

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0350]

Sankyo Pharma, 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 PRELAY (troglitazone) Tablets held by Sankyo Pharma, Inc. (Sankyo Pharma), 399 Thornall St., Edison, NJ 08837. Sankyo Pharma has requested that approval of this application be withdrawn because the product is not being marketed, thereby waiving its opportunity for a hearing.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 December 31,
cd0360

2002,

Sankyo Pharma requested that FDA withdraw approval, under § 314.150(d) (21 CFR 314.150(d)), of NDA 20-719 for PRELAY (troglitazone) Tablets. Sankyo U.S.A. Corp. (Sankyo U.S.A.) filed NDA 20-719 for PRELAY concurrently with Warner-Lambert Co.'s NDA 20-720 for REZULIN. Both these applications were for troglitazone tablets. Sankyo U.S.A. merged into Sankyo Pharma in December 1999. Neither Sankyo U.S.A. nor Sankyo Pharma has ever marketed PRELAY, and Sankyo Pharma has no plans to market troglitazone in the future. FDA has determined that never marketing an approved drug product is equivalent to withdrawing the drug from sale. PRELAY, a treatment for type 2 diabetes, was voluntarily withdrawn after review of safety data showed that REZULIN is more toxic to the liver than two other more recently approved drugs that offer a similar benefit (see the REZULIN withdrawal notice that published in the FEDERAL REGISTER of January 10, 2003 (68 FR 1469)). Sankyo Pharma 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 the NDA 20-719, and all amendments and supplements thereto, is

withdrawn, effective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: July 10, 2003.

Janet Woodcock,
Director,
Center for Drug Evaluation and Research.