Centers for Disease Control

Subject: Pulmonary Function Testing Course Approval and Reapproval Criteria—New
Respondents: State or local governments; businesses, small businesses, or other for profit organizations; Federal agencies or employees; not for profit institutions
OMB Desk Officer: Fay S. Iudicello

National Institutes of Health

Subject: Physical Examination and Testing of the Framingham Offspring (Cycle 3) (0925–0096)—New
Respondents: Individuals or households
Subject: A Next-of-Kin Case—Control Study of Esophageal Cancer Among South Carolina Coastal Males—New
Respondents: Individuals or households
OMB Desk Officer: Fay S. Iudicello

Office of the Secretary

Subject: Clearinghouse Questionnaire—New
Respondents: HMS clearinghouse
OMB Desk Officer: Milo Sunderhauf

Social Security Administration

Subject: Application for Benefits Under the Norway—U.S. International Social Security Agreement (SSA–796 (11–83))—New
Respondents: Workers eligible for Social Security benefits from U.S. and/or Norway
Subject: Request for a Certificate of Coverage—New
Respondents: Workers eligible for Social Security Coverage by U.S. and foreign countries
Subject: Quarterly Work Incentive (WIN) Demonstration Program Report (0960–0254) (SSA–4769)—Revision
Respondents: State agencies administering WIN demonstration projects
OMB Desk Officer: Milo Sunderhauf

Health Care Financing Administration

Subject: Freestanding Federally Funded Health Center Cost Report (0938–0235)—Extension/No Change
Respondents: 127 freestanding Federally funded health centers
Subject: Information Collection Requirements in Regulation Sections 405.1627 and 405.1629, Physician Certification and Recertification (Prospective Payment Regulation BERC–263) (0938–0306)—Extension/No Change
Respondents: Physicians accepting Medicare patients (outlier cases only)
OMB Desk Officer: Fay S. Iudicello

Copies of the above information collection clearance packages can be obtained by calling the HHS Reports Clearance Officer on 202–245–6511.

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Officer Building, Room 3208, Washington D.C. 20503: ATTN: (name of OMB Desk Officer).

Dated: November 15, 1983.

Robert F. Sermier,

Deputy Assistant Secretary for Management Analysis and Systems.

[FR Doc. 83–31078 Filed 11–17–83; 8:45 am]

BILLING CODE 4150–04–M

Food and Drug Administration

Consumer Participation; Open Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following consumer exchange meetings:

Minneapolis District Office, chaired by John Feldman, District Director. The topic to be discussed is Drug Use and the Elderly.

Date: Tuesday, November 29, 1983, 10 a.m.

Address: Minnesota Church Center, 122 West Franklin Ave., Minneapolis, MN 55404.

For Further Information Contact: Therese A. Bowker, Consumer Affairs Officer, Food and Drug Administration, 240 Hennepin Ave., Minneapolis, MN 55401, 612–725–2121.

Los Angeles District Office, chaired by Abraham I. Kleks, District Director. The topic to be discussed is Drug Use and the Elderly.

Date: Tuesday, November 29, 1983, 1 p.m.

Address: Cooperative Extension Auditorium, 4341 East Broadway, Phoenix, AZ 85040.

For Further Information Contact: Irene Gomez Caro, Consumer Affairs Officer, Food and Drug Administration, 1521 West Pico Blvd., Los Angeles, CA 90015, 213–688–4395.

Dallas District Office, chaired by James Anderson, District Director. The topic to be discussed is Drug Use and the Elderly.

Date: Tuesday, November 29, 1983, 7 p.m.

Address: 509 North Bell Ave., Denton, TX 76201.

For Further Information Contact: Don Aird, Consumer Affairs Officer, Food and Drug Administration, 1200 Main Tower Bldg., Dallas, TX 75202, 214–767–5433.

Brooklyn District Office, chaired by George J. Gerstenberg, District Director. The topic to be discussed is Drug Use and the Elderly.

Date: Thursday, December 1, 1983, 1:30 p.m.

Address: 26 Federal Plaza, Rm. 305A, New York, NY 10278.

For Further Information Contact: Herman B. Janiger, Consumer Affairs Officer, Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 211–965–5043.

Detroit District Office, chaired by Alan L. Hoeting, District Director. The topics to be discussed are Drug Use and the Elderly; and Aspartame Update.

Date: Monday, December 5, 1983, 1 to 3 p.m.

Address: City-County Administration Bldg., Rm. 24, Evansville, IN 47708.

For Further Information Contact: Lilyan M. Goossens, Consumer Affairs Officer, Food and Drug Administration, 575 North Pennsylvania St., Rm. 693, Indianapolis, IN 46204. 317–269–6500.

SUPPLEMENTARY INFORMATION: The purpose of these meetings is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: November 14, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83–31107 Filed 11–17–83; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 83A–0339]

Enforcement Action Under the New Drug Provisions of the Federal Food, Drug, and Cosmetic Act; Certain OTC Drug Products; Advisory Opinion

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its advisory opinion which states that the agency is prepared to take immediate enforcement action under the new drug provisions of the Federal Food, Drug, and Cosmetic Act (the act) against certain over-the-counter (OTC) drug products (1) labeled as stimulants and containing anything other than caffeine as the active ingredient and (2) labeled for any purpose and containing as their sole active ingredients any of the following combinations, including their salts, (a) caffeine in combination with ephedrine or pseudoephedrine, (b) phenylpropanolamine in combination with ephedrine or pseudoephedrine, (c) phenylpropanolamine in combination with caffeine. This action is necessary because of the widespread abuse of these products intended to produce effects similar to those produced by substances subject to the Controlled Substances Act (CSA). The intended effect of this action is to eliminate misuse and abuse of these products.

