the additional tabletop extension thickness requested would be minimal.

The Director agrees that the added structural stability that would be obtained is a necessary safety feature and that there should be little radiation dose increase from use of the product. In accordance with § 1010.4 (21 CFR 1010.4), the Director has concluded that the petitioner's tabletop extension is intended for a special purpose that cannot be performed or accomplished with equipment meeting all requirements of § 1020.30, but utilizes suitable means for providing radiation safety protection. Therefore, the Director has approved the requested variance from § 1020.30(n), provided general operating tabletop extensions manufactured under this variance shall have tabletop extensions whose thickness shall not exceed 1.5-mm aluminum equivalent. The variance is granted for the manufacture of a maximum of 50 product units per year.

The manufacturer has been directed to modify, in accordance with § 1010.4(d), the tags, labels, or other certification required by § 1010.2 (21 CFR 1010.2) and permanently affixed to or inscribed upon products that are marketed under this variance, to state the following:

This product complies with Variance No. 78004 effective on December 18, 1978.

The Commissioner of Food and Drugs has reviewed the potential environmental impact of this variance and has concluded that the action will not significantly affect the quality of the human environment and that an environmental impact statement is not required. A copy of the environmental impact analysis report is on file in the office of the Hearing Clerk, Food and Drug Administration.

Variance No. 78004 shall become effective on December 18, 1978, for the manufacture of 50 product units per year, and shall end December 18, 1981, unless written objections and supporting documentation, identified with Hearing Clerk Docket No. 78P-0177, are filed with the Hearing Clerk, Food and Drug Administration address above, on or before December 18, 1978, requesting that the variance be modified or not granted. Upon receipt of such objections and supporting documentation, the agency will stay the effective date of the variance until the Director, Bureau of Radiological Health, rules on them. Under § 1010.4(c)(3), the applicant shall be notified of the stay by certified mail, and a notice of the stay shall be published in the FEDERAL REGISTER. The ruling on the objections shall be made within 60 days, shall be published in the FEDERAL REGISTER, and shall constitute final agency action subject to judicial review under section 358(d) (42 U.S.C. 263f(d)) of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968.

The application for this variance and all related correspondence, except information covered by the confidentiality provisions of section 360A(e) of the act (42 U.S.C. 263i(e)), have been placed on public display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be seen Monday through Friday from 9 a.m. to 4 p.m., except on Federal legal holidays.

Dated: November 8, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32199 Filed 11-16-78; 8:45 am]

[4110-03-M]

PANEL ON REVIEW OF CONTRACEPTIVE AND OTHER VAGINAL DRUG PRODUCTS

Renewal

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), the Food and Drug Administration announces the renewal of the Panel on Review of Contraceptive and Other Vaginal Drug Products by the Secretary of Health, Education, and Welfare.

DATE: Authority for this committee will expire on December 31, 1978, unless the Secretary formally determines that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Officer (HFA-27), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

Dated: November 9, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32198 Filed 11-16-78; 8:45 am]

[4110-03-M]

[Docket Nos. 77N-0230, 77N-0231, 77N-0316, and 77N-0317]

PENICILLIN AND TETRACYCLINE IN ANIMAL FEEDS

Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document gives advance notice of a public hearing on the proposed withdrawal of approval of new animal drug applications for premixes containing penicillin and tetracycline.

FOR FURTHER INFORMATION CONTACT:

Richard T. Hunt, Compliance Regulations Policy Staff (HFC-10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of August 30, 1977 (42 FR 43772), the Director of the Bureau of Veterinary Medicine issued a notice of opportunity for hearing on a proposal to withdraw approval of certain new animal drug applications (NADA's) for penicillin-containing premixes intended for use in animal feed on the grounds that: (1) New evidence shows that the penicillin-containing products have not been shown to be safe for subtherapeutic use as required by section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)(1)(B)) and § 558.15 (21 CFR 558.15); (2) the applicants have failed to establish and maintain records and make reports as required by section 512(e)(2)(A) of the act (21 U.S.C. 360b(e)(2)(A)) and § 558.15; and (3) new evidence shows that there is a lack of substantial evidence that penicillin-containing premixes are effective for therapeutic uses under section 512(e)(1)(C) of the act (21 U.S.C. 360b(e)(1)(C)).

On October 21, 1977 (42 FR 56264), the Director issued a similar notice of opportunity for hearing on a proposal to withdraw approval of certain NADA's for tetracycline (chlortetracycline and oxytetracycline)-containing premixes intended for use in animal feed on the same grounds.

In response to these notices, approximately 20 drug firms, agricultural organizations, and individuals requested hearings.

The Commissioner of Food and Drugs announces, therefore, that there will be a formal evidentiary public hearing on these proposals. In accordance with § 12.35 (21 CFR 12.35), a notice of hearing will be published in the FEDERAL REGISTER as soon

as practicable. In the meantime, participants in the hearing are encouraged to begin preparation of the material required to be disclosed under § 12.85 (21 CFR 12.85).

The evidentiary hearing will be open to the public. If, however, the Commissioner finds that portions of the NADA's that serve as the basis for the hearing contain information entitled to protection as a trade secret, that part of the hearing involving those portions will not be public, unless the respondents so specify.

