

will publish a statement that the prior ranges remain in effect for the next year.

II. 2003 Refrigerator Information

The annual submissions of data for refrigerators, refrigerator-freezers, and freezers have been made and analyzed by the Commission. The ranges of comparability for the products have not changed significantly for these products.³ Therefore, the current ranges for these products (16 CFR part 305, Appendices A1 through A8 and B1 through B3) will remain in effect until further notice.⁴

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

The authority citation for Part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 1998F-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 to provide for the safe use of formaldehyde to improve the handling characteristics of canola and soybean oilseeds and/or meals in feed for beef and dairy cattle, and to provide a description of the food additive. This action is in response to a food additive petition filed by Rumentek Industries Pty Ltd.

DATES: This rule is effective November 21, 2003. Submit written objections and

request for hearing by January 20, 2004. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51 of certain publications in 21 CFR 573.460 as of November 21, 2003.

ADDRESSES: Submit written objections and request for hearing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit objections electronically to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Karen Ekelman, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6653, e-mail: kekelman@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of August 11, 1998 (63 FR 42856), FDA announced that a food additive petition (animal use) (FAP 2241) had been filed by Rumentek Industries Pty Ltd., 63-69 Market St., South Melbourne, Vic 3205 Australia. The petition proposed to amend the food additive regulations in part 573 (21 CFR part 573) to provide for the safe use of formaldehyde to improve the handling characteristics of soybean and canola oilseeds and/or meals in feeds for beef and dairy cattle. The notice of filing provided for a 60-day comment period on the petitioner's environmental assessment. No substantive comments have been received.

In the regulation in § 571.1(c) (21 CFR 571.1(c)), paragraph E of the form for petitions requires full reports of investigations of the safety of a food additive. The Center for Veterinary Medicine (CVM) evaluated information in the petition and in the scientific literature and has determined that the use of formaldehyde to improve the handling characteristics of soybean and canola oilseeds and/or meals in feeds for beef and dairy cattle is safe under the conditions of use prescribed in the amended regulation (§ 573.460).

II. Conclusion

FDA concludes that the data establish the safety and utility of formaldehyde for use as proposed and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 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 CVM by appointment with the information contact person listed previously. 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 determined under 21 CFR 25.32(r) that this action is of a 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.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written objections (see **DATES**). Each objection must be separately numbered, and each numbered objection must 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 must state that a hearing is requested. Failure to request a hearing for any particular objection will constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested must 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 will constitute a waiver of the right to a hearing on the objection. Three copies of all documents must be submitted and must 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives, Incorporation by reference.

■ 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:

³ The Commission's analysis excluded models with energy consumption figures that do not meet the current DOE energy conservation standards. See 62 FR 23102 (April 28, 1997).

⁴ See November 19, 2001 (66 FR 57867), November 26, 2001, (66 FR 59050), December 10, 2001 (66 FR 63749), and January 29, 2002 (67 FR 4173).