

Committee will conduct its review of grant applications. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(6), Title 5 U.S. Code, and the Determination of the Director, Centers for Disease Control, pursuant to Pub. L. 92-483.

Agenda items are subject to change as priorities dictate.

Contact Person: Steven L. Solomon, M.D., Assistant Director for Prevention, Training and Laboratory Program Office, Centers for Disease Control (24 EP-180), 1600 Clifton Road NE., Atlanta, Georgia 30333, Telephone: FTS: 238-1986, Commercial: 404/639-1986.

Dated: June 27, 1988.

Elvin Hilyer,

Associate Director for Policy Coordination,  
Centers for Disease Control.

[FR Doc. 88-14861 Filed 6-30-88; 8:45 am]

BILLING CODE 4160-18-M

## Food and Drug Administration

(Docket No. 88N-0242)

### Hydrocortisone Acetate and Pramoxine Hydrochloride; Drugs for Human Use; Proposal To Withdraw Approval; Opportunity for a Hearing

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to withdraw approval of abbreviated new drug applications (ANDA's) for fixed-combination drug products that contain hydrocortisone acetate and pramoxine hydrochloride, and is offering an opportunity for a hearing on the proposal. The proposal to withdraw approval is based on a finding that the drug products lack substantial evidence of effectiveness in that there is no evidence that hydrochloride contributes an effect to the combination drug. These combination drug products are used for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

**DATES:** Requests for a hearing are due on or before August 1, 1988; data in support of a hearing request are due on or before August 30, 1988.

**ADDRESS:** Requests for a hearing, supporting data, and other comments should be identified with Docket No. 88N-0242, and submitted to: Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Douglas I. Ellsworth, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-4041.

## SUPPLEMENTARY INFORMATION:

### I. Background

In the Federal Register of April 28, 1971 (36 FR 7982), FDA announced its effectiveness conclusions, under the agency's Drug Efficacy Study Implementation program, concerning topical corticosteroids. The agency concluded that the listed topical corticosteroids, including hydrocortisone acetate, were effective for symptomatic relief and adjunctive treatment of various steroid-responsive dermatoses. The agency also announced the acceptability of ANDA's for these products.

In the mid-1970's, FDA approved ANDA's for drug products in cream and lotion form sold under the trade name "Pramosone," which contained hydrocortisone acetate and pramoxine hydrochloride. The labeling of the products listed only hydrocortisone acetate as an active ingredient and contained claims relating only to hydrocortisone. The agency approved the products as single-active-ingredient hydrocortisone acetate products under the conditions of approval announced in the April 1971 notice as amended by notices published in the Federal Register of June 1, 1973 (38 FR 14424) and September 22, 1975 (40 FR 43531). Subsequently, FDA recognized that the pramoxine component was an active ingredient (a local anesthetic) and required disclosure of this information in the labeling. However, the agency did not permit any labeled indications regarding the therapeutic effects of the pramoxine component pending evaluation of the product as a combination drug. Other ANDA's for hydrocortisone acetate and pramoxine hydrochloride combination drug products were subsequently approved under the same conditions of approval as applied to the Pramoxone ANDA's.

The Center for Drug Evaluation and Research has evaluated the effectiveness of a fixed-combination of hydrocortisone acetate and pramoxine hydrochloride and finds no evidence that the pramoxine component contributes an effect to the combination drug (21 CFR 300.50). Accordingly the Director of the Center for Drug Evaluation and Research proposes to withdraw approval of the following ANDA's that provide for fixed combinations of hydrocortisone acetate and pramoxine hydrochloride:

ANDA 83-213; Pramoxone Topical Lotion; Ferndale Laboratories, Inc., 780W. Eight Mile Rd., Ferndale, MI 48220.

ANDA 83-778; Pramoxone Topical Cream; Ferndale Laboratories, Inc.,

ANDA 85-388; Pramoxone Topical Cream; Ferndale Laboratories, Inc.,

ANDA 85-879; Pramoxone Topical Cream; Ferndale Laboratories, Inc.,

ANDA 85-980; Pramoxone Topical Cream; Ferndale Laboratories, Inc.,

ANDA 86-195; Protofoam-HC Topical Aerosol; Reed & Carnick, 1 New

England Ave., Piscataway, NJ 08855.

ANDA 86-457; Epifoam Topical Aerosol; Reed & Carnick.

ANDA 89-440; Hydrocortisone Acetate and Pramoxine Hydrochloride Topical Aerosol Foam; Copely Pharmaceutical, Inc., 881 E. First St., Boston, MA 02127.

### II. Notice of Opportunity for Hearing

On the basis of all the data and information available to him, the Director of the Center for Drug Evaluation and Research is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and 21 CFR 314.126(b) and 300.50, and demonstrating the effectiveness of the drug products listed above.

