Municipal Airport and changes the title of the airspace designation for the Memphis NAS/Millington Municipal Airport located at Millington, TN, from Memphis NAS, TN, to Millington, TN.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO TN D Millington, TN [Revised]

Memphis NAS/Millington Municipal Airport, TN
(lat. 35°21′20″ N, long. 89°52′10″ W)

That airspace extending upward from the surface to and including 2800 feet MSL within a 5-mile radius of Memphis NAS/Millington Municipal Airport. This Class D airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in College Park, Georgia, on January 24, 1996.

Wade T. Carpenter,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 96–2510 Filed 2–8–96; 8:45 am]

BILLING CODE 4910–13–m

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 92F–0447]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Periodic Acid and Polyethylenimine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of periodic acid (PA) and polyethylenimine (PEI) as fixing agents for the immobilization of glucoamylase enzyme preparations from *Aspergillus niger* for use in the manufacture of beer. This action is in response to a petition filed by Enzyme Bio-Systems, Ltd.

DATES: Effective February 9, 1996; written objections and requests for a hearing by March 11, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3071.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of December 1, 1993 (58 FR 63381), FDA announced that a food additive petition (FAP 1A4288) had been filed by Enzyme Bio-Systems, Ltd., 2600 Kennedy Dr., Beloit, WI 53511, proposing that the food additive regulations be amended to provide for the safe use of periodic acid and polyethyleneimine as fixing agents for immobilizing those enzymes that are generally recognized as safe (GRAS) or approved as food additives.

In a letter of February 2, 1994 (Ref. 1), the petition was amended by the petitioner to provide for the use of PA and PEI as fixing agents for the immobilization of glucoamylase enzyme preparations from *A. niger* for use in the manufacture of light beer. The Bureau of Alcohol, Tobacco, and Firearms, the Federal agency responsible for the regulation of alcoholic beverages such as beer, has informed FDA that the term ''light,'' with respect to the description of beer, is not defined by regulation or any other regulatory standards (Ref. 2). Accordingly, FDA has omitted the term ''light'' in the regulation responding to this petition because there are no applicable Federal standards defining ''light beer.''

Although the filing notice refers to polyethyleneimine as one of the two petitioned additives under agency evaluation, it became apparent during the review of the petition that the name of the additive should be changed to be consistent with the name of the substance that is currently listed in § 173.357(a)(2) (21 CFR 173.357(a)(2)), ''polyethylenimine reaction product with 1,2-dichloroethane.'' While the name of the additives differ, the additives share the same Chemical Abstract Service (CAS) Registry Number (CAS Reg. No. 68130–97–2) and are thus considered chemically identical by the agency. The petitioner has agreed to the name change. Therefore, the petitioned additive is identified as a PEI reaction product with 1,2-dichloroethane (DCE) in the regulation set forth below. However, for purposes of discussion, this preamble will use the term ''polyethylenimine'' to refer to the additive, PEI reaction product with 1,2-dichloroethane.

Glucoamylase enzyme preparation from *A. niger* is the substance that is to be immobilized with the fixing agents set forth in the regulation below; the regulatory status of that enzyme preparation is not addressed by this action. The agency is, however, concurrently evaluating this particular enzyme preparation, along with a variety of other enzymes from other sources, in its review of petition GRASP 3G0016 (Docket No. 84G–0257) for the affirmation of the GRAS status of certain enzymes. (Eight enzyme preparations included in GRASP 3G0016 were recently affirmed as GRAS (60 FR 32904, June 26, 1995).) The petition GRASP 3G0016 contains published data and information to support the view that the enzyme preparation glucoamylase from *A. niger* has had a long history of use prior to 1958 in the preparation of food as well as fermentable materials that are used in the production of alcoholic beverages (Refs. 3 and 4). Further, FDA is not aware of any data or information showing that glucoamylase from *A. niger* poses a safety concern. Finally

FDA acknowledges that under the Federal Food, Drug, and Cosmetic Act (the act), a food manufacturer may market a substance for use in food on the basis of the manufacturer's independent determination that the substance is GRAS and thus exempt from the definition of food additive in section 201(s) of the act (21 U.S.C. 321(s)).

