[1] Approved for marketing.
[2] Exclusive approval.

Dated: January 28, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-2736 Filed 2-1-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 80N-295]

Over-the-Counter (OTC) Drug Review; Public Notice of Feedback Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the policy the agency intends to use concerning the maintenance of a public record announcing OTC drug, feedback meetings.

DATES: Effective February 4, 1985; comments by April 5, 1985.

ADDRESS: Written comments to the Docket Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockveille, MD 20857.

FOR FURTHER INFORMATION CONTACT: Melvin Lessing, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: FDA published a final rule in the **Federal Register** of September 29, 1981 (46 FR 47730), revising the procedural regulations in 21 CFR 330.10 for reviewing and classifying OTC drugs to delete the provision that authorizes the marketing of a Category III ingredient or other condition in an OTC drug product after a final monograph is established. FDA took that action to conform to the holding and order of the United States District Court for the District of Columbia in *Cutler* v. *Kennedy,* 475 F. Supp. 838 (D.D.C. 1979).

The revision in the regulations affected the time period during which new data may be submitted to FDA to support the inclusion in a final monograph of a condition not classified in Category I in a proposed or tentative final monograph. The agency also published a notice announcing its policy concerning agency meetings with industry or other interested parties, called "feedback" meetings, to discuss testing protocols and other matters related to conditions not classified in Category I (46 FR 47740; September 29, 1981, subsequently clarified in 48 FR 14050; April 1, 1983). All feedback meetings are open to the public, and a prior reservation is not necessary.

Public Record

The Center for Drugs and Biologics' Division of OTC Drug Evaluation intends to make available in the Docket Management Branch an announcement of each upcoming feedback meeting, including the date, time, location, and subject, so that interested persons can be aware in advance of these meetings. Announcements of these feedback meetings ordinarily will be filed under Docket No. 80N-0295 10 days before the meeting. Announcements are available for public examination in the Docket Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons are advised to confirm that the meeting remains scheduled as announced by telephoning the contact person listed above shortly before the announced date.

Notice and comment are not necessary before issuing this notice. (See 5 U.S.C. 553(b)(A).) It would also be contrary to the public interest to delay implementing the procedures described in this notice.

Interested persons may, on or before April 5, 1985, submit to the Docket Management Branch (address above) written comments on this notice. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Such comments will be considered in determining whether amendments or revisions to the notice are warranted. Received comments will be incorporated into the public file on the statment and may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 28, 1985.

Joseph P. Hile,

Assoicate Commissioner for Regulatory Affairs.

[FR Doc. 85-2734, Filed 2-1-85; 8:45 am]

BILLING CODE 4160-01-M

Request for Nominations for Representatives of Consumer and Industry Interests on Public Advisory Committees or Panels

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for consumer and industry representatives to serve on certain public advisory committees or panels in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and for those that will or may occur during the next 12 months.

FDA has a special interest in ensuring that women, minority groups, the physically handicapped, and small businesses are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, and physically handicapped candidates, and nominations from small businesses that manufacture medical devices subject to the regulations.

DATE: Nominations should be received by March 21, 1985 for vacancies listed in this notice.

ADDRESSES: All nominations and curricula vitae for consumer representatives must be submitted in writing to Naomi Kulakow (address below.)

All nomination and curricula vitae (which includes nominee's office address and telephone number) for industry representatives must be submitted in writing to Kay Levin (address below).

FOR FURTHER INFORMATION CONTACT:

For Consumer Interests:

Naomi Kulakow, Office of Consumer Affairs (HFE-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006.

For Industry Interests:

Kay Levin, Center for Devices and Radiological Health (HFZ-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3516.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members representing consumer and industry interests for the following panels:

Panel	Approximate date representative is needed	
	Consumer	Industry
1. Anesthesiology and Respiratory Therapy Devices Panel.	Nov. 30, 1985	Nov. 30, 1985.
2. Circulatory System Devices Panel.	NV	June 30, 1985.
3. Clinical Chemistry and Clinical Toxicology Devices Panel.	Feb. 28, 1986	NV.
4. Dental Devices Panel.	NV	Oct. 31, 1985.
5. Gastroenterology-Urology Devices Panel.	Dec. 31, 1985	NV.
6. General and Plastic Surgery Devices Panel.	Aug. 31, 1985	Aug. 31, 1985.
7. General Hospital and Personal Use Devices Panel.	NV	Dec. 31, 1985.
8. Hematology and Pathology Devices Panel.	NV	Feb. 28, 1986.