budget period. Final financial status and progress reports are required 90 days after the end of a project period.

During Fiscal Year 1983, approximately $180,000 will be available to fund two or three new cooperative agreements and 10 to 12 continuation awards. Individual project awards are expected to range from $7,000 to $20,000.

Applications should be submitted for a 1-year budget period and a 1- to 2-year project period. Continuation awards within the project period will be made by CDC on the basis of satisfactory progress in meeting project objectives and on the availability of funds. Funding estimates outlined above may vary and are subject to change due to budgetary uncertainties.

Cooperative agreement funds may be used to support personnel and to purchase supplies and services directly related to the clincal trial. Project funds may not be used to supplant funds supporting existing tuberculosis control services provided by a State or locality, or to support construction costs.

New applications for a cooperative agreement must include a narrative which summarizes: (1) The background and need for project support including information that relates to factors by which the applications will be evaluated; (2) the objectives of the proposed project which are consistent with the purpose of the clinical trial and which are specific, measurable, realistic, and time-framed; (3) the methods which will be employed to accomplish the objectives (of special importance will be the methods used to monitor and insure patients' compliance with therapy); (4) the methods which will be employed to evaluate the successfulness of enrolling eligible patients; (5) fiscal information pursuant to utilization of awarded funds in a manner consistent with the purpose and objectives of the project; and (6) any other information which will support the request for assistance.

Continuation applications need to provide only new short-term objectives for the new budget period; and progress report on activities performed during the prior budget period; a description of any changes in the method of operation, need for cooperative agreement support, and evaluation procedures compared to information provide in previous applications; and fiscal and other supporting information as indicated in (5) and (6) in the preceding paragraph.

The original and one copy of application must be submitted to the address in 1.a. below on or before 4:30 p.m. (e.d.t.) on July 5, 1983. Applicants may meet the deadline by either delivering or mailing the application on or before the date, provided the following conditions are met:

1. *Mailed applications.* Applications mailed through the U.S. Postal Service shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date by Leo A. Sanders, Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, N.E., Room 107A, Atlanta, Georgia 30305, or

b. Sent by first class mail postmarked on or before the deadline date, and received by the granting agency in time for submission to the independent review group. (Applicants are cautioned to request a legible U.S. Postal Service postmark or use U.S. Postal Service express mail, or certified mail, and obtain a legible dated mailing receipt from the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. *Applications submitted by other means.* Applications submitted by any means except mailing first class through the U.S. Postal Service shall be considered as meeting the deadline only if they are physcially received at the place specified in paragraph 1. above before close of business on or before the deadline date (4:30 p.m. e.d.t., July 5, 1985).

3. *Late applications.* Applications which do not meet the criteria in either paragraph 1. or 2. above are considered late applications and will not be considered in the current competition.

Applications are not subject to the review requirements of the National Health Planning and Resource Development Act of 1974, as amended, or to intergovernmental review pursuant to Executive Order 12372.

Information on application procedures, copies of application forms, copies of the Study 21 Protocol, and other material may be obtained from Leo A. Sanders, Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, at the address in paragraph 1.a. above, or by calling (404) 262-6575, or FTS 236-6575. Technical assistance may be obtained from Mr. Donald E. Kopanoff, Division of Tuberculosis Control, Center for Prevention Services, Centers for Disease Control, Atlanta, Georgia 30333, telephone (404) 329-2523, or FTS 236-2523.

Dated: May 4, 1983.

William H. Foege,

Director, Centers for Disease Control.

[FR Doc. 83-12900 Filed 5-12-83; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 83M-0138]

Alcon Laboratories, Inc.; Premarket Approval of OPTI-CLEAN™ Cleaning Solution

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application for premarket approval under the Medical Device Amendments of 1976 of the OPTI-CLEAN™ Cleaning Solution sponsored by Alcon Laboratories, Inc., Fort Worth, TX. After reviewing the recommendation of the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, FDA notified the sponsor that the application was approved because the device had been shown to be safe and effective for use as recommended in the submitted labeling.

DATE: Petitions for administrative review by June 13, 1983.

ADDRESS: Requests for copies of the summary of safety and effectiveness data and petitions for administrative review may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles H. Kyper, National Center for Devices and Radiological Health (HFK-402), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7445.

SUPPLEMENTARY INFORMATION: On June 2, 1982, Alcon Laboratories, Inc., Fort Worth, TX, submitted to FDA an application for premarket approval of the OPTI-CLEAN™ Cleaning Solution for use in a heat or chemical lens care system to clean daily or extended wear soft (hydrophilic) contact lenses with 55 percent or less water content. The application was reviewed by the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, an FDA advisory committee, which recommended approval of the application. On April 7, 1983, FDA approved the application by a letter to the sponsor from the Associate Director for Device Evaluation of the Office of Medical Devices.

