

be used for the test product (i.e., a draft label for each size of container and each brand of product to be market tested). The information panel of the label must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by applicable sections of 21 CFR part 101.

Therefore, under the provisions of 21 CFR 130.17(i), FDA is extending the temporary permit granted to Del Monte Corp., One Market @ The Landmark, P.O. Box 193575, San Francisco, CA 94119-3575 to provide for continued marketing tests of approximately 10.3 million cases (226.6 million pounds or 103.0 million kilograms in weight) annually of canned tomatoes previously identified. FDA is extending the expiration date of the permit so that the permit expires either on the effective date of a final rule to amend the standard of identity for canned tomatoes that may result from the petition, or 30 days after termination of such rulemaking. All other conditions and terms of this permit remain the same.

Dated: August 22, 2003.

Christine Taylor,

Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0369]

Solvay Pharmaceuticals, Inc.; Withdrawal of Approval of Two New Drug Applications; Determination That LUVOX (Fluvoxamine Maleate) 25- Milligram, 50-mg, 100-mg, and 150-mg Tablets Was Not Withdrawn for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug applications (NDAs) for ROWASA (mesalamine) Rectal Suppositories, 500 milligrams (mg), and LUVOX (fluvoxamine maleate) 25-mg, 50-mg, 100-mg, and 150-mg tablets, held by Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062. Solvay has voluntarily withdrawn these NDAs in response to audit findings indicating possible inaccuracies noted in the chemistry, manufacturing, and controls

(CMC) section of the applications. Solvay has agreed to permit FDA to withdraw approval of the applications, thereby waiving its opportunity for a hearing. In addition, FDA has determined that LUVOX (fluvoxamine maleate) 25-mg, 50-mg, 100-mg, and 150-mg tablets was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to continue to approve abbreviated new drug applications (ANDAs) for fluvoxamine maleate 25-mg, 50-mg, 100-mg, and 150-mg tablets.

DATES: Effective September 3, 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: FDA recently became aware of possible inaccuracies in the CMC section of two of Solvay's applications approved by the agency. The two Solvay NDAs involved were: (1) NDA 19-919 for ROWASA (mesalamine) Rectal Suppositories, 500 mg, and (2) NDA 20-243 for LUVOX (fluvoxamine maleate) 25-mg, 50-mg, 100-mg, and 150-mg tablets. These findings, along with other information submitted to the agency by Solvay, provided sufficient justification to initiate proceedings to withdraw approval of these two products. The agency notified Solvay in writing of these terminations and, in accordance with § 314.150(d) (21 CFR 314.150(d)), offered Solvay the opportunity to permit FDA to withdraw approval of the applications.

Subsequently, in letters dated March 28, 2002, and May 14, 2002, respectively, Solvay requested withdrawal of the NDAs under § 314.150(d), thereby waiving its opportunity for a hearing. Solvay also withdrew these drug products from the market. Under § 314.150(d), approval of these two NDAs is being withdrawn.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under an NDA. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of

an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or, (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that referred to the listed drug have been approved. FDA may not approve an ANDA that does not refer to a listed drug.

The agency has already determined that ROWASA (mesalamine) Rectal Suppositories, 500 mg, was not withdrawn from sale for reasons of safety and effectiveness. On May 24, 2001, FDA published its determination in the **Federal Register** (66 FR 28753). Since that time, ANDAs that refer to ROWASA (mesalamine) Rectal Suppositories, 500 mg, may be approved by the agency.

Because numerous approved ANDAs for fluvoxamine maleate relied on LUVOX as the reference listed drug in their applications, FDA must also make a determination of reasons for voluntary withdrawal of LUVOX under § 314.161(a)(2). The agency has determined that Solvay Pharmaceuticals, Inc.'s, LUVOX (fluvoxamine maleate) 25-mg, 50-mg, 100-mg, and 150-mg tablets was not withdrawn from sale for reasons of safety or effectiveness.

LUVOX is indicated for the treatment of obsessions and compulsions in patients with obsessive compulsive disorder. In the course of an audit, FDA discovered inaccuracies in the CMC section of the LUVOX (fluvoxamine maleate) application. Although these findings raised concerns about the drug product as manufactured by Solvay, they do not affect the safety or efficacy of fluvoxamine maleate in treating obsessive compulsive disorder. LUVOX was withdrawn from sale following