In this scientific and legal context, FDA believes that it is appropriate to proceed with a final rule approving the use of PEI and PA as fixing agents for immobilizing glucoamylase from *A. niger* for use in the manufacture of beer even though the agency has not completed the GRAS affirmation process for all of the enzymes that are the subject of GRASP 3G0016, including glucoamylase enzyme preparation.

In its evaluation of PA and PEI for the proposed use, FDA reviewed the safety of the additives and the chemical impurities that may be present in the additives resulting from the manufacturing processes. Although neither PA nor PEI has been shown to cause cancer, PEI may contain minute amounts of unreacted ethylenimine (EI) and 1,2-dichloroethane because these reactants are used in the manufacture of the additive. EI and 1,2-dichloroethane have been shown to be carcinogens in bioassays with mice and rats (Refs. 5, 6, and 7). The presence of such impurities is not unique to this additive. Residual amounts of reactants and manufacturing aids are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), the so-called ''general safety clause,'' a food additive cannot be approved for a particular use unless a fair evaluation of the data and information available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The anticancer or Delaney clause (section 409(c)(3)(A)) of the act) further provides that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the constituents of the additive. That is, where an additive has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive. (See *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984).)

II. Evaluation of Safety of Petitioned Use of the Additives

FDA estimates that the petitioned use of the additives PA and PEI to fix glucoamylase enzyme preparations would result in mean exposures to these additives of 0.7 micrograms per person per day (µg/person/day) for iodate, which is formed from the decomposition of PA (Ref. 8), and no greater than 330 µg/person/day for PEI (Ref. 9).

FDA does not ordinarily consider chronic toxicological testing to be necessary to determine the safety of additives whose use will result in such low exposure levels (Ref. 10), and the agency has not required such testing here. The agency has reviewed the available toxicological data from acute toxicity studies on the additives. No adverse effects were reported in these studies (Ref. 11).

FDA has evaluated the safety of PEI under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by EI and DCE that may be present as impurities in the additive. This risk evaluation of EI and DCE has two aspects: (1) Assessment of the exposure to the impurities from the proposed use of the additive, and (2) extrapolation of the risk observed in animal bioassays to the conditions of probable exposure to humans.

A. Ethylenimine (EI)

Using estimates of the average intake of beer, FDA estimates the potential exposure to EI from the petitioned use of PEI as an immobilizing agent for glucoamylase enzyme preparations from *A. niger* used in the production of beer to be 0.33 nanograms (ng)/person/day (Ref. 9). To estimate the risk from EI (Ref. 5), the agency used data from a carcinogen bioassay with the B6C3F1 strain of mice using the oral route of exposure. EI treatment caused an increased incidence of both lung and liver tumors that were neoplastic (Ref. 5).

Based on a potential exposure of 0.33 ng/person/day, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to EI from the use of PEI is 1.2×10^{-7}, or less than 1.2 in 10 million (Refs. 12 and 13). Because of the numerous conservative assumptions used in calculating the exposure estimate, actual lifetime averaged individual exposure to EI is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm will result from the proposed use of the additive as a result of exposure to EI.

B. 1,2-Dichloroethane (DCE)

Again, using estimates of average intake of beer, FDA estimates the potential exposure to DCE to be 0.33 ng/person/day (Ref. 9). The agency used data from two bioassays sponsored by the National Cancer Institute to estimate risk; the bioassays showed that DCE is carcinogenic to mice and rats at multiple tissue sites (Ref. 6). Based on the potential exposure of 0.33 ng/person/day, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to DCE from the use of PEI is 6.4×10^{-11}, or less than 6.4 in 100 billion (Refs. 12 and 13). Because of the numerous conservative assumptions used in calculating this exposure estimate, actual lifetime averaged individual exposure to DCE is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm will result from the proposed use of PEI as a result of exposure to DCE.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of EI and DCE impurities in PEI. The agency finds that specifications for PEI are necessary, and that the specifications in § 173.357(a)(2) should be retained. The PA does not require specifications for its use (Ref. 14) because it does not contain impurities that need to be controlled.

