PART 217—APPLICATION FOR ANNUITY OR LUMP SUM

1. The authority citation for part 217 continues to read as follows:

Authority: 45 U.S.C. 231d and 45 U.S.C. 231f.

2. Section 217.9, paragraph (b)(1), is amended by adding directly after the words ''paragraph (b)(2)'', the words ''and paragraph (b)(3)'', and by adding a new paragraph (b)(3) to read as follows:

§ 217.9 Effective period of application.

* * * * *

(b) * * *

(3) *Application for spouse annuity filed simultaneously with employee disability annuity application.* When the qualifying employee's annuity application effective period is determined by the preceding paragraph (b)(2) of this section, a spouse who meets all eligibility requirements may file an annuity application on the same date as the employee claimant. The spouse application will be treated as though it were filed on the later of the actual filing date or the employee's annuity beginning date.

* * * * *

3. Section 217.30 is amended by removing paragraph (b), redesignating paragraph (c) as paragraph (b), and by adding a new paragraph (c) to read as follows:

§ 217.30 Reasons for denial of application.

* * * * *

(c) The applicant files an application more than three months before the date on which the eligible person's benefit can begin except if the application is for an employee disability annuity or for a spouse annuity filed simultaneously with the employee's disability annuity application.

Dated: June 18, 2002.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 02–15911 Filed 6–24–02; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 89F–0452]

Secondary Direct Food Additives Permitted for Direct Addition to Food for Human Consumption; Materials Used as Fixing Agents in the Immobilization of Enzyme Preparations

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 dimethylamine-epichlorohydrin and acrylamide-acrylic acid resins, individually or together, as fixing agents for the immobilization of glucose isomerase enzyme preparations. This action is in response to a petition filed by Enzyme Bio-Systems Ltd.

DATES: This rule is effective June 25, 2002. Submit written objections and requests for a hearing by July 25, 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: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3107.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of November 17, 1989 (54 FR 47828), FDA announced that a food additive petition (FAP 9A4175) had been filed by Enzyme Bio-Systems Ltd., International Plaza, Route 9W, Englewood Cliffs, NJ 07632. The petition proposed to amend the food additive regulations to provide for the safe use of dimethylamine-epichlorohydrin copolymer (DEC) and acrylamide-acrylic acid resin (AAR) as fixing agents for immobilizing glucose isomerase enzyme.

DEC and AAR will be used, individually or together, to immobilize glucose isomerase enzymes for the purpose of converting glucose to a mixture of glucose and fructose for the production of high fructose corn syrup (HFCS). The glucose isomerase immobilized with the petitioned polymers may be used as a substitute for one or more of the immobilized glucose isomerases currently in use.

In its evaluation of the safety of the petitioned substances, FDA has reviewed the safety of the additives and the chemical impurities that may be present in them resulting from the manufacturing processes. Although the petitioned polymers have not been shown to cause cancer, they may contain minute amounts of carcinogenic impurities resulting from their manufacture. DEC may contain traces of unreacted epichlorohydrin and its degradation product, 1,3-dichloro-2-propanol. AAR may contain minute amounts of the unreacted monomer, acrylamide. These chemical impurities have been shown to cause cancer in test animals. Residual amounts of reactants and their impurities commonly are found as contaminants of chemical products, including food additives.

II. Determination of Safety

Under the general safety standard of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data 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 food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed 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 impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is evaluated properly under the general safety standard using risk assessment procedures to determine whether there is reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

III. Safety of the Petitioned Use of the Additives

FDA has estimated that the petitioned use of the additives, DEC and AAR, will result in a daily intake of 210 micrograms per person per day (µg/p/d) and 83 µg/p/d, respectively (Ref. 1).

FDA has evaluated the safety of DEC and AAR under the general safety

standard and concludes that the estimated dietary exposure to the additives resulting from the petitioned uses is safe. In reaching this conclusion, FDA reviewed all available toxicological data and used risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by the carcinogenic impurities that may be present in the petitioned additives. The chemical impurities considered are acrylamide in AAR and epichlorohydrin and 1,3-dichloro-2-propanol in DEC.

