sensorineural hearing impairment, and obtain limited benefit from appropriate binaural hearing aids. Limited benefit from amplification is defined by test scores of 30 percent or below in the best-aided (i.e., testing on left ear, right ear, and binaurally to determine communication ability obtained in that particular hearing-aided condition) listening condition on tape recorded tests of open set sentence recognition. These patients typically have low frequency residual hearing in the moderate to profound range and profound (greater than equal to 90 dBHL (decibels in hearing level)) hearing loss in the mid to high speech frequencies.

On April 20, 1995, the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the supplemental application. On August 21, 1995, CDRH approved the supplemental 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 (21 U.S.C. 360e(d)(3)) 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 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 November 27, 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: October 4, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–27613 Filed 10–25–96; 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:

Veterinary Medicine Advisory Committee

Date, time, and place. November 20, 1996, 8:30 a.m., Best Western, Grand Ballroom, 1251 West Montgomery Ave., Rockville, MD.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; Richard E. Geyer, Center for Veterinary Medicine (HFV–244), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1764, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Veterinary Medicine Advisory Committee, code 12546. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

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 November 13, 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 continue the discussion about the status of the sometribove Post-Approval Monitoring Program. FDA approved sometribove, a recombinant bovine somatotropin, on November 12, 1993 (58 FR 55946), and the product, Posilac®, began commercial distribution on February 4, 1994.

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, 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 (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. 96–27612 Filed 10–25–96; 8:45 am]

BILLING CODE 4160–01–F

[FDA 225–96–2006]

Memorandum of Understanding Between the Food and Drug Administration and the Agricultural Marketing Service, United States Department of Agriculture

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Agricultural Marketing Service, United States Department of Agriculture (USDA). The purpose of the MOU is to clarify and delineate the responsibilities of each agency with respect to the National Laboratory Accreditation Program (NLAP). Each agency has specific responsibilities under the NLAP that are mandated by the 1990 Food, Agriculture, Conservation, and Trade Act (7 U.S.C. 138–138i).

DATES: The agreement became effective May 31, 1996.

FOR FURTHER INFORMATION CONTACT: Marion G. Clower, Center for Food Safety and Applied Nutrition (HFS–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4036.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the Federal Register, the agency is publishing notice of this memorandum of understanding.

Memorandum of Understanding Between the Food and Drug Administration and the Agricultural Marketing Service, USDA

I. Title: National Laboratory Accreditation Program

II. Purpose

This agreement between the Food and Drug Administration (FDA) and Agricultural Marketing Service (AMS) of the United States Department of Agriculture (USDA) clarifies and delineates the responsibilities of each agency with respect to the National Laboratory Accreditation Program (NLAP). Each agency has specific responsibilities under the NLAP that are mandated by the 1990 Food, Agriculture, Conservation, and Trade (FACT) Act (7 U.S.C. 138–138i).

III. Background

The FACT Act of 1990, approved November 28, 1990, authorizes the creation of the NLAP. Under NLAP, laboratories that request accreditation and conduct pesticide residue analysis of agricultural products for human consumption, or that make claims to the public or buyers of agricultural products concerning pesticide residue levels on agricultural products, shall be determined to meet certain minimum quality and reliability standards. The Secretary of Agriculture is charged with administering the NLAP.

The FACT Act requires the Secretary of Health and Human Services, after consultation with the Secretary of Agriculture and the Administrator of the Environmental Protection Agency (EPA), to establish, through regulations, standards for the NLAP. The Secretary of Health and Human Services is also required to approve accrediting bodies, and oversee and review the performance of such accrediting bodies, to act on behalf of the Secretary of Agriculture in implementing the certification and quality assurance programs. FDA will carry out these responsibilities under delegation from the Secretary of Health and Human Services. The Secretary of Agriculture is required to issue certificates of accreditation to laboratories who meet the requirements for the accreditation program, provide proficiency test samples to laboratories that apply for accreditation, establish a fee schedule, collect fees from the private laboratories involved in NLAP, and promulgate regulations to carry out the NLAP.

IV. Substance of Agreement

It is understood and agreed between the parties as follows:

A. FDA Responsibilities:

1. Promulgate regulations establishing standards for NLAP, after consultation with AMS and EPA (7 U.S.C. 138a(b)), including:
   a. standards applicable to laboratories;
   b. qualifications of laboratory personnel; and
   c. standards and procedures for quality assurance programs.
2. Approve accrediting bodies (7 U.S.C. 138a(c)), which may include:
   a. state agencies; and
   b. private non-profit organizations.