The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

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: October 21, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–27489 Filed 10–24–96; 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:

Science Board to the Food and Drug Administration

Date, time, and place. November 7, 1996, 8:30 a.m., Sheraton National Hotel, North Ballrooms 1 and 2, 900 South Orme St. (Columbia Pike and Washington Blvd.), Arlington, VA.

Type of meeting and contact person. Closed board deliberations, 8:30 a.m. to 11 a.m.; open board discussion, 11 a.m. to 3 p.m.; open public hearing, 3 p.m. to 4 p.m., unless public participation does not last that long; open board discussion, 4 p.m. to 4:30 p.m.; Susan K. Meadows, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Science Board to the Food and Drug Administration, code 12603. Please call the hotline for information concerning any possible changes.

General function of the board. The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Those desiring to make formal presentations must notify the contact person before October 31, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely fashion will be provided to the board.

Open board discussion. The board will receive an update on the FDA Information Retrieval System developed within FDA's Office of Science, and an update on the creation of a Biomaterials Forum designed to foster information exchange on issues related to safety testing of biomaterials and new developments in biomaterials science. Additionally, the board will discuss the formation of a subcommittee on toxicology, which will address issues related to the research and development of toxicological methods and mechanisms that better predict adverse health effects. A complete agenda will be available in advance of the meeting.

Closed board deliberations. The board will discuss information concerning nominations for the FDA award for scientific achievement; if these nominations are discussed in public, information of a personal nature would be disclosed which would constitute a clearly unwarranted invasion of

personal privacy (5 U.S.C. 552b(c)(6)). The board will also hear an interim status report from its subcommittee on FDA research. FDA believes that premature disclosure of the subcommittee's work is likely to significantly impede discussion of the issues being reviewed by the subcommittee and potential agency action on future recommendations (5 U.S.C. 552b(c)(9)(B)). Thus, the interim status report from the subcommittee will be presented in a closed session. However, the issues related to FDA science and research being reviewed by the subcommittee will be presented to the board for public discussion at a later date.

FDA regrets that it was unable to publish this notice 15 days prior to the Science Board to the Food and Drug Administration meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Science Board to the Food and Drug Administration were available at this time, the Commissioner 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.

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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, 5600 Fishers Lane, rm. 12A–16, 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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

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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: October 21, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–27490 Filed 10–24–96; 8:45 am]

BILLING CODE 4160–01–F

Indian Health Service

[0917–ZA___]

Notice of Redesignation of Contract Health Service Delivery Area; Jamestown S'Klallam Tribe

AGENCY: Indian Health Service, HHS.

ACTION: Final notice.