The risk evaluation of the carcinogenic impurities has two aspects: (1) Assessment of exposure to the impurities from the petitioned use of the additives; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. Acrylamide

FDA has estimated the upper-bound exposure to acrylamide from the petitioned use of AAR to be 2 nanograms per person per day (ng/p/d), corresponding to a dietary concentration of 0.67 part-per-trillion (pptr) in the daily diet (3 kg) (Ref. 2). This estimate is conservative, as it does not account for the removal of impurities, including acrylamide, from the crude HFCS during the purification process.

1. Acrylamide as a Neurotoxin

Acrylamide is a recognized neurotoxin. To derive the safe exposure level to acrylamide as a neurotoxin, the agency used a study by J. D. Burek et al. (Ref. 3). FDA, using an uncertainty factor of 1,000 (equivalent to a safety factor), determined the acceptable daily intake of acrylamide with respect to neurotoxicity to be 12 µg/p/d based on the neurotoxicity evaluation and absence of a neurotoxic effect (Refs. 4 and 5). Therefore, based on the agency's estimate that the exposure to acrylamide will not exceed 2 ng/p/d, FDA concludes that the exposure to acrylamide from the petitioned use of AAR does not pose a neurotoxic risk.

2. Acrylamide as a Carcinogen

To estimate the upper-bound limit of lifetime human risk from exposure to acrylamide as a carcinogen resulting from the petitioned use of AAR, the agency used published data from a long-term rat bioassay on acrylamide, conducted by Johnson et al., in addition to unpublished data from this bioassay in the agency's files (Refs. 6 and 7). The authors of this bioassay reported that acrylamide administered to rats via drinking water is associated with statistically significant increased incidences of thyroid follicular adenomas and testicular mesotheliomas in male rats, and of mammary tumors (adenomas or adenocarcinomas, fibromas or fibroadenomas, adenocarcinomas alone), central nervous system tumors (brain astrocytomas, brain or spinal cord glial tumors), and uterine tumors (adenocarcinomas) in female rats.

Based on the agency's estimate that exposure to acrylamide will not exceed 2 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from exposure to acrylamide from the petitioned use of the subject additive is 2.2×10^{-8} or 22 in 1 billion (Ref. 8). Considering that this estimated upper-bound risk is based on very conservative assumptions, the agency believes that the probable lifetime human risk would be significantly less than the estimated upper-bound limit of lifetime human risk. Therefore, the agency concludes that there is reasonable certainty that no harm from exposure to acrylamide would result from the petitioned use of AAR.

B. Epichlorohydrin

FDA has estimated the exposure to epichlorohydrin from the petitioned use of DEC to be 2.1 ng/p/d or 0.7 pptr of the daily diet (Refs. 1 and 9). This estimate is conservative, as it does not account for the removal of residual impurities, including epichlorohydrin, during the processing of the crude HFCS.

The agency used data from a carcinogenesis bioassay conducted by Konishi et al. (Ref. 10), on rats fed epichlorohydrin via their drinking water, to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of DEC. The authors reported that the test material caused significantly increased incidence of stomach papillomas and carcinomas in rats.

Based on the agency's estimate that exposure to epichlorohydrin will not exceed 2.1 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from exposure to epichlorohydrin resulting from the petitioned use of the subject additive is 9.5×10^{-11} or 95 in 1 trillion (Ref. 8). Considering that this upper-bound estimated risk is based on very conservative assumptions, the agency believes that the probable lifetime human risk would be significantly less than the estimated upper-bound limit of lifetime human risk. Therefore, FDA concludes that there is reasonable certainty that no harm from exposure to epichlorohydrin would result from the petitioned use of DEC.

C. 1,3-Dichloro-2-propanol (DCP)

DCP is the product of epichlorohydrin degradation in water. The current regulation for the use of DEC resin establishes a residual limit for DCP at 1,000 ppm in the DEC resin (21 CFR 173.60 (b)(3)). The agency has estimated that exposure to DCP from the petitioned use for DEC will not exceed 210 ng/p/d (Refs. 1 and 9). This estimate is conservative, as it does not account for the removal of residual impurities, including DCP, during the processing of the crude HFCS.

The agency used data from a 1986 drinking water bioassay in rats (Ref. 11) to estimate the worst case upper-bound lifetime cancer risk from exposure to DCP from the petitioned use of DEC. This risk was calculated as 1.2×10^{-7} or 12 in 100 million (Refs. 12 and 13). Considering that this upper-bound estimated risk is based on very conservative assumptions, the agency believes that the probable lifetime human risk would be significantly less than the upper-bound limit of lifetime human risk. Therefore, FDA concludes that there is reasonable certainty that no harm from exposure to DCP would result from the petitioned use of DEC.