EFFECTIVE DATE: November 18, 1983.

FOR FURTHER INFORMATION CONTACT: Edwin V. Dutra, Jr., Nationa' Center for

Drugs and Biologics (HFN–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6490.

SUPPLEMENTARY INFORMATION: Certain over-the-counter (OTC) drug products have a highly suspect marketing history and, in some cases, no known medical rationale. They are frequently used as recreational drugs to mimic the effects of, and capitalize on the market for, certain controlled substances and thus are misused and abused. The specific drug products (including their ingredients and salts) that are the subject of this notice are (1) products that contain anything other than caffeine as their active ingredient and are labeled or otherwise promoted for use as a stimulant or alertness aid, or for other such similar uses; and (2) products, labeled for any purpose, that contain as their sole active ingredients any of the following combinations (a) caffeine in combination with ephedrine or pseudoephedrine, (b) phenylpropanolamine in combination with ephedrine or pseudoephedrine, (c) phenylpropanolamine in combination with caffeine.

The agency is aware that the individual active ingredients contained in the products that are the subject of this notice, as well as certain combinations of them, have been or are being considered within the context of the agency's ongoing OTC Drug Review. The agency has previously refrained from taking action against these products in accordance with its announced policy to defer enforcement actions with respect to products included in the ongoing OTC Drug Review until the administrative process applicable to those products has been completed. Because the products that are the subject of this notice have, in some instances, been marketed and promoted as products capable of producing effects similar to those produced by certain substances subject to the CSA and are widely misued and abused, the agency is changing its enforcement policy with respect to the products described. The agency will now begin enforcement of the new drug approval provisions of the act with respect to these drugs.

The notice is an official advisory opinion by the agency under 21 CFR 10.85. Any statement by the agency, in its Compliance Policy Guide or otherwise, that suggests in any way that enforcement actions will not be taken against the products referred to in this notice is revoked to the extent that that statement applies to such products. The agency has determined that, with respect to all products covered by this notice with the exception of certain caffeine plus phenylpropanolamine combinations discussed below, substantial public interest considerations preclude continued acceptance of any action undertaken or completed in alleged conformity with previously articulated agency policy (see 21 CFR 10.85(h)). Also, because there is no legitimate use for such products, no transition period with the one exception discussed below for use of the products is applicable, *id.*

FDA believes that a transitional period for the removal from the market of the product combination of caffeine and phenylpropanolamine, but not other products covered by this notice, is appropriate. Although FDA believes that this combination is clearly a "new drug" within the meaning of the act, a panel report to FDA as part of the OTC Drug Review did recommend that this combination be classified as generally recognized as safe and effective as an "Anorectic/Stimulant" (see 47 FR 8476). No other combination covered by this notice was the subject of the same type of recommendation.

Therefore, the agency is prepared to allow, and thus not to commence enforcement action with respect to, the sale of products (1) that contain caffeine and phenylpropanolamine as their sole active ingredients; (2) that are labeled solely as appetite suppressants, diet aids, or diet aids/stimulants; (3) that have been manufactured before the date of publication of this notice or as part of a batch of products actually in process on the date of publication of this notice provided that the manufacturers or other holders of those drugs provide FDA information sufficient to allow it to determine the date of manufacture of such products encountered on the market; and (4) that have never been labeled for any purposes other than as an appetite suppressant, a diet aid, or diet aid/stimulant.

The agency is not, at this time, setting a final date after which no marketing of caffeine plus phenylpropanolamine combinations may be marketed. The agency will monitor the market for these products. It may conclude, based on such monitoring, that it is appropriate to set a final cut-off date. It will not, however, do so until January 17, 1984 and any cut-off date that is set will extend at least 4 months after the announcement of such a date. Thus, those involved in the marketing of this product may be assured that there will be a grace period during which they can sell inventories of this product providing the product complies with the four factors stated above.

The agency has considered whether there is a need to undertake notice and comment rulemaking to state its position on these drug products in **Federal Register** and has concluded that no such requirement exists. This statement, which is arguably a revocation of a prior advisory opinion, is in accordance with FDA's regulations that do not require notice and comment rulemaking for publication of such revocation (see 21 CFR 10.85(g)). In addition, this statement of agency policy with respect to these drugs is not a substantive rule because it does not have, in and of itself, the force and effect of law. *Cf. Burroughs Wellcome Co.* v. *Schweiker,* 649 F. 2d 221, 225 (4th Cir. 1981). This statement is not a "declaration" that a drug is a new drug made after appropriate administrative proceedings. Rather, it is a statement of the official position of FDA and an announcement that the agency is prepared to initiate enforcement actions in which the government would, if called upon to do so, establish in court the new drug status of the products referred to.

Dated: November 7, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83–31108 Filed 11–17–83; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Commission on Fair Market Value Policy for Federal Coal Leasing; Business Meeting

AGENCY: Commission on Fair Market Value Policy for Federal Coal Leasing.

ACTION: Notice of business meeting of the Commission.

SUMMARY: Notice is hereby given that the Commission on Fair Market Value Policy for Federal Coal Leasing will hold a Business Meeting on December 21 and 22, 1983. The meeting will be held in the Brick Room at 1925 K St., NW., Washington, D.C. 20036. The meetings will convene at 9:00 a.m. each day.

FOR FURTHER INFORMATION CONTACT: F. Scott Bush, Executive Director, or Sorrell Caplan, Public Affairs Director, Commission on Fair Market Value Policy for Federal Coal Leasing, Suite 400, 1015 20th Street, NW., Washington, D.C. 20036 Phone: (202) 632–6501.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to the authority and requirements of Pub. L. 98–63, approved July 30, 1983, making supplemental appropriations tor fiscal