13, 1976, the data, information, and analyses on which he relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of any such drug product. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in quintuplicate with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

All submissions pursuant to this notice, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk Monday through Friday from 9 a.m. to 4 p.m., except on Federal legal holidays.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 52 Stat. 1052–1053, as amended; 21 U.S.C. 355), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 2.121).

Dated: December 5, 1975.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.75–33650 Filed 12–12–75;8:45 am]

[Docket No. 75N–0357]

OTC DRUG REVIEW PANEL ON ANTACID DRUG PRODUCTS

Availability of Certain Transcripts of Closed Sessions

On March 20, 1974, Dr. Sidney Wolfe, Director of the Health Research Group, filed suit in the United States District Court for the District of Columbia to obtain copies of verbatim transcripts of closed sessions of the over-the-counter (OTC) drug review panel on antacid drug products. *Wolfe* v. *Weinberger*, No. 74–454. The suit was based on the Freedom of Information Act (5 U.S.C. 552) and the Federal Advisory Committee Act (5 U.S.C. App. I). The Food and Drug Administration had denied access to the transcripts on the ground that they reflected internal deliberations of the antacid panel, and so were exempt from disclosure under both statutes pursuant to exemption 5 of the Freedom of Information Act (5 U.S.C. 552(b)(5)).

On October 31, 1975, the District Court (Richey, J.) ordered the transcripts to be produced. The court held that the transcripts are not exempt under 5 U.S.C. 552(b)(5). However, since all but one of the panel's meetings had occurred before January 5, 1973, the court expressly declined to reach any issue involving the Federal Advisory Committee Act, which was not effective until that date.

For this reason, and because the issue of the availability of exemption 5 to close deliberative sessions of advisory committees (and, by implication, to protect advisory committee transcripts) under the Federal Advisory Committee Act is presented in a case now pending in the United States Court of Appeals for the District of Columbia Circuit (*Aviation Consumer Action Project* v. *Washburn*, No. 75–1086), the Government has decided not to appeal the District Court's decision in *Wolfe* v. *Weinberger*. Moreover, the transcripts at issue were made available to the staff of the Subcommittee on Intergovernmental Relations and Human Resources of the House Committee on Government Operations. As a result, substantial portions of the transcripts about which some controversy had developed were introduced into the public record of hearings held before the subcommittee on May 9 and 12, 1975.

Accordingly, although no appeal of the narrow ruling in *Wolfe* will be taken, and the antacid panel's transcripts are therefore now available, the Commissioner of Food and Drugs does not regard the decision as necessitating a modification in existing policy, and where necessary and appropriate, will continue to authorize the closing of the deliberative portions of advisory committee meetings pursuant to exemption 5. The basis for this policy has been set forth numerous times; see, e.g., Notice of Meetings of Food and Drug Administration Advisory Committees published in the FEDERAL REGISTER of February 5, 1973 (38 FR 3345, 3347). The Department of Justice has advised the Food and Drug Administration that, because the decision in *Wolfe* is explicitly not based on the Federal Advisory Committee Act, the agency may adhere to its existing policy and, if necessary, defend that policy in court.

Dated: December 8, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75–33651 Filed 12–12–75;8:45 am]

Health Resources Administration

MEETINGS

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory bodies scheduled to assemble during the month of January 1976:

Name: National Advisory Council on Health Professions Education.

Date and Time: January 6–7, 1976, 8:30 a.m.

Place: Conference Room Number 6, Building 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014.

Open on January 6, 8:30 a.m.—10:30 a.m.

Closed remainder of meeting.

Purpose: The Council advises the Secretary with respect to the administration of programs of financial assistance for the health professions and makes recommendations based on its review of applications requesting such assistance.

Agenda: During the open portion of the meeting, the Council will receive general announcements, discuss pending legislation, review past minutes and set future meeting dates. During the closed session the Council will meet for the purpose of considering applications for Federal assistance submitted under the Dental Health Training of Auxilliary Management, the Dental Health Continuing Education, and the Special Project Preceptorship Training Programs, and will not be open to the public in accordance with the provisions set forth in section 552(b)(5) and (6), Title 5, U.S. Code and the Determination by the Administrator, Health Resources Administration, pursuant to Public Law 92–463.

Anyone wishing to obtain a roster of members, minutes of meeting, or other relevant information should contact Mrs. Lynn Stevens, Room 4C–02, Building 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014, Telephone (301) 496–6601.

Name: Health Services Research Study Section.

Date and Time: January 11–14, 1976, 9:00 a.m.

Place: Connecticut Room—3rd Floor, Holiday Inn—Bethesda, 8130 Wisconsin Avenue, Bethesda, Maryland 20014.