Before enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-925, 90 Stat. 539-583), cleaning solutions for use in cleaning hydrophilic contact lenses were regulated as new drugs. Because the amendments broadened the definition of

the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)), such cleaning solutions are now regulated as class III devices (premarket approval). As FDA explained in a notice published in the **Federal Register** of December 16, 1977 (42 FR 63472), the amendments provide transitional provisions to ensure continuation of premarket approval requirements for class III devices formerly regulated as new drugs. Furthermore, FDA requires, as a condition for approval, that sponsors of applications for premarket approval of soft contact lenses or the cleaning solutions for the above use comply with the records and reports provisions of Part 310 (21 CFR Part 310), Subpart D, until these provisions are replaced by similar requirements under the amendments.

A summary of the safety and effectiveness data on which FDA's approval is based is on file with the Dockets Management Branch (address above), and is available upon request from that office. A copy of all approved final labeling is available for public inspection at the Office of Medical Devices—contact Charles H. Kyper (HFK-402), address above. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

The labelling of the OPTI-CLEAN ™ Cleaning Solution states that the solution is indicated for use in a heat or chemical lens care system to clean daily or extended wear soft (hydrophilic) contact lenses with 55 percent or less water content. Sponsors of any such soft (hydrophilic contact lenses that have been approved for marketing are advised that whenever FDA publishes a notice in the **Federal Register** of the agency's approval of a new solution for use with such an approved soft contact lens, the sponsor of each such lens shall correct its labeling to refer to the new solution at the next printing or at such other time as FDA prescribes by letter to the sponsor. A sponsor who fails to update the restrictive labeling may violate the misbranding provisions of section 502 of the act (21 U.S.C. 352) as well as the Federal Trade Commission Act (15 U.S.C. 41–58), as amended by the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act (Pub. L. 93–637). Furthermore, failure to update the restrictive labeling to refer to the new cleaner that may be used with an approved lens may be grounds for withdrawing approval of the application for the lens under section 515(e)(1)(F) of the act (21 U.S.C. 360e(e)(3)(1)(F)).

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 505(g) of the act (21 U.S.C. 360e(g)), for administrative review of FDA's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and FDA's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration of FDA action under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issues to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before June 13, 1983, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 5, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-12721 Filed 5-12-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 80N-0276; DESI 7630]

Drugs for Human Use; Certain Anabolic Steroids, Drug Efficacy Study Implementation; Withdrawal of Approval

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new drug applications for certain anabolic steroid products for which FDA offered an opportunity for hearing, but for which no hearing was requested. The products lack substantial evidence of effectiveness.

EFFECTIVE DATE: June 13, 1983.

ADDRESS: Requests for an opinion of the applicability of this notice to a specific drug product should be identified with Docket No. 80N-0276 and reference number DESI 7630 and directed to the Division of Drug Labeling Compliance (HFN-310), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nicholas Reuter, National Center for Drugs and Biologics (HFN-8), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 18, 1983 (48 FR 2208), the Director of the National Center for Drugs and Biologics revoked the temporary exemption (37 FR 266231) for the continued marketing of certain anabolic steroid drug products. The manufacturers of these products had not complied with the marketing conditions announced on October 31, 1980 (45 FR 72292). The notice also proposed to withdraw approval of the new drug applications, including conditionally approved abbreviated applications, that provide for these products and offered an opportunity for a hearing on the proposal. The basis of the proposal was a lack of substantial evidence of effectiveness.

Products for Which No Hearing Was Requested

Because the holders of the following new drug applications did not request a hearing, approval of the applications is now being withdrawn.

1. NDA 8-736; Methylandrostenediol Aqueous Suspension containing methandriol 25 or 50 mg/mL; Maurry Biological Co., Inc., South Western Ave., Los Angeles, CA 90047.

2. NDA 11-761; Adroyd Tablets containing oxymetholone 2.5, 5, or 10 mg/tablet; Parke-Davis, Division of Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950.

3. NDA 12-226; Dianabol Tablets containing methandrostenolone 2.5 or 5 mg/tablet; Ciba Pharmaceutical Co., Division Ciba-Geigy Corp., 556 Morris Ave., Summit, NJ 07901.

4. NDA 12-733; Anadrol Tablets containing oxymetholone 2.5 mg/tablet; Syntex Laboratories, Inc., 3401 Hillview Ave., Stanford Industrial Park, Palo Alto, CA 94304.

(This notice does not affect Anadrol-50 Tablets, containing oxymetholone 50

mg/tablet, marketed by Syntex for use in the treatment of certain anemias.)

