In support of its assertion, Public Citizen references a report from the International Consultative Group on Food Irradiation titled ''The Development of X-Ray Machines for Food Irradiation (Proceedings of a Consultants' Meeting),'' dated October 1995 (ICGFI report), for its statement that ''neutron activity produced by 5 MeV x-rays is in the order of 60 times greater than that produced by 10 MeV electrons.''

However, contrary to Public Citizen's objection, the ICGFI report shows that the difference in expected neutron activation in irradiated food from electron beams and x-rays has been calculated, thereby permitting use of electron beam studies to estimate neutron activation expected from irradiation with x-rays. Public Citizen has offered no evidence to support its assertion that electron beam studies are inappropriate to support conclusions about x-ray irradiation. FDA is denying the request for a hearing on this point because the evidence submitted by Public Citizen in support of their argument, even if established at a hearing, would not be adequate to justify resolution of the factual issue in the way sought by the objector (§ 12.24(b)(3)).

Moreover, it bears noting that the ICGFI report directly supports FDA's conclusion of safety in the final rule, when it cites 10 MeV x-rays at doses less than 0.5 Gy (the maximum energy and dosage in the final rule) as an example of ''extremely low'' dosage that ''would not produce any significant radioactivity.'' Public Citizen's reference to the conclusion in the ICGFI report that ''increasing the energy of x-rays above 7.5 MeV would result in * * * possible induction of radioactivity in the irradiated food'' is unavailing because that conclusion refers to the uses permitted by the Codex Alimentarius Commission for treating food at dosages up to 10 kGy, which is 20,000 times higher than the 0.5 Gy maximum dosage permitted by the final rule for inspecting food.

Although Public Citizen alleged that the studies that FDA evaluated do not support the safety of x-rays of 10 MeV or lower used for inspection of cargo containers that may contain food, Public Citizen did not present any evidence that would have led to a different conclusion concerning the safety of the subject additive. Because Public Citizen's first and second objections provided no information to support their assertions regarding FDA's safety review, they provide no basis for FDA to reconsider its decision to issue the cargo inspection final rule. As noted previously, a hearing will not be granted on the basis of general descriptions of positions and contentions (see § 12.24(b)(1) and (b)(2)). Public Citizen's third objection relied on information that, even if established at a hearing, would not be adequate to justify resolution of the factual issue in the way sought by the objector. A hearing will be denied if the information submitted are insufficient to justify the factual determination urged, even if accurate (§ 12.24(b)(3)). The issues posed by Public Citizen in support of the objections do not justify the granting of a hearing.

V. Summary and Conclusions

The safety of x-rays produced by a machine source at energies of 10 MeV or lower, to inspect food irradiated at doses up to 0.5 Gy has been thoroughly tested, and the data have been reviewed by the agency. As discussed previously, FDA concluded that the available studies establish the safety of food for human consumption irradiated at doses up to 0.5 Gy as a result of being subjected to x-rays produced by a machine source at energies of 10 MeV or lower. The petitioner has the burden to demonstrate safety before FDA can approve the use of a food additive. Nevertheless, once the agency makes a finding of safety in an approval document, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (*American Cyanamid Co.* v. *FDA*, 606 F. 2d 1307, 1314–1315 (D.C. Cir. 1979)). For the reasons set out previously, the objections do not raise genuine and substantial issues of fact supported by specifically identified reliable evidence that, if established at a hearing would be adequate to justify resolution in the way sought by Public Citizen. Therefore, Public Citizen's objections are not sufficient to justify a hearing under the requirements of § 12.24(b). Accordingly, FDA is overruling the objections and is denying the requests for a hearing.

Dated: July 11, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13947 Filed 7–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[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 July 19, 2007. Submit written or electronic objections and requests for a hearing by August 20, 2007. 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:

- 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: July 6, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–13954 Filed 7–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AM50

Increase in Rates Payable Under the Montgomery GI Bill—Selected Reserve and Other Miscellaneous Issues

AGENCIES: Department of Defense, Department of Homeland Security (United States Coast Guard), and Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends Department of Veterans Affairs (VA) regulations to increase the monthly rates of basic educational assistance payable under the Montgomery GI Bill—Selected Reserve (MGIB–SR) program for fiscal years 2005 and 2006 in accordance with statutory requirements, increase the percentage of basic educational assistance payable to reservists pursuing apprenticeship or other on-the-job training in accordance with the Veterans Benefits Act of 2004, and remove obsolete education break-pay provisions.

