

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Applications; Determination That LUVOX (Fluvoxamine Maleate) 25- Milligram, 50-mg, 100-mg, and 150-mg Tablets Was Not Withdrawn for Reasons of Safety or Effectiveness**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 Solvay has voluntarily withdrawn these NDAs in response to audit findings indicating possible inaccuracies noted in the chemistry, manufacturing, and controls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 In addition, FDA has determined that LUVOX (fluvoxamine maleate) 25-mg, 50-mg, 100-mg, and 150-mg tablets was not withdrawn from sale for reasons of safety or effectiveness.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

FDA's written request under § 314.150(d). The agency's independent evaluation of relevant information has not found any data that would indicate LUVOX (fluvoxamine maleate) was withdrawn for reasons of safety or effectiveness.

After reviewing its records, FDA determines that, for the reasons outlined in the previous paragraph, LUVOX (fluvoxamine maleate) 25-mg, 50-mg, 100-mg, and 150-mg tablets was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will list Solvay's LUVOX (fluvoxamine maleate) 25-mg, 50-mg, 100-mg, and 150-mg tablets in the "Discontinued Drug Product List" section of the "Orange Book." The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs for fluvoxamine maleate 25-mg, 50-mg, 100-mg, and 150-mg tablets may continue to be approved by the agency.

Therefore, under section 505(e) of the act approval of the NDAs listed above, and all amendments and supplements thereto, is withdrawn, effective September 3, 2003.

Dated: August 21, 2003.  
**Jeffrey Shuren,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 03-22359 Filed 9-2-03; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

*Safe Schools/Healthy Students Sustainability Study—New—*This study, a project of SAMHSA's Center for Mental Health Services (CMHS), involves a survey of project directors or other designated staff associated with the Safe Schools/Healthy Students (SS/

HS) Initiative. The SS/HS Initiative is a collaborative effort between the U.S. Departments of Education, Health and Human Services, and Justice. Under this initiative, Local education agencies (LEAs) were awarded grants in partnership with their local mental health agency and their local juvenile justice agency. Between September 1999 and September 2002, 143 communities received three-year awards under the SS/HS Initiative.

As this Initiative was designed to facilitate sustainable change within communities, CMHS would like to determine the extent to which systems-level changes, programs, and services initiated as part of SS/HS continue when the grant ends. A web-based survey of project directors will be conducted annually for three years. Respondents will be project directors or other designated staff responsible for continuing programs and services following the SS/HS grant.

This information will be used by CMHS to improve the grant making process and the provision of technical assistance. The following table describes the response burden associated with this data collection.

Year	Number of respondents	Responses per respondent	Hours per response	Total burden hours
One .....	77	3	.5	116
Two .....	20	2	.5	20
Three .....	46	1	.5	23
Total .....	143	.....	.....	159
3-yr. Annual Average .....	106	.....	.....	53

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Lauren Wittenberg, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: August 26, 2003.  
**Anna Marsh,**  
*Acting Executive Officer, SAMHSA.*  
 [FR Doc. 03-22379 Filed 9-2-03; 8:45 am]  
**BILLING CODE 4162-20-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Border and Transportation Security; Meeting of the Data Management Improvement Act of 2000 Task Force**

**AGENCY:** Border and Transportation Security Directorate, DHS  
**ACTION:** Notice of meeting.

*Committee meeting:* Department of Homeland Security (DHS), Data Management Improvement Act of 2000 (DMIA) Task Force.

*Date and Time:* Tuesday, September 23, 2003, 9 a.m. to 5 p.m.

*Place:* Double Tree Hotel, 300 Army Navy Drive, Arlington, VA 22202.

*Status:* Closed meeting. Notice is hereby given that the Data Management Improvement Act Task Force will meet on Tuesday, September 23, 2003, from 9 a.m. to 5 p.m. All times noted are

Eastern Time. The information that will be discussed at this meeting could seriously compromise the security and integrity of existing data collection systems as well as the proposed new entry/exit system and integration. Due to the nature of the issues being discussed, the Department of Homeland Security has determined that the meeting will be closed to the public (Section 10(d) of the Federal Advisory Committee Act (FACA)). The information discussed at this meeting is protected from disclosure under the Government in the sunshine Act, 5 U.S.C. 552b(c)(9)(B). In accordance with the provisions of the Federal Advisory Committee Act, minutes of the meeting will be kept for department and congressional review.

*Purpose:* The DMIA Task Force is focusing on the development of recommendations directly related to the