Sunflower oil (unhydrogenated) (identification)
Talc (description, identification, extractable fluoride)
Tannic acid (definition, heavy metals, loss on drying)
Terpene resin, natural (heavy metals)
Terpene resin, synthetic (heavy metals)
Thiamine mononitrate (assay)
Thiamine hydrochloride (assay)
L-Threonine (specific rotation)
DL-α-Tocopherol (lead, heavy metals)
d-α-Tocopherol concentrate (description, heavy metals, lead)
Tocopherols concentrate, mixed (description, heavy metals, lead)
DL-α-Tocopheryl acetate (lead, heavy metals)
d-α-Tocopheryl acetate (heavy metals, lead)
d-α-Tocopheryl acetate concentrate (description, heavy metals, lead)
d-α-Tocopheryl acid succinate (heavy metals, lead)
Tragacanth (heavy metals, lead)
L-Tryptophan (description, specific rotation)
L-Tyrosine (specific rotation)
L-Valine (specific rotation)
Vitamin B_{12} (identification, assay)
Vitamin D_2 (identification)
Vitamin D_3 (identification)
Xanthan gum (ash, heavy metals)
Xylitol (lead)
Yeast extract ([formerly Autolyzed yeast extract] description, requirements, assay, other tests)
Zinc gluconate (numerous changes)

Interested persons may, on or before April 17, 1995, submit to NAS (address above) written comments regarding the monographs listed in this notice. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments are to be submitted. Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and should include a statement that it is in response to this **Federal Register** notice. NAS will forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 3, 1995.

L. Robert Lake,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–6529 Filed 3–15–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0063]

Dey Laboratories, et al.; Withdrawal of Approval of 14 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 14 abbreviated new drug applications (ANDA's). The holders of the ANDA's notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: April 17, 1995.

FOR FURTHER INFORMATION CONTACT: Carolyn C. Harris, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of the ANDA's listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA no.	Drug	Applicant
70–805	Metaproterenol Sulfate Inhalation Solution, U.S.P., 5%	Dey Laboratories, 2751 Napa Valley Corporate Dr., Napa, CA 94558.
80–086	Sulfadiazine Tablets, 167 milligrams (mg) Sulfamerazine Tablets, 167 mg Sulfamethazine Tablets, 167 mg.	Purepac Pharmaceutical, Co., 200 Elmora Ave., Elizabeth, NJ 07207.
80–120	Isoniazid Tablets, 100 mg	Towne, Paulsen & Co., Inc., 14527 South San Pedro St., Gardena, CA 90248.
80–132	Isoniazid Tablets, U.S.P.	Purepac Pharmaceutical, Co.
80–276	Testosterone Propionate Injection	Elkins-Sinn, Inc., 2 Esterbrook Lane, Cherry Hill, NJ 08003–4099.
80–308	Methyltestosterone Buccal Tablets, 10 mg	Purepac Pharmaceutical, Co.
80–309	Methyltestosterone Tablets, 10 mg	Do.
80–310	Methyltestosterone Tablets, 25 mg	Do.
80–459	Hyrocortisone Emulsion Cream, 1%	Elder Pharmaceuticals, Inc., ICN Plaza, 3300 Highland Ave., Costa Mesa, CA 92626.
80–475	Methyltestosterone Tablets	Purepac Pharmaceuticals, Inc.
80–489	Hydrocortisone Ointment, 0.5%	Altana Inc., 60 Baylis Rd., Melville, NY 11747.
80–581	Pyridoxine Hydrochloride Injection U.S.P., 100 mg/milliliter (mL)	Elkins-Sinn, Inc.
80–797	Chlorpheniramine Maleate Injection, 10 mg/mL and 100 mg/mL	Do.
80–928	Propantheline Bromide Tablets, 15 mg	Geneva Pharmaceuticals, Inc., 2555 West Midway Blvd., Broomfield, CO 80038–0446.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the ANDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective April 17, 1995.

Dated: March 2, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95–6426 Filed 3-15–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which

interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Antiviral Drugs Advisory Committee

Date, time, and place. April 3 and 4, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, April 3, 1995, 8 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12:30 p.m., unless public participation does not last that long; closed committee deliberations, 12:30 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 5:30 p.m.; closed committee deliberations, April 4, 1995, 8 a.m. to 4 p.m.; Lee L. Zwanziger or Liz Ortuzar, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Antiviral Drugs Advisory Committee, code 12531.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify a contact person before March 24, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will hear presentations and discuss scientific issues relevant to liposomal antifungal agents.

Closed committee deliberations. On April 3 and 4, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to pending new drug applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation

of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: March 9, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–6427 Filed 3-15–95; 8:45 am]

BILLING CODE 4160–01–F

Office of the Secretary

Correction of Notice of Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Correction.

