association between chronic administration of the drug and human mammary tumorigenesis. While long-term clinical observation has not suggested such an association, the available evidence is considered too limited to be conclusive at this time. An association of reserpine intake with pheochromocytoma or tumors of the seminal vesicles has not been explored.

This notice applies to all single-entity and combination reserpine-containing drug products that are the subject of approved new drug applications and also to any identical, related, or similar drug product that contains reserpine (21 CFR 310.6), whether or not it is the subject of an approved new drug application. Any person may request an opinion of the applicability of this notice to a specific drug product the person manufactures or distributes by writing to the Division of Drug Labeling compliance (address given above).

Supplements to approved NDA's or ANDA's providing for appropriate revision of labeling to add the above precaution statement shall be submitted on or before May 31, 1983. Applicants shall put the revised labeling into use by September 1, 1983. The revised labeling may be used without advance approval by the Food and Drug Administration under the provisions of 21 CFR 314.8(d).

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 502, 505, 52 Stat. 1041, 1050–1053, as amended (21 U.S.C. 321(n), 352, 355)) and under the authority delegated to the Director of the National Center for Drugs and Biologics (21 CFR 5.70).

Dated: March 25, 1983.

Harry M. Meyer, Jr.,

Director, National Center for Drugs and Biologics.

[FR Doc. 83-8422 Filed 3-31-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 80N-0295]

Clarification of Policy; Over-the-Counter Drug Review

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is clarifying its policy on placing "feedback" communications in the administrative records of appropriate over-the-counter (OTC) drug rulemaking proceeding.

DATE: Comments by May 31, 1983.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFN–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 29, 1981 (46 FR 47740), FDA published a policy statement concerning (1) the submission and review of proposed protocols to evaluate an ingredient or condition in the OTC drug review, (2) meetings with industry or other interested persons, (3) communications by the agency on submissions of test data and other information, and (4) maintenance of a public record involving these activities.

The policy statement explained that "feedback" information provided by FDA to manufacturers on Category II or III conditions would be placed on public file in the Dockets Management Branch (address above) and be available to all interested persons. However, these communications would not be included in the administrative record for the related OTC drug rulemaking proceeding unless the communication directly influenced an agency decision on a particular matter in the rulemaking or provided the substantiation for the agency's decision on that matter. For example, the results of a study that were communicated to the agency in response to "feedback" would be included in the administrative reecord of a particular OTC drug rulemaking proceeding if the study was relied upon by the agency in reaching a decision on the status of an ingredient covered by that rulemaking.

Questions have arisen concerning the mechanism by which "feedback" material is included in the administrative record of an OTC drug rulemaking proceeding, for example, whether "feedback" material is included in the appropriate rulemaking only in response to a petition by an interested party. The agency advises that when such material directly influences or is used by the agency in reaching a decision on a matter in an OTC drug rulemaking proceeding, the agency will add it to the administrative record prior to publication of the applicable document without the submission of a formal petition by an interested party. Appropriate reference to the material will be included in the relevant proposed rule or final rule document.

Any "feedback" communication that is submitted before a proposed rule is published, but which is not used by the agency in preparing the proposed rule, will be placed in the administrative record when it is opened during the comment period following publication of the proposed rule. As provided in 21 CFR 330.10(a)(7), following publication of a proposed rule, the administrative record is open 60 days for comments or objections, 12 months for the submission of new data and information, and an additional 60 days for reply comments on the new data and information. "Feedback" communications that occur after the usual closing of the administrative record following publication of the proposed rule, and which are not relied upon or used by the agency in developing the final rule, will remain part of the public record; however, these communications will not be added to the administrative record unless the agency subsequently determines in response to a petition that they should be.

Notice and comments are not necessary before issuing this clarification. (See 5 U.S.C. 553(b)(B).) Furthermore, the purpose and major aspects of this policy statement were described in the preamble to the May 13, 1980 proposed rule on the agency's Category III regulations (45 FR 31422) and in the "feedback" policy statement of September 29, 1981 (46 FR 47740).

Interested persons may, on or before May 31, 1983, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this clarification. Three copies of any comment are to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket No. 80N–0295. Such comments will be considered in determining whether amendments or revisions to the clarification are warranted. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 24, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-8423 Filed 3-31-83; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Advisory Committee; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 1983:

Name: Material and Child Health Research Grants Review Committee.

Date and Time: June 9–10, 1983, 9:00 a.m.–5:00 p.m.