FOR FURTHER INFORMATION CONTACT: Sally Atwater, Executive Director, President's Committee on Mental Retardation, Aerospace Center Building, Suite 701, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone—(202) 619–0634, Fax—(202) 205–9519, e-mail—*satwater @acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: The President's Committee for People with Intellectual Disabilities acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with mental retardation, and for reviewing legislative proposals that impact on the quality of life that is experienced by citizens with mental retardation and their families.

Dated: August 6, 2003.

Sally Atwater,

Executive Director, President's Committee for People With Intellectual Disabilities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002N–0178]

Canned Tomatoes Deviating From Identity Standard; Extension of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of a temporary permit issued to Del Monte Corp. to market test canned tomato products that deviate from the U.S. standard of identity for canned tomatoes. The extension will allow the permit holder to continue to collect data on consumer acceptance of the products while the agency takes action on a petition to amend the standard of identity for canned tomatoes that was submitted by the permit holder.

DATES: The new expiration date of the permit will be either 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.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17, FDA issued a temporary permit to Del Monte Corp., One Market @ The Landmark, P.O. Box 193575, San Francisco, CA 94119–3575, to market test canned tomato products that deviate from the U.S. standards of identity for canned tomatoes § 155.190 (21 CFR 155.190) (67 FR 43325, June 27, 2002). The agency issued the permit to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

The permit covered limited interstate marketing tests of products identified as ''Stewed Tomatoes, Original Recipe,'' ''Chunky Tomatoes, Pasta Style,'' ''Diced Tomatoes, basil, garlic & oregano,'' ''Diced Tomatoes, garlic & onion,'' ''Diced Tomatoes, green pepper & onion,'' ''Tomato Wedges,'' ''Zesty Chunky Tomatoes, Chili Style,'' ''Stewed Tomatoes, Cajun Recipe with pepper, garlic, and Cajun spices,'' ''Stewed Tomatoes, Italian Recipe with basil, garlic & oregano,'' ''Stewed Tomatoes, Mexican Recipe with garlic, cumin, and jalapeños,'' and ''Stewed Tomatoes, no salt added.'' These canned tomato products deviate from the U.S. standard of identity for canned tomatoes (§ 155.190) in two ways. First, a liquid carbohydrate sweetener, either corn syrup or high fructose corn syrup, is used as an optional ingredient in lieu of dry nutritive carbohydrate sweeteners. The liquid carbohydrate sweetener, corn syrup or high fructose corn syrup, is used in a quantity reasonably necessary to compensate for the tartness resulting from added organic acids, except that such addition of the liquid sweetener, in no case, may result in a finished canned tomato product with a tomato soluble solids content of less than 5.0 percent by weight as defined in 21 CFR 155.3(e) (which accounts for any added salt) and accounting for the soluble solids of the liquid sweetener. Second, the permit provided for use of the term ''chunky'' in lieu of the styles (i.e., whole, sliced, diced, and wedges) required by the standard. Except for the use of a liquid sweetener and the use of the alternative term ''chunky'' on some products, the test products meet all the requirements of the standard.

On April 23, 2003, Del Monte Corp. requested that its temporary marketing permit be extended to allow for additional time for the market testing of its test products. The petitioner requested FDA to amend the standard of identity for canned tomatoes. In addition, Del Monte Corp. also requested that additional varieties of canned tomatoes be included under this permit extension. The additional products are as follows: (1) Del Monte Brand ''Diced Tomatoes, Petite Cut, garlic and olive oil;'' (2) Contadina Brand ''Stewed Tomatoes with onions, celery, and green peppers,'' ''Stewed Tomatoes with garlic, oregano, and basil, Italian Style,'' ''Diced Tomatoes with roasted garlic,'' ''Diced Tomatoes, Italian Herbs,'' ''Diced Tomatoes with Roasted Red Pepper,'' ''Diced Tomatoes, Primavera with zucchini, bell peppers, and carrots,'' ''Diced Tomatoes, Marinara with burgundy wine and olive oil;'' and (3) S&W Brand ''Stewed Tomatoes, Italian Recipe, sliced pear tomatoes with oregano and basil, 14 1/2 ounces,'' ''Stewed Tomatoes, Italian Recipe, sliced pear tomatoes with oregano and basil, 28 ounces,'' ''Diced Tomatoes in tomato juice with roasted garlic,'' ''Stewed Tomatoes with onion, celery, and bell pepper,'' ''Stewed Tomatoes with bell pepper, celery, and onion, no salt added,'' ''Diced tomatoes, Petite Cut, with roasted garlic and sweet onions,'' ''Stewed Tomatoes, Mexican Recipe with mild chili and Mexican seasoning,'' and ''Stewed Tomatoes, Cajun Recipe with bell pepper, onion, and Creole spices.''

The agency finds that it is in the interest of consumers to issue an extension of the time period for the market testing of products identified in the original permit (67 FR 43325) as well as to permit limited interstate marketing tests of additional canned tomato products identified in the previous paragraph. FDA is inviting interested persons to participate in the market test under the conditions that apply to Del Monte Corp. except that the designated area of distribution shall not apply. Any person who wishes to participate in the extended market test must notify, in writing, the Team Leader, Regulations and Review Team, Division of Food Labeling and Standards, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. The notification must include a description of the test product to be distributed, a justification statement for the amount requested, the area of distribution, and the labeling that will

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.

[FR Doc. 03–22420 Filed 9–2–03; 8:45 am]

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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 eterminations 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