SUMMARY: A Notice beginning on page 10588 in the issue of February 27, 1995, entitled ''Findings of Scientific Misconduct'' is hereby reprinted in its entirety because of an omission in the original printing:

Vivian N. Tanner, Cleveland Clinic Foundation: The Division of Research Investigations of the Office of Research Integrity (ORI) conducted an investigation into possible scientific misconduct on the part of Vivian N. Tanner while she was a clinic coordinator for the Collaborative Ocular Melanoma Study (COMS) at the Cleveland Clinic Foundation (CCF). ORI concluded that Ms. Tanner committed scientific misconduct by falsifying and fabricating clinical trial data on research data forms related to a multicenter study on the treatment of choroidal melanoma, a rare form of eye cancer. Due to these falsifications and fabrications, inaccurate clinical data were entered into the clinical trial database. These acts were committed over a period of several years, were material, and, therefore, were potentially detrimental to the study. The CCF COMS project has received U.S. Public Health Service support from 1985 to the present through subcontract funds from a National Eye Institute cooperative agreement award to the COMS Coordinating Center, The Wilmer Ophthalmological Institute, The Johns Hopkins Medical Institutions, Baltimore, Maryland. Ms. Tanner has been debarred from eligibility for and involvement in grants as well as other assistance awards and contracts from the Federal Government for a period of three years. Because the COMS is an ongoing study, no publications were affected by the falsified or fabricated data, and no clinical treatment has been based on the results of the study.

FOR FURTHER INFORMATION, CONTACT: Director, Division of Research Investigations, Office of Research Integrity, 301–443–5330.

Lyle W. Bivens, Ph.D.,

Director, Office of Research Integrity.

[FR Doc. 95–6446 Filed 3–15–95; 8:45 am]

BILLING CODE 4160–17–P

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Chemistry and Related Sciences.

Date: March 27, 1995.

Time: 2:00 p.m.

Place: NIH, Westwood Building, Room 320, Telephone Conference.

Contact Person: Dr. Zakir Bengali, Scientific Review Administrator, 5333 Westbard Ave., Room 320, Bethesda, MD 20892, (301) 594–7317.

Name of SEP: Microbiological and Immunological Sciences.

Date: April 3, 1995.

Time: 10:00 a.m.

Place: NIH, Westwood Building, Room 407B, Telephone Conference.

Contact Person: Dr. Betty Hayden, Scientific Review Administrator, 5333 Westbard Ave., Room 407B, Bethesda, MD 20892, (301) 594–7310.

Name of SEP: Microbiological and Immunological Sciences.

Date: April 3, 1995.

Time: 3:00 p.m.

Place: NIH, Westwood Building, Room 407B, Telephone Conference.

Contact Person: Dr. Betty Hayden, Scientific Review Administrator, 5333 Westbard Ave., Room 407B, Bethesda, MD 20892, (301) 594–7310.

Name of SEP: Behavioral and Neurosciences.

Date: April 3, 1995.

Time: 8:30 a.m.

Place: Holiday Inn, Chevy Chase, MD.

Contact Person: Dr. Teresa Levitin, Scientific Review Admin., 5333 Westbard Ave., Room 303, Bethesda, MD 20894, (301) 594–7141.

Name of SEP: Chemistry and Related Sciences.

Date: April 4, 1995.

Time: 1:00 p.m.

Place: NIH, Westwood Building, Room 435, Telephone Conference.

Contact Person: Dr. Marcelina Powers, Scientific Review Administrator, 5333 Westbard Ave., Room 435, Bethesda, MD 20892, (301) 594–7120.

Name of SEP: Microbiological and Immunological Sciences.

Date: April 4, 1995.

Time: 3:00 p.m.

Place: NIH, Westwood Building, Room 407B, Telephone Conference.

Contact Person: Dr. Betty Hayden, Scientific Review Administrator, 5333 Westbard Ave., Room 407B, Bethesda, MD 20892, (301) 594–7310.

Name of SEP: Chemistry and Related Sciences.

Date: April 6, 1995.

Time: 1:30 p.m.

Place: NIH, Westwood Building, Room 339B, Telephone Conference.

Contact Person: Dr. Jerry Critz, Scientific Review Administrator, 5333 Westbard Ave., Room 339B, Bethesda, MD 20892, (301) 594–7322.

Name of SEP: Microbiological and Immunological Sciences.

Date: April 7, 1995.

Time: 1:00 p.m.

Place: NIH, Westwood Building, Room 403C, Telephone Conference.

Contact Person: Dr. Anita Weinblatt, Scientific Review Admin., 5333 Westbard Ave., Room 403C, Bethesda, MD 20892, (301) 594–7175.

Name of SEP: Chemistry and Related Sciences.

Date: April 12, 1995.

Time: 1:00 p.m.

Place: NIH, Westwood Building, Room 435, Telephone Conference.

Contact Person: Dr. Marcelina Powers, Scientific Review Administrator, 5333 Westbard Ave., Room 435, Bethesda, MD 20892, (301) 594–7120.