Dated: November 9, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 78-32045 Filed 11-9-78; 11:31 am]

[4110-83-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Resources Administration

AGENDA PLANNING SUBCOMMITTEE OF THE NATIONAL COUNCIL ON HEALTH PLANNING AND DEVELOPMENT

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 December 1978:

Name: Agenda Planning Subcommittee of the National Council on Health Planning and Development.

Date and time: December 5, 1978, 10:30 a.m. to 2 p.m.

Place: HEW North Building, Room 1137, 330 Independence Avenue SW., Washington, D.C. 20201.

Open for entire meeting.

Purpose: The objectives of the Agenda Planning Subcommittee are to: (1) Assist the chairperson in planning the order and timing of agenda topics for full Council consideration and action to assure that the Secretary will receive advice and/or recommendations on each of its three areas of functional responsibilities under section 1503(a) in an appropriate time and manner; (2) coordinate information about and among subcommittee activities and plans; and (3) provide preliminary review of proposed changes in Council operations.

Agenda: The subcommittee will assist the chairperson in planning the order and timing of agenda topics for full Council consideration for the January 12, 1979, meeting; coordinate information about and among subcommittee activities and plans; and provide preliminary review of the Council budget.

Anyone requiring information regarding the subject subcommittee should contact Mrs. S. Judy Silsbee, Executive Secretary, National Council on Health Planning and Development, Room 10-27, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, telephone 301-436-7175.

Agenda items are subject to change as priorities dictate.

Dated: November 13, 1978.

JAMES A. WALSH,
Associate Administrator for Operations and Management.

[FR Doc. 78-32304 Filed 11-16-78; 8:45 am]

[4110-83-M]

NATIONAL ADVISORY COUNCIL ON HEALTH PROFESSIONS EDUCATION

Filing of Annual Report

Notice is hereby given that pursuant to section 13 of Pub. L. 92-463, the annual report for the following Health Resources Administration Federal Advisory Committee has been filed with the Library of Congress: National Advisory Council on Health Professions Education.

Copies are available to the public for inspection at the Library of Congress, Special Forms Reading Room, Main Building, or weekdays between 9 a.m. and 4:30 p.m., at the Department of Health, Education, and Welfare, Department Library, North Building, Room 1436, 330 Independence Avenue SW., Washington, D.C. 20201, telephone 202-245-6791. Copies may be obtained from Mr. Robert L. Belsley, Bureau of Health Manpower, Room 4-27, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782, telephone 301-436-6564.

Dated: November 13, 1978.

JAMES A. WALSH,
Associate Administrator for Operations and Management.

[FR Doc. 78-32303 Filed 11-16-78; 8:45 am]

[4110-08-M]

National Institutes of Health

REPORT ON BIOASSAY OF 4'-(CHLOROACETYL)-ACETANILIDE FOR POSSIBLE CARCINOGENICITY

Availability

4'-(Chloroacetyl)-acetanilide (CAS 140-49-8) has been tested for cancer-causing activity with rats and mice in the Bioassay Program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary: A bioassay for the possible carcinogenicity of 4'-(chloroacetyl)-acetanilide was conducted using Fischer 344 rats and B6C3F1 mice. Applications of the chemical include use as an intermediate in the manufacture of dyes and drugs. 4'-(Chloroacetyl)-acetanilide was administered in the feed, at either of two concentrations, to groups of 50 male and 50 female animals of each species.

Under the conditions of this bioassay, 4'-(chloroacetyl)-acetanilide was not carcinogenic when administered in the diet to Fischer 344 rats or B6C3F1 mice of either sex.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Md. 20014.

(Catalog of Federal Domestic Assistance Program No. 13.393, Cancer Cause and Prevention Research.)

Dated: November 6, 1978.

DONALD S. FREDRICKSON,
Director, National Institutes of Health.

[FR Doc. 78-31766 Filed 11-16-78; 8:45 am]

[4110-08-M]

REPORT ON BIOASSAY OF 2,4-DIMETHOXYANILINE HYDROCHLORIDE FOR POSSIBLE CARCINOGENICITY

Availability

2,4-Dimethoxyaniline hydrochloride (CAS 54150-69-5) has been tested for cancer-causing activity with rats and mice in the Bioassay Program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary: A bioassay for the possible carcinogenicity of 2,4-dimethoxyaniline hydrochloride was conducted using Fischer 344 rats and B6C3F1 mice. 2,4-Dimethoxyaniline hydrochloride was administered in the feed, at either of two concentrations, to groups of 50 male and 50 female animals of each species.

Under the conditions of this bioassay there was no convincing evidence for the carcinogenicity of 2,4-dimethoxyaniline hydrochloride in Fischer 344 rats or B6C3F1 mice.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Md. 20014.

(Catalog of Federal Domestic Assistance Program No. 13.393, Cancer Cause and Prevention Research.)

Dated: November 6, 1978.

DONALD S. FREDRICKSON,
Director, National Institutes of Health.

[FR Doc. 78-31767 Filed 11-16-78; 8:45 am]