Dated: November 25, 1998.

**Charles W. Gollmar,**

*Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).*

[FR Doc. 98–32056 Filed 12–1–98; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0363]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; New Animal Drugs for Investigational Use

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the collection of information by January 4, 1999.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

### New Animal Drugs for Investigational Use ( 21 CFR Part 511) (OMB Control Number 0910–0117)

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is responsible for the approval of new animal drugs for investigational use. Section 512(j) of the act (21 U.S.C. 360b(j)) requires that a sponsor submit to FDA ''Notice of Claimed Investigational Exemption'' (INAD), prior to shipment of the new animal drug for clinical tests in animals. The regulations implementing statutory requirements for INAD approval have been codified under part 511 (21 CFR part 511). The INAD application must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices, and (4) name and address of each clinical investigator and the approximate number of animals to be treated or the amount of new animal drugs to be shipped. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to ensure that its use is safe, that distribution is controlled to prevent potential abuse, and that edible products of treated animals will not be distributed for food without proper authorization from FDA. The agency utilizes these required records under its ''Bio-Research Monitoring Program'' to monitor the validity of the studies and to ensure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are sponsored primarily by drug industry firms, academic institutions, and the Government. Investigators may include individuals from these entities as well as research firms and members of the medical profession. Respondents to this collection of information are both sponsors and investigators.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 511.1(b)(4) | 190 | 6 | 1,147 | 8 | 9,176 |
| 511.1(b)(5) | 190 | 1.5 | 287 | 140 | 40,180 |
| 511.1(b)(6) | 190 | .005 | 1 | 250 | 250 |
| 511.1(b)(8)(ii) | 190 | .005 | 1 | 20 | 20 |
| 511.1(b)(9) | 190 | .16 | 30 | 8 | 240 |
| Total Burden Hours | | | | | 49,866 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 511.1(a)(3) | 190 | 7.5 | 1,434 | 9 | 12,906 |
| 511.1(b)(3) | 190 | 10 | 1,912 | 1 | 1,912 |
| 511.1(b)(7)(ii) | 190 | 2 | 956 | 3.5 | 3,346 |
| 511.1(b)(8)(i) | 190 | 4 | 956 | 3.5 | 3,346 |
| Total Burden Hours | | | | | 21,510 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated time required for reporting requirements, record preparation, and maintenance for this collection of information is based on agency communication with industry. Additional information needed to make a final calculation of the total burden hours (i.e., the number of respondents, the number of recordkeepers, the number of INAD applications received, etc.) is derived from agency records.

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