

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

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Certifier D. Hawkins

[Docket No. 1998F-0196] (formerly 98F-0196)

Food Additives Permitted in Feed and Drinking Water of Animals; Selenium Yeast

AGENCY: Food and Drug Administration, HHS

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted (FAP) in feed to provide for the safe use of selenium yeast as a source of supplemental selenium in feed supplements for limit feeding for beef cattle and in salt mineral mixes for free-choice feeding for beef cattle. This action is in response to an amendment of a food additive petition filed by Alltech, Inc.

DATES: This rule is effective [insert date of publication in the **Federal Register**]. Submit written or electronic objections and requests for a hearing by [insert date 30 days after date of publication in the **Federal Register**]. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit written or electronic objections and requests for a hearing identified by Docket No. 1998F-0196, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

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- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written objections in the following ways:

- FAX: 301-827-6870.

- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:
Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine (HFV-226), 7519 Standish Pl., Rockville, MD 20855, 240-453-6853.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of May 12, 1998 (63 FR 26193), FDA announced that a food additive petition (animal use) (FAP 2238) had been filed by Alltech Biotechnology Center, 3031 Catnip Hill Pike, Nicholasville, KY 40356. The petition proposed to amend the food additive regulations in § 573.920 *Selenium* (21 CFR 573.920) to provide for the safe use of selenium yeast as a source of selenium in feeds for poultry, swine, and cattle. Based on the information in the petition, the selenium food additive regulation was amended to include the use of selenium yeast in feed for chickens on June 6, 2000 (65 FR 35823). FDA sought additional data from the sponsor before approving use in other species. After these data were submitted for turkeys and swine, the selenium food additive regulation was amended to extend the use of selenium yeast in the complete feeds of turkeys and swine on July 17, 2002 (67 FR 46850). Additional data submitted by the sponsor and further amendments to the petition provided information to extend the use to beef and dairy cattle. Based on the information in the petition, the selenium food additive regulation was again amended to include the use of selenium yeast in the complete feed of beef and dairy cattle on September 3, 2003 (68 FR 52339). Additional data submitted by the sponsor and further amendments to the petition provided information for safe use of selenium yeast as a source of supplemental selenium in feed supplements for limit feeding for beef cattle and in salt mineral mixes for free-choice feeding for beef cattle. The notice

of filing provided for a 60-day comment period on the petitioner's environmental assessment. No substantive comments have been received.

II. Conclusion

FDA concludes that the data establish the safety and utility of selenium yeast, 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) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Veterinary Medicine by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). 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 or electronic objections. 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 are to be submitted and are to 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.

■ 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 573.920 is amended by revising paragraph (h) to read as follows:

§573.920 Selenium.

(h) Selenium yeast is a dried, non-viable yeast (*Saccharomyces cerevisiae*) cultivated in a fed-batch fermentation which provides incremental amounts of cane molasses and selenium salts in a manner which minimizes the detrimental effects of selenium salts on the growth rate of the yeast and allows

for optimal incorporation of inorganic selenium into cellular organic material. Residual inorganic selenium is eliminated in a rigorous washing process and must not exceed 2 percent of the total selenium content in the final selenium yeast product.

(1) Selenium, as selenium yeast, is added to feed as follows:

(i) In complete feed for chickens, turkeys, swine, beef cattle, and dairy cattle at a level not to exceed 0.3 part per million.

(ii) In feed supplements for limit feeding for beef cattle at a level not to exceed an intake of 3 milligrams per head per day.

(iii) In salt-mineral mixtures for free-choice feeding for beef cattle up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(2) Guaranteed organic selenium content from selenium yeast must be declared on the selenium yeast product label.

(3) The additive, as selenium yeast, shall be incorporated into feed as follows:

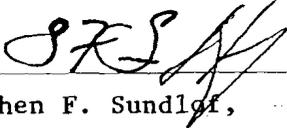
(i) It shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(ii) It shall be incorporated into each ton of salt-mineral mixture for beef cattle from a premix containing no more than 4.5 grams of added selenium per pound.

(4) Usage of this additive must conform to the requirements of paragraphs (e) and (f) of this section.

Dated: 07/06/07

July 6, 2007.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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COPY OF THE ORIGINAL**

Dawn P. Hawkins