Approval of the new drug applications for the following anabolic steroids was withdrawn in previous **Federal Register** notices, at the request of the applicants because they had discontinued marketing the products. (The January 18, 1983 notice incorrectly stated the reasons for the previous actions withdrawing approval.) These products were named in the January 18 notice offering an opportunity for a hearing because the question of the effectiveness of the drugs had not previously been resolved and neither those applicants nor firms marketing identical, similar, or related drugs had had an opportunity to request a hearing on that decision or on issue relating to the legal status of the products. No hearing on these products has been requested.

1. NDA 7–630; Stenediol Injection containing methandriol 25 or 50 mg/mL; Organon, Inc., 375 Mount Pleasant Ave., West Orange, NJ 07052.

2. NDA 10–400; Nilevar Tablet containing norethandrolone 10 mg/tablet; G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680.

3. NDA 11–019; Nilevar Injection containing norethandrolone in sesame oil, 25 mg/mL; G. D. Searle & Co.

4. NDA 11–638; Nilevar Drops; containing norethandrolone 8.3 mg/mL; G. D. Searle & Co.

Any drug products that are identical, related, or similar to one of the eight products name above and are not the subject of an approved application are covered by the applications listed above, and are subject to this notice. Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Drug Labeling Compliance at the address given above.

The Director of the National Center for Drugs and Biologics, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052–1053 as amended (21 U.S.C. 355)), and under authority delegated to him (see 21 CFR 5.82 and 47 FR 26913 published in the **Federal Register** of June 22, 1982) finds that, on the basis of new information before him with respect to the products, evaluated together with the evidence available to him when the applications listed above were approved, there is a lack of substantial evidence that the drug products will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling. Therefore, pursuant to this finding, approval of application numbers 8–736, 11–761, 12–226, and 12–733 and all amendments and supplements applying to them is withdrawn effective June 13, 1983. Shipment in interstate commerce of the above products or of any identical, related, or similar product that is not the subject of an approved new drug application will then be unlawful.

Products for Which Hearing Was Requested

This notice does not apply to the products that are the subject of the following conditionally approved abbreviated new drug applications, the holders of which have requested hearings. These products will be addressed in a future **Federal Register** notice.

1. ANDA 87–465; Methandrostenolone 2.5 mg tablets; Bolar Pharmaceutical Co. Inc., 130 Lincoln St., Copiage, NY 11726.

2. ANDA 87–466; Methandrostenolone 5 mg tablets; Bolar Parmaceutical Co. Inc.

3. ANDA 87–945; Methandrostenolone 5 mg tablets; Par Parmaceutical Inc., 12 Industrial Ave., Upper Saddle River, NJ 07458.

4. ANDA 87–951; Methandrostenolone 2.5 mg tablets; Par Parmaceutical Inc.

Products for Which Exemption Has Not Been Revoked

The six products covered by the NDA's and the conditionally approved ANDA's listed below are still subject to the exemption identified above and the action taken in this notice does not apply to them. Nandrolone phenpropionate which was listed in the January 18, 1983 notice as still exempt was the subject of a subsequent **Federal Register** notice (48 FR 11515) which revoked the exemption.

1. NDA 12–885; Winstrol Tablets containing stanozolol 2 mg/tablet; Winthrop Laboratories, Division of Sterling Drug Inc., 90 Park Ave., New York, NY 10016. (Note: NDA 13–268 for Winsteroid Tablets (stanozolol) listed in the June 24, 1970 notice has been assimilated into NDA 12–885 at the request of the holder because both NDA's cover the same product.)

2. NDA 13–132; Deca-Durabolin Injection containing nandrolone decanoate 50 mg/mL, 100 mg/mL, or 200 mg/mL (previous notices listed the 50 mg/mL strength only); Organon, Inc.

3. ANDA 86–385; Nandrolone Decanoate 50 mg/mL; Carter Glogau Laboratories, Inc., 5160 W. Bethany Home Rd., Glendale, AZ 85301.

4. ANDA 86–598; Nandrolone Decanoate 100 mg/mL; Carter Glogau Laboratories, Inc.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052–1053 as amended (21 U.S.C. 355)), and under authority delegated to the Director of the National Center for Drugs and Biologics (see 21 CFR 5.82 and 47 FR 26913 published in the **Federal Register** of June 22, 1982).

Dated: May 2, 1983.

Harry M. Meyer, Jr.,

Director, National Center for Drugs and Biologics.

[FR Doc. 83-12534 Filed 5-12-83; 8:45 am]

BILLING CODE 4160-01-M

Elanco Products Co., Corderm Ointment, Renazide Tablets, Tylan Boluses, and Methagon Tablets; Withdrawal of Approval of NADA'S

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADA's) providing for use of the following products: (1) Corderm Ointment, a corticosteroid/antibiotic for canine use; (2) Renazide Tablets, a canine diuretic; (3) Tylan Boluses, an antibiotic for intrauterine use in beef cattle; and (4) Methagon Tablets, a corticosteroid for canine and feline use in certain dermatoses. The sponsoring firm, Elanco Products Co., requested the withdrawal of approvals.

