

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0384]

Hoffmann-La Roche, Inc.; Withdrawal of Approval of a New Drug Application

AGENCY: Food and Drug Administration, HHS.

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 Hoffmann-La Roche has requested that approval of this application be withdrawn because the product is no longer marketed, thereby waiving its opportunity for a hearing.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 [Insert date of publication in the FEDERAL REGISTER].

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 The letter also stated that TEGISON had been replaced by NDA 19-821 for SORIATANE (acitretin) and that TEGISON was not withdrawn for safety reasons.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and Research (21 CFR 5.105(a)), approval of NDA 19-369, and all amendments and supplements thereto, is hereby withdrawn, effective [insert date of publication in the FEDERAL REGISTER].

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: _____