Therefore, notice is given to the holders of the ANDA's listed above, 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 act, withdrawing approval of the ANDA's and all amendments and supplements thereto on the ground that new information before him, evaluated together with the evidence available to him at the time of approval of the ANDA's, shows there is a lack of substantial evidence that the products will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

In accordance with section 505 of the act and 21 CFR Part 314, the applicants are hereby given an opportunity for a hearing to show why approval of the ANDA's should not be withdrawn.

An applicant who decides to seek a hearing shall file: (1) on or before August 1, 1988, A written notice of appearance and request for hearing, and (2) on or before August 30, 1988, the data, information, and analyses relied on to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for a hearing,

a notice of appearance and request for a hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in 21 CFR 314.200.

The failure of an applicant to file a timely written notice of appearance and request for hearing, as required by 21 CFR 314.200, constitutes an election by that person not to make use of the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug product.

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. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the applications, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for hearing are to 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 (secs. 502, 505, 52 Stat. 1050-1053 as amended (21 U.S.C. 352, 355)) and under authority delegated to the Director of Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: June 22, 1988.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 88-14876 Filed 6-30-88; 8:45 am]

BILLING CCDE 4160-01-M

### Health Care Financing Administration

[BERC-499-N]

#### Medicare and Medicaid Programs; ICD-9-CM Coordination and Maintenance Committee Meeting

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the next meeting of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Coordination and Maintenance Committee. The public is invited to participate in the discussion of the topic areas.

**DATES:** The meeting will be held on Thursday and Friday, July 21 and 22, 1988, from 9:00 a.m. to 5:00 p.m. Eastern Daylight Saving Time.

**ADDRESS:** The meeting will be held in Room 703A Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Jan Niessing (301) 966-5319.

**SUPPLEMENTARY INFORMATION:** The ICD-9-CM is the clinical modification of the World Health Organization's International Classification of Diseases, Ninth Revision. It is the coding system required for use by hospitals and other health care facilities in reporting both diagnoses and surgical procedures for Medicare, Medicaid, and all other health-related DHHS programs. The work of the ICD-9-CM Coordination and Maintenance Committee will allow this coding system to continue to be an appropriate reporting tool for use in Federal programs.

The Committee is composed entirely of representatives from various Federal agencies interested in the International Classification of Diseases (ICD) and its modification, updating, and use for Federal programs. It is co-chaired by the National Center for Health Statistics and the Health Care Financing Administration.

At this meeting, the Committee will discuss: endoscopic procedures of the gastrointestinal system; orthopedic procedures; spinal fusion; excision of acoustic neuroma and other cranial lesions; coronary arteriography using two catheters; extracorporeal lithotripsy of the gall bladder; photon absorptiometry; endoscopic retrograde cholangiopancreatography; acute exacerbation of COPD; ICD-10 update; and other topics.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; No. 13.773, Medicare—Hospital Insurance Program; No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: June 22, 1988.

William L. Roper,

Administrator, Health Care Financing Administration.

[FR Doc. 88-14890 Filed 6-30-88; 8:45 am]

BILLING CODE 4120-01-M

### DEPARTMENT OF THE INTERIOR

#### Bureau of Land Management

[AA-150-08-4830-11-ADVB-2410]

#### Call for District Advisory Council Nominations

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Call for Nominations for District Advisory Councils.

**SUMMARY:** The purpose of this notice is to solicit public nominations to fill those positions for which terms expire this year on each of the Bureau of Land Management's 52 district advisory councils. Each council has four such positions to fill—except the California Desert District Advisory Council and the Northern Alaska Advisory Council, each of which has five such positions to fill.

Each affected council comprises 10 members, except the California Desert District Advisory Council and the Northern Alaska Advisory Council, which comprise 15 and 11 members, respectively. Under the staggered-term arrangement instituted by the Secretary of the Interior in 1982, the terms of five members on the California Desert District Advisory Council and the terms of four members on each of the remaining 51 councils will expire on December 31, 1988. The Northern Alaska Advisory Council has five positions to fill because its membership is being increased from 10 to 11 members. Current council members may be reappointed or new members may be appointed. However, the eligibility of current council members for reappointment may be affected by governing regulations (43 CFR 1784.3(b), revised as of October 1, 1987). Appointments made by the Secretary pursuant to this call will assure continued representation of specific categories of interest on each council. The new terms will expire December 31, 1991.

To ensure council membership that is balanced in terms of categories of interest represented and functions performed, nominees must be qualified to provide advice in specific areas identified with each council position now up for appointment. Categories for specific councils will be announced through local news releases in the appropriate States and Districts and will include the following:

Elected General Purpose Government  
Environmental Protection  
Recreation  
Renewable Resources (livestock, forestry, agriculture)