ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for TEGISON (etretinate) Capsules held by Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110. Hoffmann-La Roche has requested that approval of this application be withdrawn because the product is no longer marketed, thereby waiving its opportunity for a hearing.

DATES: Effective September 10, 2003.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In a letter dated September 23, 1999, Hoffmann-La Roche requested that FDA withdraw approval of NDA 19–369 for TEGISON (etretinate) Capsules, stating that it had discontinued marketing the product. The letter also stated that TEGISON had been replaced by NDA 19–821 for SORIATANE (acitetrin) and that TEGISON was not withdrawn for safety reasons. In FDA's acknowledgment letter of December 30, 2002, the agency informed Hoffmann-La Roche that TEGISON (etretinate) Capsules, a treatment for psoriasis, was removed from the market, under § 314.150(d) (21 CFR 314.150(d)), because it poses a greater risk of birth defects than SORIATANE (acitretin), the product that replaced TEGISON. Acitretin, the active metabolite of etretinate, has a much shorter half-life than etretinate. Thus, acitretin poses a risk of serious birth defects for a shorter period of time than etretinate after a woman stops taking the drug product. Hoffmann-La Roche waived its opportunity for a hearing, provided under § 314.150(a) and (b).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105(a)), approval of NDA 19–369, and all amendments and supplements thereto, is hereby withdrawn, effective September 10, 2003.

Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and 331(d)).

Dated: August 5, 2003.

Steven K. Galson,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 03–22956 Filed 9–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Technical Electronic Product Radiation Safety Standards Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Technical Electronic Product Radiation Safety Standards Committee.

General Function of the Committee: To provide advice on technical feasibility, reasonableness, and practicality of performance standards for electronic products to control the emission of radiation under 21 U.S.C. 360kk(f).

Date and Time: The meeting will be held on October 1, 2003, from 8:30 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Richard Kaczmarek, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–0865, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12399. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear an informal review of ongoing activities associated with electronic products.

Following the overview, FDA will discuss proposed amendments to the U.S. performance standard for sunlamp products (21 CFR 1040.20) and certain initiatives of international standards organizations concerning sunlamp products.

In the afternoon, there will be a presentation regarding proposed amendments to the diagnostic x-ray system performance standard (21 CFR 1020.30). Following this, the final topic will be public health considerations of x-ray security screening systems and the development of policies for safe use of these systems.

Background information on the discussion topics will be posted under the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2003 and scroll down to TEPRSSC.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 19, 2003. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:30 a.m., and between 3 p.m. and 3:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 19, 2003, 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 requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, at 301–594–1283, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 3, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–22961 Filed 9–9–03; 8:45 am]

BILLING CODE 4160–01–S