PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.113 is revised to read as follows:

§ 556.113 Ceftiofur.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of ceftiofur is 30 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine, poultry, and sheep.* A tolerance for residues of ceftiofur in edible tissue is not required.

(2) *Cattle.* Tolerances are established for residues of desfuroylceftiofur (marker residue) in edible cattle tissues at 8 parts per million in kidney (target tissue), 2 parts per million in the liver, 1 part per million in muscle, and 100 parts per billion in milk.

Dated: September 23, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–26650 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 97F–0522]

Food Additives Permitted in Feed and Drinking Water of Animals; Formaldehyde

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution), at a rate of 5.4 pounds (2.5 kilograms) per ton, as an antimicrobial food additive for maintaining animal feeds and feed ingredients *Salmonella* negative for up to 21 days. This action is in response to a food additive petition filed by Anitox Corp. of Buford, GA.

DATES: Effective October 6, 1998; written objections and request for hearing should be submitted by November 5, 1998.

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

FOR FURTHER INFORMATION CONTACT: Henry E. Ekperigin, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0174.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of February 11, 1998 (63 FR 6945), FDA announced that a food additive petition (animal use) (FAP 2237) had been filed by Anitox Corp., P. O. Box 1929, Buford, GA 30519. The petition proposed that the food additive regulations in § 573.460 *Formaldehyde* (21 CFR 573.460) be amended to provide for the safe use of formaldehyde (37 percent aqueous solution) at a rate of 5.4 pounds per ton of animal feeds and feed ingredients to maintain the animal feeds and feed ingredients free of *Salmonella*. The notice of filing provided for a 30-day comment period on the petitioner's environmental assessment. No comments have been received.

The sponsor has amended the petition three times since it was originally filed, on March 2, 1998, providing additional data to establish utility of formaldehyde for the intended use; July 14, 1998, providing the proposed wording to be included on the product labeling that indicated formaldehyde treatment maintains complete feed and feed ingredients *Salmonella* negative up to 21 days from date of application; and July 20, 1998, providing information requested by CVM on the Good Laboratory Practice Statement, clarifying the chemical description of the product on the labeling and in the proposed regulation, and modifying the references to environmental authorities on the labeling and in the proposed regulation. The amended petition proposes that § 573.460 be amended to provide for the safe use of formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution), at a rate of 5.4 pounds (2.5 kilograms) per ton, as an antimicrobial food additive for maintaining animal feeds and feed ingredients *Salmonella* negative for up to 21 days.

Data submitted by the sponsor in support of the petition permitted the agency to make an independent evaluation of whether formaldehyde could be safely used to achieve the intended purpose. When included in complete feed or feed ingredients as proposed, formaldehyde will constitute 0.1 percent of the feed or feed ingredient. The sponsor submitted data showing that this level of formaldehyde should not present a human food safety concern. Formaldehyde occurs in animals as a normal metabolite and is rapidly oxidized to formic acid which further metabolizes into carbon dioxide and water. Formaldehyde is currently approved for use in poultry feed at the inclusion level requested by the petitioner.

Also, formaldehyde has been approved for use in feeds for beef and non-lactating dairy cattle (§ 573.460(a)(2)). The level of formaldehyde in feeds manufactured according to the approval under § 573.460(a)(2) can be as high as 0.25 percent. Formaldehyde is exempted from tolerance requirements under 40 CFR 180.1032 when used as a pesticide/fungicide in cereal grains and forages. Furthermore, although formaldehyde has been found in chronic rat studies to be carcinogenic when inhaled continuously at high doses (> 2 ppm), it has *not* been found to be carcinogenic in rodents when orally ingested at high doses (~5 percent) for a lifetime (Ref. 1).

Formalin (formaldehyde 37 percent aqueous solution) can be life threatening if improperly handled. The proposed label for formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution) acknowledges this fact. To further minimize concerns for worker safety, the label contains adequate directions for use, strong cautionary statements about potential carcinogenic and adverse respiratory effects; information about emergency aid in case of inhalation, ingestion or skin or eye contact, and a contact address and telephone number for reporting adverse reactions experienced by users or to request a copy of the material safety data sheet (MSDS). The label also contains a statement that ''Formaldehyde is subject to SARA Title III, Section 313 reporting'' (Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations). The petition contains assurances by the sponsor that the proposed label will be placed on all containers of the product. However, because formaldehyde is nonproprietary, FDA will include these requirements in the amended formaldehyde food additive regulation. That will enable others marketing formaldehyde to be informed of the requirements and to comply with them.

The petition also includes satisfactory information about the chemical identity of formaldehyde and indicates that formaldehyde will achieve its intended effect in a manner that is safe to the animals consuming the treated products.

II. Conclusion

FDA concludes that the data establish the safety and functionality of formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution), for use as proposed and that the food additive regulations should be amended as set forth below.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person listed above. As provided in § 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may at any time on or before November 5, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA Talk Paper ''Formaldehyde,'' T80–27, May 21, 1980, and T82–40, June 17, 1982.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 573.460 is amended by revising paragraphs (b)(1), (b)(2)(ii), (b)(2)(iii), and (b)(3)(iv), and by adding paragraph (b)(2)(iv) to read as follows:

§ 573.460 Formaldehyde.

* * * * *

(b)(1) The food additive is formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution). It is used at a rate of 5.4 pounds (2.5 kilograms) per ton of animal feed or feed ingredient. It is an antimicrobial agent used to maintain complete animal feeds or feed ingredients *Salmonella* negative for up to 21 days.

(2) * * *

(ii) A statement that formaldehyde solution which has been stored below 40 °F or allowed to freeze should not be applied to complete animal feeds or feed ingredients.

(iii) Adequate directions for use including a statement that formaldehyde should be uniformly sprayed on and thoroughly mixed into the complete animal feeds or feed ingredients and that the complete animal feeds or feed ingredients so treated shall be labeled as containing formaldehyde. The label must prominently display the statement: ''Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days.''

(iv) The labeling for feed or feed ingredients to which formaldehyde has been added under the provisions of paragraph (b)(1) of this section is required to carry the following statement: ''Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days.''

(3) * * *

(iv) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

* * * * *

Dated: September 28, 1998.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 98–26646 Filed 10-5-98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Federal Highway Administration

23 CFR Part 1270

[Docket No. NHTSA–98–4493]

RIN 2127–AH41

Open Container Laws

AGENCY: National Highway Traffic Safety Administration (NHTSA) and Federal Highway Administration (FHWA), Department of Transportation.

ACTION: Interim final rule; request for comments.

SUMMARY: This interim final rule implements a new program established by the Transportation Equity Act for the 21st Century (TEA–21) Restoration Act, which provides for the transfer of Federal-aid highway construction funds to 23 U.S.C. 402 State and Community Highway Safety Program grant funds for any State that fails to enact and enforce a conforming ''open container'' law.

This regulation is being published as an interim final rule, which will go into effect prior to providing notice and the opportunity for comment. Following the close of the comment period, NHTSA will publish a separate document responding to comments and, if appropriate, will amend provisions of the regulation.

DATES: This interim final rule becomes effective on November 5, 1998. Comments on this interim rule are due no later than December 7, 1998.

ADDRESSES: Written comments should refer to the docket number of this notice