DATES: *Effective Date:* This final rule is effective July 19, 2007.

Applicability Dates: The changes in the MGIB–SR rates for fiscal years 2005 and 2006 are applied retroactively to October 1, 2004, and October 1, 2005, respectively to conform to statutory requirements. The change in the percentage of basic educational assistance payable to reservists pursuing apprenticeship or other on-the-job training is applied retroactively to October 1, 2005, to conform to statutory requirements. The changes in the break-pay regulations contained in 38 CFR 21.7640 are effective July 19, 2007.

FOR FURTHER INFORMATION CONTACT: Brandye R. Kidd, Management and Program Analyst, Education Service (225C), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202) 273–7420. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Increase in MGIB–SR Monthly Rates

Under the formula mandated by 10 U.S.C. 16131(b), the rates of basic educational assistance under the MGIB–SR payable to students pursuing a program of education full-time, three-quarter-time, and half-time must be increased by the percentage by which the total monthly Consumer Price Index-W for the 12-month period ending on June 30 preceding the fiscal year during which the increase is applicable exceeds the Consumer Price Index-W for the 12-month period ending on June 30 the previous fiscal year. Using this formula, VA calculated a 2 percent increase for fiscal year 2005 and a 3 percent increase for fiscal year 2006.

Section 16131(b) also requires that VA pay reservists, who are pursuing a program of education at less than half-time, an appropriately reduced rate. Since payment for less than half-time educational programs became available under the MGIB–SR in fiscal year 1990, VA has paid less than half-time students at 25 percent of the full-time rate. In this rule, VA continues that practice and will pay eligible reservists 25 percent of the increased full-time rate described above.

Section 16131(d) requires that reservists pursuing a full-time program of apprenticeship or other on-the-job training be paid a percentage of the basic educational monthly rate. Benefits for the first 6 months of training, the second 6 months of training, and the remainder of the program, are payable at 75 percent, 55 percent, and 35 percent respectively. Based on the section 16131(b) formula described above, there is a 2 percent increase for the apprenticeship and other on-the-job training pursued during fiscal year 2005 and a 3 percent increase for training during fiscal year 2006.

The increase in the MGIB–SR rates are applied in accordance with the applicable statutory provisions discussed above. Thus, VA began paying the 2005 and 2006 fiscal year increases effective October 1, 2004 and October 1, 2005 respectively.

II. Increase in the Percentage of Basic Educational Assistance Payable to Reservists Pursuing Apprenticeship or Other On-the-Job Training

The Veterans Benefits Improvement Act of 2004, Public Law 108–454, temporarily increased the percentages payable for apprenticeship and other on-the-job training from 75 percent, 55 percent, and 35 percent, to 85 percent, 65 percent, and 45 percent of the full-time rate of basic educational assistance, respectively, after September 30, 2005, and before January 1, 2008.

VA began paying the increased rates for reservists pursuing apprenticeship or other on-the-job training effective October 1, 2005, in accordance with Public Law 108–454.

III. Changes to Education Break-Pay Regulations Including the Removal of Obsolete Provisions

We are amending 38 CFR 21.7640(b) to remove obsolete provisions and provide greater clarity of regulations regarding benefit payments for school break periods between terms. In 2003, 38 CFR 21.4138(f), governing payment for breaks between terms, quarters or semesters, was amended to conform to statutory requirements. The final rule was published June 9, 2003, in the **Federal Register** (68 FR 34327–34332). The preamble to that final rule states that changes made to § 21.4138(f) are applicable to the Montgomery GI Bill—Active Duty, Survivors' and Dependents' Educational Assistance Program, Veterans Educational Assistance Program, and MGIB–SR. Although we amended the language in § 21.4138(f) in that final rule, we neglected to make a conforming amendment to § 21.7640(b) regarding payment for breaks, including intervals between terms. This document amends the language in the aforementioned section in accordance with statutory requirements and the previously published rule.

The changes to the break-pay regulations, including the removal of obsolete provisions, are effective from July 19, 2007.

Administrative Procedure Act

Changes to 38 CFR part 21 are being published without regard to the notice-and-comment and delayed-effective-date provisions of 5 U.S.C. 553 since they merely conform VA's existing rules to the statutory requirements. Accordingly, these changes involve interpretive rules that are exempt from