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 |
|---|---|---|---|---|---|
| 170.36 | 50 | 1 | 50 | 150 | 7,500 |
| 570.36 | 10 | 1 | 10 | 150 | 1,500 |
| Total | | | | | 9,000 |

[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 of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 170.36(c)(v) | 50 | 1 | 50 | 15 | 750 |
| 570.36(c)(v) | 10 | 1 | 10 | 15 | 150 |
| Total | | | | | 900 |

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

The reporting requirement is for a proposed rule that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were submitted under the terms of the proposed rule; between January 1, 1999, and November 30, 1999, FDA received 23 notices. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: November 10, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 99–32681 Filed 12–16–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98F–1199]**

### Avecia, Inc.; Withdrawal of Food Additive Petition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 7B4525) proposing that the food additive regulations be amended to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper coatings intended for use in contact with aqueous food.

**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.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of January 6, 1999 (64 FR 884), FDA announced that a food additive petition (FAP 7B4525) had been filed by Zeneca Biocides, Foulkstone 1405, 2d, 1800 Concord Pike, P.O. Box 15457, Wilmington, DE 19850–5457. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper coatings intended for use in contact with aqueous foods. Since publication of the filing notice, Zeneca Biocide's specialty chemicals group has been spun-off as Avecia, Inc., 1405 Foulk Rd., P.O. Box 15457, Wilmington, DE 19850–5457. Avecia, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: November 29, 1999.

**Alan M. Rulis,**

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

[FR Doc. 99–32682 Filed 12–16–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98D–0969]**

### Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals (GFI #78); Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78). After the agency considered public comments on a draft of this guidance, announced in the **Federal Register** of November 18, 1998, it determined that revision of the draft guidance was necessary. GFI #78 announces that FDA believes that it should consider the potential human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. For additional information regarding the subject matter dealt with in GFI #78, see the notice of availability of the document entitled ''FDA Response to Comments on a Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing

Animals'' that appears elsewhere in this issue of the **Federal Register**.

**DATES:** Submit comments at any time.

**ADDRESSES:** Submit written comments on GFI #78 to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852.

FDA will also accept electronic comments. Persons who wish to submit electronic comments should go to the FDA home page at www.fda.gov and select ''Dockets'' and follow the instructions.

Submit written requests for single copies of the document entitled ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78) to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See section **III. Electronic Access** of this document for information on electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sharon Thompson, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: sthompso@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of November 18, 1998 (63 FR 64094), FDA announced the availability of a draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78). This draft guidance announced that FDA believed that it should evaluate the human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. The publication of the draft of GFI #78 was the first step in the agency's consideration of the issues related to the use of antimicrobial new animal drugs in food-producing animals. The draft of GFI #78 laid out the agency's rationale for its current thinking about its authority under the Federal Food, Drug, and Cosmetic Act to consider the human health impact of the microbial effects associated with the use of antimicrobial new animal drugs in food-producing animals.

In the **Federal Register** of January 6, 1999 (64 FR 887), FDA announced the availability of a discussion paper entitled ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (Framework Document). The Framework Document was the second step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. FDA made the Framework Document available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop microbial safety policies protective of the public health. The Framework Document is related to GFI #78 in that it sets out a conceptual risk-based framework for evaluating the microbial safety (related to human health impact) of antimicrobial new animal drugs intended for use in food-producing animals.

After considering comments received by the public for both the draft of GFI #78 and the Framework Document, FDA determined that it was necessary to make some revisions to GFI #78. The revisions are intended to make GFI #78 more clearly reflect the agency's intentions regarding this issue. For example, the words ''evaluate'' and ''evaluation'' have been changed to ''consider'' and ''consideration,'' and other changes have been made to indicate that additional testing would not always be needed to determine the potential human health impact of the microbial effects associated with antimicrobial new animal drugs intended for use in food-producing animals.

GFI #78 represents the agency's current thinking that it should consider the potential human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. It does not create or confer any right for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

## II. Comments

Interested persons may, at any time, submit written or electronic comments on GFI #78 to the Dockets Management Branch (address above). Two copies of written comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets in the heading of this document. GFI #78 and written and electronic comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain copies of ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78) at http://www.fda.gov/cvm.

Dated: December 8, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99–32313 Filed 12–14–99; 4:09 pm]

**BILLING CODE 4160–01–F**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98D–0969]**

### Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals (GFI #78); Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78). After the agency considered public comments on a draft of this guidance, announced in the **Federal Register** of November 18, 1998, it determined that revision of the draft guidance was necessary. GFI #78 addresses how under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) FDA intends to consider the potential human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. For additional information regarding the subject matter dealt with in GFI #78, see the notice of availability of the document entitled ''FDA Response to