III. Conclusions

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of PA and PEI as fixing agents for the immobilization of glucoamylase enzyme preparations from *A. niger* used in the manufacture of beer is safe (Ref. 15). Based on this information, the agency has also concluded that the additives will function as intended. Therefore, § 173.357(a)(2) should be amended as set forth below.

FDA is also amending § 173.357(a)(2) to revise the division name and address listed in the regulation as a source of methods incorporated by reference. The change results from a reorganization of

the Center for Food Safety and Applied Nutrition announced in a final rule published in the Federal Register of April 1, 1993 (58 FR 17091).

In accordance with § 171.1(h) (21 CFR 171.1(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 Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(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

In the notice of filing for this petition that published in the Federal Register of December 1, 1993, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment by January 3, 1994, to the Dockets Management Branch (address above). FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before March 11, 1996, file with the Dockets Management Branch (address above) written objections thereto. 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 shall be submitted and shall 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.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from McKenna & Cuneo to the Direct Additives Branch (HFS–217), amending the filing of Food Additive Petition No. 1A4288, February 2, 1994.

2. Memorandum from Wine and Beer Branch, Bureau of Alcohol, Tobacco, and Firearms to the Direct Additives Branch (HFS–217), regarding regulations for ''light'' beer, October 6, 1994.

3. Underkofler, L. A., R. R. Barton, and S. S. Rennert, ''Microbiological Process Report—Production of Microbial Enzymes and their Applications,'' *Applied Microbiology*, 6:212–221, 1958.

4. Beckhorn, E. J., M. D. Labbee, and L. A. Underkofler, ''Production and Use of Microbial Enzymes for Food Processing,'' *Journal of Agricultural Food Chemistry*, 13:30–34, 1965.

5. Memorandum from the Quantitative Risk Assessment Committee to the Office of Toxicological Sciences (HFS–100), concerning risk estimate for ethyleneimine, August 22, 1985.

6. Memorandum from the Cancer Assessment Committee, Color and Cosmetics Evaluation Branch (HFF–158) to Division of Food and Color Additives (HFF–330), Preliminary Risk Assessment on 1,2-Dichloroethane (DCE) Migrating from Food and Beverage Contact Paper, June 23, 1982.

7. Memorandum from Quantitative Risk Assessment Committee to the Office of Toxicological Sciences (HFF–100), Epichlorohydrin, 1,2-Dichloroethane, and 2,4-Toluenediamine in Reverse Osmosis Membranes (FAP 6B3955), February 2, 1988.

8. Memorandum from the Chemistry Review Branch (HFS–247) to the Direct Additives Branch (HFS–217), concerning letter dated October 20, 1993, and submission dated October 27, 1993, from McKenna & Cuneo, January 11, 1994.

9. Memorandum from the Chemistry Review Branch (HFS–247) to the Direct Additives Branch (HFS–217), Enzyme Bio-Systems Ltd., Submission of September 12, 1991; February 17, 1993.

10. Kokoski, C. J., ''Regulatory Food Additive Toxicology'', in *Chemical Safety Regulation and Compliance*, edited by Homburger, F. and J. K. Marquis, S. Karger, New York, NY, pp. 24–33, 1985.

11. Memorandum from the Additive Evaluation Branch (HFF–158) to the Direct Additives Branch (HFF–217), concerning evaluation of Food Additive Petition No. 1A4288, February 25, 1992.

12. Memorandum from the Chemistry Review Branch (HFS–247) to the Direct Additives Branch (HFS–217), Exposure estimate for QRAC evaluation, February 8, 1994.

13. Memorandum from the Direct Additives Branch (HFS–217) to the Quantitative Risk Assessment Committee (HFS–308), Estimation of the upper-bound lifetime risk for ethyleneimine (EI) and 1,2-dichlorethane (DCE) for uses requested in FAP 1A4288 (Enzyme Bio-Systems Ltd.), April 15, 1994.

14. Memorandum from the Chemistry Review Branch (HFS–247) to the Direct Additives Branch (HFS–217) concerning Food Additive Petition No. 1A4288, April 5, 1994.

