

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DWB

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Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 6 and 7, 1999, 8:30 a.m. to 5 p.m.

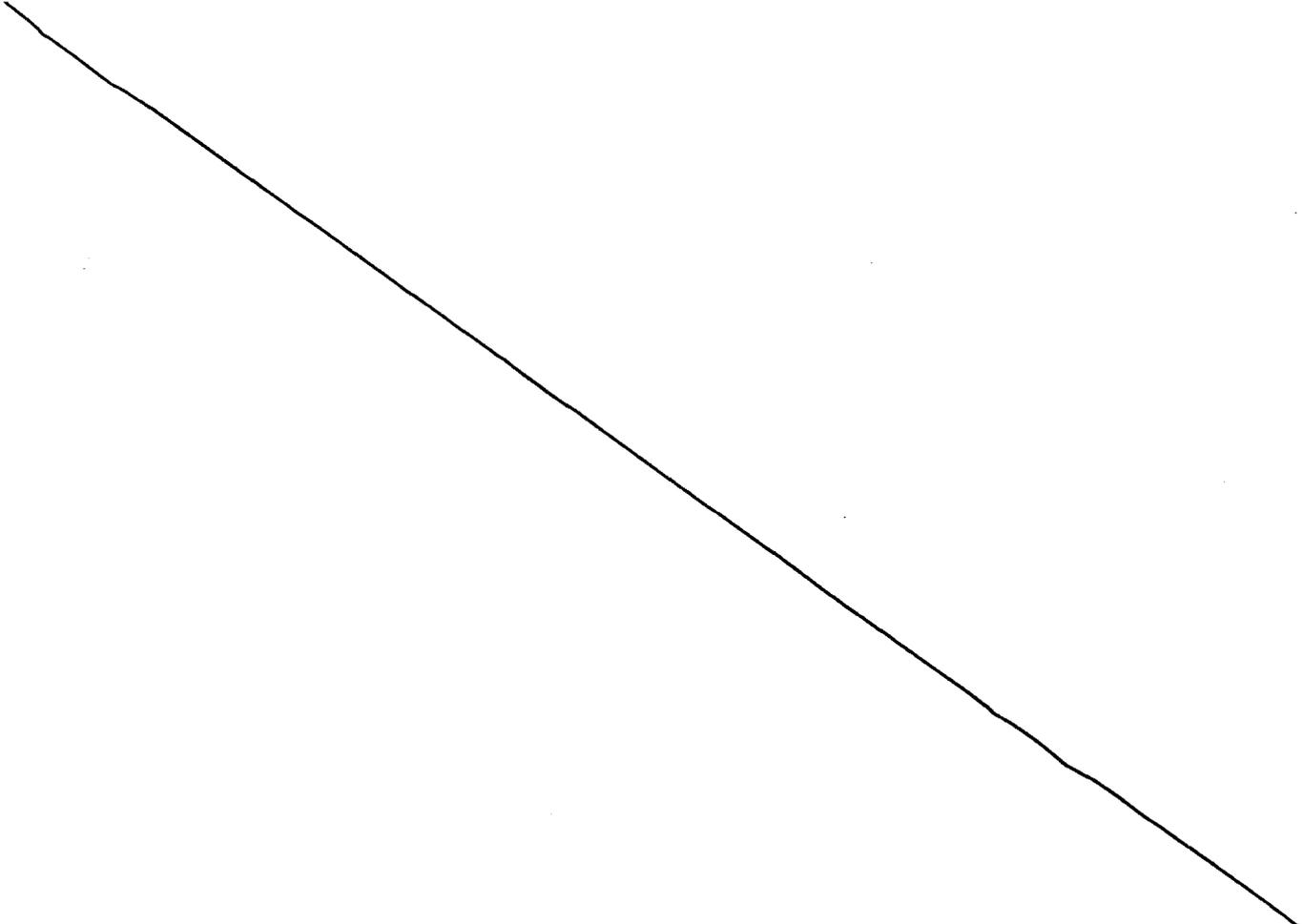
Location: CDER Advisory Committee Conference Room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Igor Cerny, or Tony Slater, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or by e-mail at CERNY@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12440. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and provide FDA with advice about the agency's development and publication of a list of bulk drug substances that may be used in pharmacy compounding that do not have a United States Pharmacopeia or National Formulary monograph and are not components of FDA-approved drugs. Specifically, the committee is likely to address the following drug substances as candidates for the bulk drugs list: 4-aminopyridine, 3,4-diaminopyridine, betahistine dihydrochloride, chloramine-T, cyclandelate, dinitrochlorobenzene,

diphenylcyclopropanone, hydrazine sulfate, mild silver protein, monosodium aspartate, pentylentetrazole, peruvian balsam, and squaric acid dibutyl ester.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 23, 1999. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. for dinitrochlorobenzene, diphenylcyclopropanone, and squaric acid dibutyl ester, and between approximately 2:45 p.m. and 3:15 p.m. for 4-aminopyridine, 3,4-diaminopyridine, and betahistine dihydrochloride on May 6, 1999; and between approximately 10:15 a.m. and 10:45 a.m. for mild silver protein, cyclandelate, and monosodium aspartate, and between approximately 2:45 p.m. and 3:15 p.m. for hydrazine sulfate on May 7, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 23, 1999, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 4/16/99

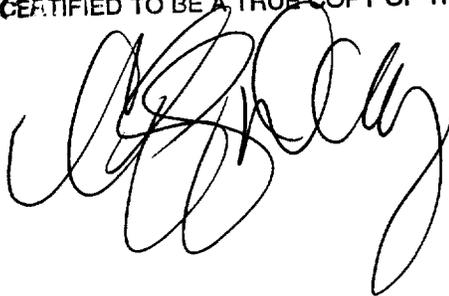
MA Friedman

Michael A. Friedman
Deputy Commissioner for
Operations

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

A large, stylized handwritten signature in black ink, appearing to be a cursive representation of a name, possibly "Michael A. Friedman".