Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–0708.

Dated: March 11, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–6191 Filed 3–14–96; 8:45 am]

BILLING CODE 4163–70–M

Food and Drug Administration

[Docket No. 96N–0075]

Hance Brothers and White Co., et al.; Proposal to Withdraw Approval of 17 Abbreviated Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 3 abbreviated antibiotic applications (AADA's) and 14 abbreviated new drug applications (ANDA's). The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Written requests for a hearing are due by April 15, 1996; data and information in support of the hearing request are due by May 14, 1996.

ADDRESSES: Requests for a hearing, supporting data, and other comments should be identified with Docket No. 96N–0075 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs or antibiotic drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the AADA's and ANDA's listed in the table below have failed to submit the required annual reports, and have not responded to the agency's requests by certified mail for submission of the reports.

Application no.	Drug	Applicant
AADA 60–276	Neomycin and Polymyxin B Sulfates and Bacitracin Ointment	Hance Brothers and White Co.
AADA 60–422	Tetracycline Hydrochloride Tablets	Premo Pharmaceutica Laboratories, Inc.
AADA 62–362	Erythromycin Estolate Suspension, 250 Milligrams (mg) per 5 Milliliters (mL)	Life Laboratories, Inc.
ANDA 80–126	Isoniazid Tablets, 300 mg	Everylife.
ANDA 80–689	Cyanocobalamin Injection USP, 30 micrograms (µg) per mL, 100 µg/mL, and 100 µg/mL	Dell Laboratories, Inc.
ANDA 83–387	Lidocaine Hydrochloride Injection USP, 1%	Do.
ANDA 83–388	Lidocaine Hydrochloride Injection USP, 2%	Do.
ANDA 83–665	Vitamin A Capsules USP	Wharton Laboratories.
ANDA 83–771	Pyridoxine Hydrochloride Injection USP, 50 mg/mL	Dell Laboratories, Inc.
ANDA 83–772	Pyridoxine Hydrochloride Injection USP, 100 mg/mL	Do.
ANDA 83–775	Thiamine Hydrochloride Injection USP, 100 mg/mL	Do.
ANDA 86–519	Chlorpheniramine Maleate Tablets, USP, 4 mg	Newtron Pharmaceuticals, Inc
ANDA 86–987	Brompheniramine Maleate Tablets, USP, 4 mg	Do.
ANDA 87–791	Fluorouracil Injection, 50 mg/mL	Marcher Laboratories, Ltd.
ANDA 88–871	Hydrocodone Bitartrate and Acetaminophen, 5 mg/500mg	Abana Pharmaceuticals, Inc.
ANDA 89–184	Acetaminophen and Codeine Phosphate Tablets, USP, 300 mg/30 mg	Superpharm Corp.
ANDA 89–538	Meprobamate Tablets, USP, 400 mg	K. M. Lee Laboratories

Therefore, notice is given to the holders of the AADA's and ANDA's listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the AADA's and ANDA's and all amendments and supplements thereto on the ground that the applicants have

failed to submit reports required under § 314.81.

In accordance with section 505 of the act and 21 CFR part 314, the applicants are hereby provided an opportunity for a hearing to show why the applications listed above should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file:

(1) On or before April 15, 1996, a written notice of participation and request for a hearing, and (2) on or before May 14, 1996, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: February 28, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–6174 Filed 3–14–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings 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.

MEETINGS: The following advisory committee meetings are announced:

Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. April 1, 1996, 8:30 a.m., Holiday Inn—Gaithersburg, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 or 1–800–465–4329, and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Alice Hayes, Sociometrics, Inc., 8300 Colesville Rd., suite 550, Silver Spring, MD 20910, 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ophthalmic Devices Panel, code 12396.

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 March 22, 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 Division of Ophthalmic Devices will present the proposed draft guidance document for Photorefractive Keratectomy (PRK) Laser Systems and request comments and recommendations from the Panel on designated sections. The scope of the discussion will include a proposal from the Division to expand the guidance to address high myopia, hyperopia, astigmatism, and Laser Assisted In Situ Keratomileusis (LASIK). Single copies of the proposed outline for the discussion are available from the contact person (see above).