immunology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. January 22, 1996, 9:30 a.m., Gaithersburg Hilton Hotel, Salons D & E, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–977–8900 and reference FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, 9:30 a.m. to 10:30 a.m., unless participation does not last that long; open committee discussion, 10:30 a.m. to 4 p.m. For information regarding the analyte specific reagents classification—Kaiser J. Aziz, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084. For information regarding the conduct of the meeting—Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Immunology Devices Panel, code 12516.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 before January 8, 1996, 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 consider the classification of analyte specific reagents as in vitro diagnostic devices. FDA intends to develop a regulatory scheme to handle products currently being used by clinical laboratories as materials for in-house (''home brew'') assays. Analyte specific reagents are chemical, poly or monoclonal antibodies, proteins, nucleic acid sequences, which, by their physio-chemical reaction with substances in a specimen, allow a test procedure to distinguish or quantify an individual chemical substance or ligand in a biological specimen. These are used in the production of in-house tests which are of high complexity under the Clinical Laboratory Improvement Act of

1988. They are considered medical devices. Currently, such reagents are being made widely available to clinical laboratories under ''research use only'' or ''investigational use only'' labeling or as unlabeled components of a final test.

FDA believes that most analyte specific reagents may be considered for classification as class I devices and exempted from the premarket notification (510(k)) procedure in subpart E of 21 CFR part 807 if the reagents do not make analytical or clinical performance claims. FDA is currently considering an approach under which such analyte specific reagents would be subject to other general controls: (1) Registration and listing, (2) medical device reporting requirements, and (3) good manufacturing practice requirements. FDA is also considering establishing restrictions under section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(e)) on the sale, distribution, or use of the devices.

The issue of classification and the nature of appropriate restrictions will be the subject of the panel meeting.

Although FDA believes that most analyte specific reagents may be considered for regulation in this way, the agency also believes that a small number of analyte specific reagents (e.g., those used to diagnose communicable diseases through blood or other means) would be more properly classified into class II or III and subject to the premarket controls (510(k) or premarket approval) applicable to such classification.

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 each meeting 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, rm. 1–23, 12420 Parklawn Dr., 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 (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: December 21, 1995.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 95–31554 Filed 12–29–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Conservation Advisory Group, Yakima River Basin Water Enhancement Project, Yakima, WA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of meetings.

SUMMARY: Title XII, The Act of October 31, 1994 (Public Law 103–434), directs the Secretary of the Interior, in consultation with the State of Washington, the Yakama Indian Nation, Yakima River Basin Water Conservation Advisory Group and a Facilitator within 12 months of enactment. The purpose of the Conservation Advisory Group is to provide technical advice and counsel to the Secretary and the State on the structure, implementation, and oversight of the Yakima River Basin Water Conservation Program.

DATES: Meetings will be held at the Upper Columbia Area Office, Bureau of Reclamation, 1917 Marsh Road, Yakima, Washington, beginning at 12 noon on the following dates: January 16, 1996, February 20, 1996, March 19, 1996.

FOR FURTHER INFORMATION CONTACT:

Walt Fite, Program Manager, Yakima River Water Enhancement Project, PO Box 1749, Yakima, Washington 98907, (509) 575–5848 ext. 267.

SUPPLEMENTARY INFORMATION: The Basin Conservation Program is structured to provide economic incentives with cooperative Federal, State, and local funding to stimulate the identification and implementation of structural and nonstructural cost-effective water conservation measures in the Yakima River basin. Improvements in the efficiency of water delivery and use will result in improved streamflows for fish and wildlife and improve the reliability of water supplies for irrigation.

Dated: December 20, 1995.

Jim Cole,

Area Manager, Upper Columbia Area Office, Bureau of Reclamation, Yakima, Washington.

[FR Doc. 95–31551 Filed 12–29–95; 8:45 am]

BILLING CODE 4310–94–M