EFFECTIVE DATE: May 23, 1983.

FOR FURTHER INFORMATION CONTACT: David N. Scarr, Bureau of Veterinary Medicine (HFV–214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3183.

SUPPLEMENTARY INFORMATION: Elanco Products Co., a Division of Eli Lilly & Co., 740 S. Alabama St., Indianapolis, IN 46206, is sponsor of the following four NADA's: (1) NADA 13–133, Corderm Ointment (Flurandrenolide/neomycin), originally approved on September 27, 1962, for use on dogs for topical management of allergic dermatitis, otitis externa, and superficial pyoderma which may be threatened or complicated by bacterial infections; (2) NADA 13–547, Renazide Tablets (cyclothiazide), originally approved on May 24, 1963, for use in dogs for its diuretic and saluretic effects; (3) NADA 13–730, Tylan Boluses (tylosin base), originally approved on July 10, 1963, for treating intrauterine infections in beef cattle; and (4) NADA 33–240, Methagon Tablets (flumethasone), originally approved December 1, 1966, for use in dogs and cats to help control the pruritis, irritation, and inflammation associated with certain dermatoses.

By letter of October 7, 1982, to the Bureau of Veterinary Medicine, Elanco

requested withdrawal of approval of the NADA's because the products are not being manufactured or marketed and the firm has no intention of marketing them in the future.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345–347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA's and all supplements for NADA 13–133, Corderm Ointment; NADA 13–547, Renazide Tablets; NADA 13–730, Tylan Boluses; and NADA 33–240, Methagon Tablets, is hereby withdrawn, effective May 23, 1983.

Approval of NADA's 33–240 and 13–730 have not been codified in the Code of Federal Regulations, but approval of NADA's 13–547 and 13–133 is reflected in § 520.526 *Cyclothiazide tablets* and § 524.1000 *Flurandrenolide with neomycin sulfate ointment.* In a separate document published elsewhere in this issue of the **Federal Register**, the agency is removing those sections that reflect approval of the NADA's.

Dated: May 2, 1983.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 83-12544 Filed 5-12-83; 8:45 am]

BILLING CODE 4160-01-M

Advisory Committees; Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770–776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meetings are announced:

Panel on Review of Allergenic Extracts

Date, time, and place. June 3 and 4, 9 a.m., Rm. 115, Bldg. 29, 8800 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. Open public hearing, June 3, 9 a.m. to 10 a.m.; open committee discussion, June 3, 10 a.m. to 5 p.m., June 4, 8:30 a.m. to 1:30 p.m.; Clay Sisk, National Center for Drugs and Biologics (HFN–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455.

General function of the committee. The committee reviews and evaluates data on the safety, effectiveness, and appropriate use of allergenic products intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, or issues pending before the committee.

Open committee discussion. The committee will continue the reevaluation of allergenic biological products previously classified in Category IIIA, the designation for those licensed biological products judged to have insufficient available data to classify as safe and effective, but which should remain licensed pending completion of further testing as provided in 21 CFR 601.25(e). The products are being reclassified under the procedures described in the **Federal Register** of October 15, 1982 (47 FR 46138) and 21 CFR 601.26. Allergenic extracts of pollens, molds, basidiomycetes, insects, foods, house dust, and inhalant allergens will be discussed.

Dematologic Drugs Advisory Committee

Date, time, and place. June 13, 9 a.m., Conference Rms. G and H, Parklawn, Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 4:30 p.m.; David Bostwick, National Center for Drugs and Biologics (HNF–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6798.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drug products for use in the treatment of dermatological disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open committee discussion. The committee will discuss ketoconazole (NDA 18–533, Janssen Pharmaceutica) and lindane (NDA 6–309, Reed and Carnrick, Inc.).

FDA public advisory committee meetings 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. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meetings 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 chairman determines will facilitate the committee's work.

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 chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be requested from the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

Dated: May 9, 1983.

William F. Randolph,

Acting Assistant Commissioner for Regulatory Affairs.

[FR Doc. 83-12847 5-12-83; 8:45 am]

BILLING CODE 4160-01-M

Consumer Participation: Notice of Open Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following consumer exchange meetings:

Philadelphia District Office, chaired by Loren Y. Johnson, District Director. The topic to be discussed is Direct-to-Consumer Advertising of Prescription Drugs.

Date: Friday, May 20, 1983, 10 a.m. to 12 m.

Address: Federal Bldg., Rm. 3306–10, 6th and Arch Sts., Philadelphia, PA 19106.

For further information contact: Theresa A. Young, Consumer Affairs Officer, Food and Drug Administration, U.S. Customhouse, Rm.