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.

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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]

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