Dated: November 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–32021 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0867]

Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of policy interpretation; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice issued jointly by FDA and the Environmental Protection Agency (EPA) that appeared in the **Federal Register** of October 9, 1998 (63 FR 54532). The document set forth legal and policy interpretations of the Federal Food, Drug, and Cosmetic Act (FFDCA) as they relate to the jurisdiction of EPA and FDA over antimicrobial substances used in or on food, including food-contact articles; discussed interpretations of certain terms in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the implementing regulations relevant to the authority of the two agencies; provided a description of how EPA and FDA propose to clarify the post-Food Quality Protection Act (FQPA) regulatory authority over certain antimicrobial substances; and discussed how EPA and FDA plan to handle the review of petitions for antimicrobial substances that will remain under EPA's jurisdiction, and for those that EPA proposes to return to FDA's regulatory authority through EPA rulemaking. The document was published with an incorrect address for FDA's Dockets Management Branch. This document corrects that error. EPA's addresses remain the same.

EFFECTIVE DATE: October 9, 1998.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

In FR Doc. 98–27261, appearing on page 54532 in the **Federal Register** of Friday, October 9, 1998, the following correction is made:

On page 54532, in the first column, under the **ADDRESSES** caption, in the first and second lines from the bottom ''Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.'' is corrected to read ''5630 Fishers Lane, rm. 1061, Rockville, MD 20852.''

Dated: November 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–32025 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–1034]

Solvay S.A.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Solvay S.A., has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of naphthalene sulfonic acid-formaldehyde condensate, sodium salt as an emulsifier in vinylidene chloride copolymer or homopolymer coatings applied to polypropylene polymer films and polyethylene phthalate polymer films intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4634) has been filed by Solvay S.A., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.3400 *Emulsifiers and/or surface active agents* (21 CFR 178.3400) to provide for the expanded safe use of naphthalene sulfonic acid-formaldehyde condensate, sodium salt as an emulsifier in vinylidene chloride copolymer or homopolymer coatings applied to polypropylene polymer films and polyethylene phthalate polymer films intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 16, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–32023 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1036]

Vale Chemical Co., Inc., et al.; Proposal to Withdraw Approval of 13 New Drug Applications and 1 Abbreviated New Drug Application; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDA's) and 1 abbreviated new drug application (ANDA). The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Written requests for a hearing are due by January 4, 1999; data and information in support of the hearing request are due by February 1, 1999.

ADDRESSES: Requests for a hearing, supporting data, and other comments should be identified with Docket No. 98N–1036 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the applications listed in the following table have failed to submit the required