Flora, IL, Flora Muni, NBD RWY 21, Amdt 5

The FAA published an Amendment in Docket No. 30313, Amdt No. 3009 to Part 97 of the Federal Aviation Regulations 67 FR 40594–40595; dated June 13, 2002) under section 97.23 effective August 8, 2002, which is hereby amended as follows:

San Juan, PR, Luis Munoz Marin Intl, VOR Rwy 26, Amdt 19

The FAA published the following procedures in Docket No. 30313; Amdt. No. 3009 to Part 97 of the Federal Aviation Regulations (67 FR 40594–40595: dated, June 13, 2002) under section 97.33 effective August 8, 2002 which are hereby rescinded:

Mammoth Lakes, CA, Mammoth Yosemite, RNAV (GPS) RWY 27, Orig

Mammoth Lakes, CA, Mammoth Yosemite, GPS RWY 27, Orig–A CANCELLED

The FAA published an Amendment in Docket No. 30316, Amdt No. 3011 to Part 97 of the Federal Aviation Regulations (67 FR 43530–43532; dated June 28, 2002) under section 97.23 effective August 8, 2002, which is hereby amended as follows:

New York, NY, John F. Kennedy Intl, COPTER RNAV (GPS) 028, Orig

The FAA published the following procedures in Docket No. 30316, Amdt No. 3011 to Part 97 of the Federal Aviation Regulations (67 FR 43530–43532; dated June 28, 2002) under section 97.23 effective August 8, 2002, which is hereby amended as follows:

Searcy, AR, Searcy Muni, RNAV (GPS) RWY 1, Orig

Searcy, AR, Searcy Muni, RNAV (GPS) RWY 19, Orig

Searcy, AR, Searcy Muni, NDB RWY 1, Amdt 4

Searcy, AR, Searcy Muni, GPS RWY 19, Amdt 1B, CANCELLED

Dallas-Fort Worth, TX, Dallas/Fort Worth International, ILS RWY 18R, Amdt 6

Dallas-Fort Worth, TX, Dallas/Fort Worth International, Converging ILS RWY 18R, Amdt 4

Dallas-Fort Worth, TX, Dallas/Fort Worth International, RNAV (GPS) RWY 18R, Orig

[FR Doc. 02–17581 Filed 7–16–02; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 700 to 799

Title 15 CFR Parts 300 to 799; Republication

CFR Correction

Title 15 CFR parts 300 to 799, revised as of January 1, 2002, is being republished in its entirety. The earlier issuance inadvertently omitted and duplicated text in § 772.1 appearing on pages 553 through 575 inclusive.

[FR Doc. 02–55518 Filed 7–16–02; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 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 in feed to provide for the safe use of selenium yeast as a source of selenium in animal feeds intended for turkeys and swine. This action is in response to a food additive petition filed by Alltech Biotechnology Center.

DATES: This rule is effective July 17, 2002. Submit written objections and request for hearing by September 16, 2002.

ADDRESSES: Submit written objections and requests for a hearing to the Dockets Management Branch (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, subsequent amendments to the petition provided information to extend its use in turkeys and swine.

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 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 at any time file with the Dockets Management Branch (see **ADDRESSES**) written objections by September 16, 2002. 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 Dockets Management Branch 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, and swine at a level not to exceed 0.3 part per million. Usage of this additive must conform to the requirements of paragraphs (d)(1), (e), and (f) of this section.

Dated: July 1, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–17959 Filed 7–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 00N–1457]

Medical Devices; Apnea Monitor; Special Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to create a separate classification for the apnea monitor. The device currently is included in the generic type of device called breathing frequency monitors. The apnea monitor will remain in class II, but will be subject to a special control. The special control is an FDA guidance document that identifies minimum performance, testing, and labeling recommendations for the device. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a ''new'' apnea monitor will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control. FDA is taking these actions because it believes that they are necessary to provide reasonable assurance of the safety and effectiveness of the apnea monitor.

DATES: This rule is effective October 15, 2002.

FOR FURTHER INFORMATION CONTACT: Joanna H. Weithershausen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 22, 2000 (65 FR 57301), FDA published a proposed rule to create a separate classification for the apnea monitor. FDA proposed that the apnea monitor remain in class II, but be subject to a special control. The proposed special control was an FDA guidance document that identified minimum performance, testing, and labeling recommendations for the device.

In the same edition of the **Federal Register**, FDA withdrew its proposed mandatory standard for infant apnea monitors (65 FR 57303) and announced the availability of the draft guidance that FDA intended to serve as the special control for the device (65 FR 57355).

FDA invited interested persons to comment on the proposed rule by December 21, 2000. FDA received no comments. Based on a review of the available information, referenced in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA concludes that special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of this device. FDA has made some revisions to the identification paragraphs in §§ 868.2375 and 868.2377 for clarity. Otherwise, FDA is finalizing the rule as proposed. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the special control guidance.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

III. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a ''new'' apnea monitor will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In the past 10 years, the agency estimates that it has received, on average, approximately four 510(k) submissions per year for breathing frequency monitor devices. FDA estimates that only one or two of these submissions per year pertained to apnea monitor devices.

Based on its review of these 510(k) submissions, FDA believes that presently marketed apnea monitors conform to the guidance and, therefore, the manufacturers of these devices will not have to take further action because of this rule. New manufacturers of apnea monitors will only need to submit 510(k)s, as the statute now requires them to do, and demonstrate that they meet the recommendations of the guidance or in some other way provide equivalent assurances of safety and effectiveness. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will