

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]

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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]

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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

annual reports and have not responded to the agency's request by certified mail for submission of the reports.

Application No.	Drug	Applicant
NDA 7-112	Nisaval (pyrilamine maleate) 25 milligram (mg) Tablets.	Vale Chemical Co., Inc., 1201 Liberty St., Allentown, PA 18102.
NDA 11-863	Flavhist Cough Syrup	Boyle & Co., 6330 Chalet Dr., Los Angeles, CA 90022.
NDA 50-042	Potassium Penicillin G Diagnostic Sensitivity Powder, 20,000 units.	Pfizer Inc., 235 East 42d St., New York, NY 10017-5755.
NDA 50-067	Compocillin-VK Chewable Wafers	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.
NDA 50-088	Unipen Injection	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 50-121	Compocillin-VK Tablets	Abbott Laboratories.
NDA 50-122	Compocillin-V Chewable Wafers	Do.
NDA 50-129	Pen-Vee Suspension and Drops	Wyeth-Ayerst Laboratories.
NDA 50-189	Omnipen Tablets	Do.
NDA 50-197	Unipen Injection	Do.
NDA 50-305	Unipen Capsules	Do.
NDA 50-319	Omnipen Chewable Tablets	Do.
NDA 50-413	Geopen Diagnostic Susceptibility Powder	Pfizer Inc.
ANDA 87-387	Aminophylline Injection USP, 25 mg/milliliter	Pharma-Serve, Inc., 218-20 98th Ave., Queens Village, NY 11429.

Therefore, notice is given to the holders of the applications listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) On or before January 4, 1999, a written notice of participation and request for a hearing, and (2) on or before February 1, 1999, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are

contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be

seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: November 12, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98-32069 Filed 12-1-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and