provide fundamental food safety and nutrition information to the public and private sector.

V. Reporting Requirements

Program progress reports and financial status reports will be required annually, based on date of award. These reports will be due within 30 days after the end of the budget period. A final program progress report and financial status report will be due 90 days after expiration of the project period of the cooperative agreement.

VI. Delineation of Substantive Involvement

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

(1) FDA will appoint a project officer or coproject officers who will actively monitor the FDA-supported program under this award.

(2) FDA shall have prior approval on the appointment of all key administrative and scientific personnel proposed by the grantee.

(3) FDA will be directly involved in the guidance and development of the program and of the management structure for the program.

(4) FDA scientists will participate, with the grantee, in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings, and, where appropriate, coauthorship of publications.

Dated: May 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13446 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0183]

Bausch & Lomb, Inc.; Premarket Approval of Bausch & Lomb® Soflens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Bausch & Lomb, Inc., Rochester, NY, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 16, 1996, of the approval of the application.

DATES: Petitions for administrative review by June 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

SUPPLEMENTARY INFORMATION: On June 28, 1996, Bausch & Lomb, Inc., Rochester, NY 14692–0450, submitted to CDRH an application for premarket approval of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear. The device is a soft (hydrophilic) contact lens and is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this application was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the application substantially duplicates information previously reviewed by this panel.

On December 16, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

The labeling of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 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 issue 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 23, 1997, 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.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs

(21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 22, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–13535 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Open Meeting for Representatives of Health Professional Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an open meeting with representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. This meeting will provide participants an opportunity to hear a discussion on prescription (Rx) to over-the-counter (OTC) switches and the new OTC proposed labeling initiative.

DATES: The meeting will be held on Thursday, May 29, 1997, from 1:30 p.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at the Bethesda Holiday Inn, 8210 Wisconsin Ave., Bethesda, MD. Interested persons may register with Betty Palsgrove at 301–443–1652. Registrations also may be transmitted by FAX to 1–800–344–3332 or 301–443–2446.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5470.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff and to provide an opportunity for informal discussion on the switching of drug products from prescription to OTC status and on FDA's proposed regulation for labeling of OTC drug products, which would amend 21 CFR parts 201, 330, and 358 (62 FR 9024, February 27, 1997).

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received and should be sent to the contact person listed above. Registration should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: May 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13447 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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:

Science Advisory Board to the National Center for Toxicological Research

Date, time, and place. June 5 and 6, 1997, 9 a.m., Bldg. 12, conference room, National Center for Toxicological Research, Jefferson, AR.

Type of meeting and contact person. Open board discussion, June 5, 1997, 9 a.m. to 4:30 p.m.; open board discussion, June 6, 1997, 9 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; closed board deliberations, 12 m. to 1:30 p.m.; Ronald F. Coene, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3155, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Science Advisory Board to the National Center for Toxicological Research, code 12559. Please call the hotline for information concerning any possible changes.

General function of the board. The board advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs to fulfill regulatory responsibilities.

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 the contact person before May 26, 1997, 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 board discussion. The board will be presented with draft reports, for review and discussion, from two site visit review teams: (1) On the Estrogen Knowledge Base Program, and (2) on the Information Management Program. Staff from the Analytical Methods Program will provide a progress report on the recommendations made by the Science Advisory Board. Also there will be discussion of an agenda for future program review site visits, an update from the Director, and a review of the progress the agency has made in establishing the Arkansas Regional Laboratory at the Jefferson, AR site.

A final agenda will be available on June 3, 1997, from the contact person.

Closed board deliberations. The board will discuss personal information concerning individuals associated with the research programs at the center, disclosure of which would constitute a clearly unwarranted invasion of personal privacy. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(6)).

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Each public advisory committee meeting listed above may have as many