15. Memorandum from the Additives Evaluation Branch No. 1 (HFS–226) to the Direct Additives Branch (HFS–217), final evaluation memorandum, May 31, 1994.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Section 173.357 is amended in the table in paragraph (a)(2) under the headings ''Substances'' and ''Limitations'' by alphabetically adding a new entry for ''periodic acid'' and by revising the entry for ''polyethylenimine reaction product with 1,2-dichloroethane'' to read as follows:

§ 173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

* * * * *

(a) * * *

(2) * * *

Substances	Limitations
* * * *	* * *
Periodic acid (CAS Reg. No. 10450–60–9).	
Polyethylenimine reaction product with 1,2-dichloroethane (CAS Reg.No. 68130–97–2) is the reaction product of homopolymerization of ethylenimine in aqueous hydrochloric acid at 100 °C and of cross-linking with 1,2-dichloroethane. The finished polymer has an average molecular weight of 50,000 to 70,000 as determined by gel permeation chromatography. The analytical method is entitled ''Methodology for Molecular Weight Detection of Polyethylenimine,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS–215), 200 C St. SW., Washington, DC 20204, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.	May be used as a fixing material in the immobilization of glucoamylase enzyme preparations from *Aspergillus niger* for use in the manufacture of beer. May be used as a fixing material in the immobilization of: 1. Glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter. 2. Glucoamylase enzyme preparations from *Aspergillus niger* for use in the manufacture of beer. Residual ethylenimine in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography-mass spectrometry. The residual ethylenimine is determined by an analytical method entitled ''Methodology for Ethylenimine Detection in Polyethylenimine,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Residual 1,2-dichloroethane in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography. The residual 1,2-dichloroethane is determined by an analytical method entitled, ''Methodology for Ethylenedichloride Detection in Polyethylenimine,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS–215), 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

Dated: January 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–2747 Filed 2–8–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 520, 522, and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name for SmithKline Animal Health Products, Division of SmithKline Beckman Corp. to SmithKline Beecham Animal Health due to a merger with Beecham Laboratories, Division of Beecham, Inc., and to reflect a change of sponsor for approved new drug applications (NADA's) previously held by SmithKline Beecham Animal Health to Pfizer, Inc.

EFFECTIVE DATE: February 9, 1996.

FOR FURTHER INFORMATION CONTACT: Judith M. O'Haro, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 8, 1991 (56 FR 50652), the animal drug regulations were amended to reflect the change of sponsor name for SmithKline Animal Health Products, Division of SmithKline Beckman Corp. to SmithKline Beecham Animal Health due to a merger with Beecham Laboratories, Division of Beecham, Inc. The regulations were amended to reflect the change of sponsor for 28 new animal drug applications (NADA's) from Beecham Laboratories, Division of Beecham Inc., to SmithKline Beecham Animal Health, and the change of sponsor for 22 NADA's from Norden Laboratories, Inc., to SmithKline Beecham Animal Health also due to the merger. The new company was assigned a new sponsor labeler code. The amended regulations did not reflect SmithKline Beecham Animal Health as the new sponsor in §§ 558.58, 558.311, 558.355, and 558.625. The sponsor currently listed for these products is Pfizer, Inc. Accordingly, the agency is amending these sections to reflect the change of sponsor.

In the Federal Register of November 2, 1995 (60 FR 55657), FDA published a document that amended the animal drug regulations to reflect a change of sponsor for 62 NADA's from SmithKline Beecham Animal Health to Pfizer, Inc. FDA inadvertently amended the regulations in 21 CFR 520.2260a, 520.2260b, and 520.2260c to reflect Pfizer, Inc. as the sponsor. However, Solvay Animal Health remains the sponsor of these sulfamethazine containing applications. The codified sections that should have been amended are 520.2220a, 520.2220b, 520.2220c, 520.2220d, and 522.2220. In addition, the agency omitted an amendment to 21 CFR 520.45a(a)(2). Accordingly, the agency is amending these sections to reflect this change of sponsor.

List of Subjects

21 CFR Parts 520 and 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.