

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 1998F-0196]

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Certifier R. LEDESMA

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

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed to provide for the safe use of selenium yeast as a source of selenium in animal feeds 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 Alltech Biotechnology Center.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and request for hearing by [*insert date 60 days after date of publication in the Federal Register*].

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

**FOR FURTHER INFORMATION CONTACT:** Sharon Benz, Center for Veterinary Medicine (HFV 228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6656.

**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 animal 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 this data was submitted for turkeys and swine, the selenium food additive regulation was amended to extend its use in turkeys and swine on July 17, 2002 (67 FR 46850). Additional data submitted by the sponsor and further amendments to the petition provide information to extend its use to 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 there is an acceptable daily intake of 0.4 milligram (mg) per person per day for selenium in the human diet. It has further determined that when supplemental selenium is incorporated at the maximal allowable levels of 0.3 part per million (ppm) of complete feeds, selenium levels in edible animal products are at or below the upper limit of the normal range of selenium in untreated

animals. These upper limits are as follows: Swine, 0.8 ppm in muscle and 1.1 ppm in liver, and dairy cattle (milk) 0.14 ppm. Further, CVM considers the normal range for selenium in beef (liver) is 0.1 to 1.2 ppm; turkeys, 0.6 ppm in muscle and 1.4 ppm in liver; for chicken (liver) 0.1 to 0.9 ppm and for eggs 0.1 to 0.5 ppm.

## **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), 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. 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 by (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.

■ 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:

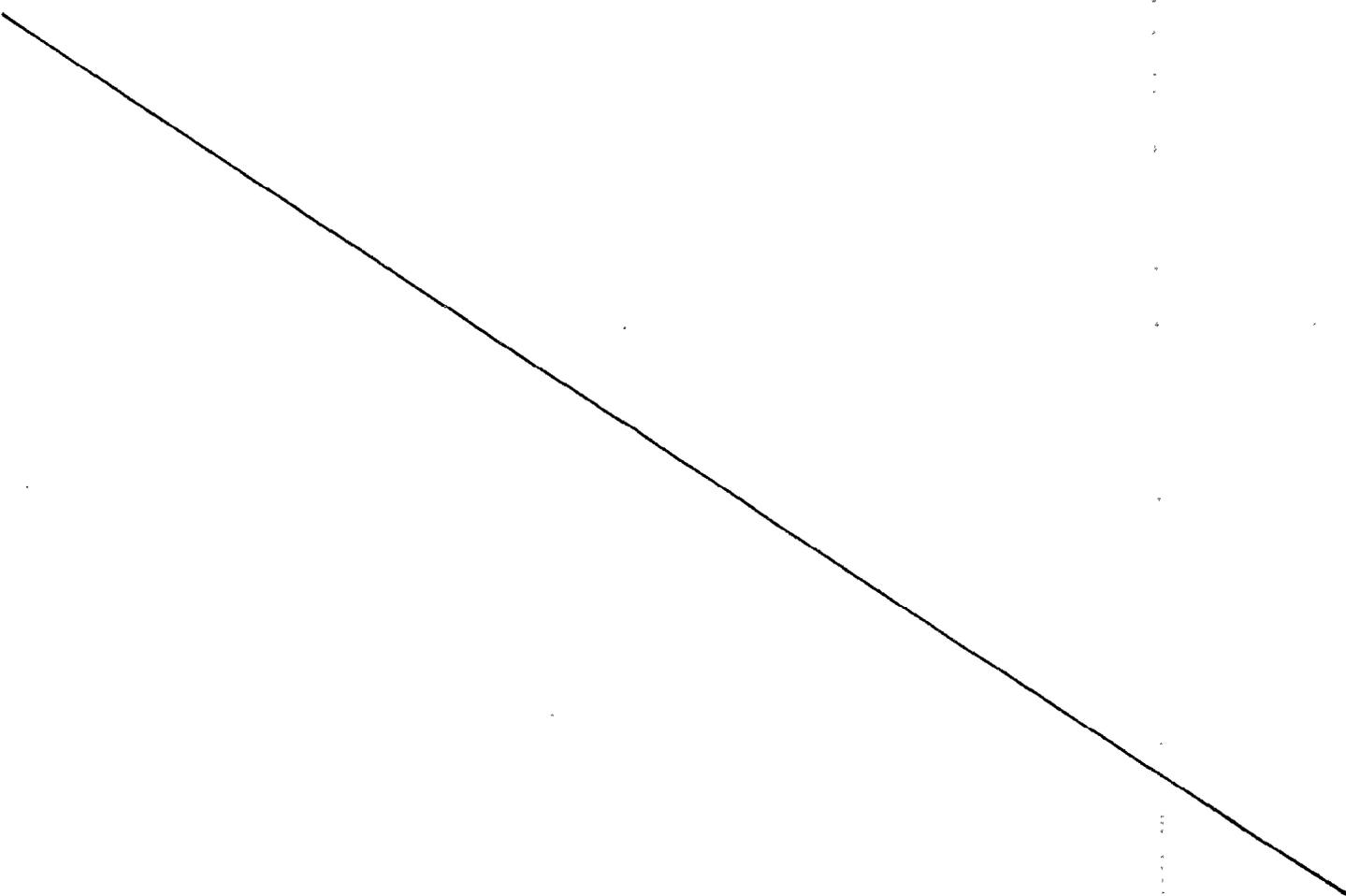
**§ 573.920**     **Selenium.**

\*     \*     \*     \*     \*

(h) The additive selenium yeast is added to complete feed for chickens, turkeys, swine, beef cattle and dairy cattle at a level not to exceed 0.3 part per million.

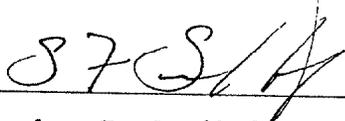
(1) Selenium yeast is a dried, nonviable yeast (*Saccharomyces cerevisiae*) cultivated in a fed-batch fermentation which provides incremental amounts of cane molasses and selenium salts in a manner which minimizes the detrimental effects of selenium salts on the growth rate of the yeast and allows for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

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



(3) Usage of this additive must conform to the requirements of paragraphs (d)(1), (e), and (f) of this section.

Dated: 8/19/03  
August 19, 2003.



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

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