D. Need for Specifications

The agency also has considered whether specifications are necessary to control the amount of acrylamide present as an impurity in AAR and epichlorohydrin and DCP in DEC. The agency finds that specifications are not necessary for the following reasons:

1. The agency would not expect these impurities to become components of food at other than extremely low levels because of the low levels at which acrylamide, epichlorohydrin, and DCP may be expected to remain as impurities following production and purification of the additives and HFCS, and

2. The upper-bound limits of lifetime human risk from exposure to acrylamide, epichlorohydrin, and DCP are very low, 2.2×10^{-8}, 9.5×10^{-11}, and 1.2×10^{-7} respectively.

IV. Conclusions

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additives as fixing agents in the immobilization of glucose isomerase enzyme preparations is safe, (2) that the additives will achieve their intended technical effect, and therefore, (3) the regulations in § 173.357 (21 CFR 173.357) should be amended as set forth below.

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. 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.

V. Environmental Impact

The agency has determined under 21 CFR 25.32(j) that this action is of a type that individually or cumulatively does not have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

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 July 25, 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 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.

VIII. References

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

1. Memorandum dated November 22, 1989, from the Food and Color Additives Review Section to the Direct Additives Branch, ''FAP 9A4175: Enzyme Bio-Systems Ltd. Dimethylamine-Epichlorohydrin Resin (DEC) and Acrylic Acid-Acrylamide Resin (AAR) as Fixing Agents for Glucose Isomerase Immobilized Enzyme Preparations. Submission of 9–25–89.''

2. Memorandum dated August 17, 1998, from the Division of Product Policy, Scientific Support Branch, Chemistry and Environmental Review Team (CERT) to the Division of Petition Control, ''FAP 9A4175 (MATS# 438)—Enzyme Bio-Systems Ltd. Exposure to Acrylamide Monomer from the Use of Acrylic Acid-Acrylamide Resin (AAR) as a Fixing Agent for Glucose Isomerase Immobilized Enzyme Preparations. Division of Petition Control (DPC, HFS–215) Verbal Request dated 8–4–98.''

3. Burek, J. D., R. R. Albee, J. E. Beyer, et al., ''Subchronic Toxicity of Acrylamide Administered to Rats In the Drinking Water Followed by Up to 144 Days of Recovery,'' *Journal of Environmental Pathology and Toxicology*, 4:157–182, 1980.

4. Memorandum dated September 9, 1997, from the Division of Health Effects Evaluation to the Division of Product Policy, ''Acrylamide, New Information and Re-evaluation of the Neurotoxicity Potential and Tentative ADI of Acrylamide as a Migrant.''

5. Memorandum dated January 24, 2000, from the Division of Health Effects Evaluation to the Division of Product Policy, ''Final Safety Evaluation of Acrylamide-Acrylic Acid Resin (AAR) and Dimethylamine-epichlorohydrin Resin (DEC) as Fixing Agents for Immobilized Glucose Isomerase Used in Foods. Memo of Div. of Product Manufacture and Use, Chemistry and Environmental Review Team (CERT) 4/28/99, Received 5/5/99. QRAC Concurrence of Estimation of the Upper Bound Lifetime Risk from Residual Epichlorohydrin and Acrylamide (S. Henry Memo Dated Dec. 20, 1999).''

6. Johnson, K. A., S. J. Gorzinski, K. M. Bodner, R. A. Campbell, C. H. Wolf, M. A. Friedman, and R.W. Mast, ''Chronic Toxicity and Oncogenicity Study on Acrylamide Incorporated in the Drinking Water of Fischer 344 Rats,'' *Toxicology and Applied Pharmacology*, 85:154–168, 1986.

7. Memorandum of Conference, FDA, CFSAN, Washington, DC Cancer Assessment Committee Meeting on Acrylamide, February 13 and June 6, 1985, and May 31, 1996.

8. Memorandum dated May 7, 1999, from the Regulatory Policy Branch to the Quantitative Risk Assessment Committee, ''Estimation of the Upper-Bound Lifetime Risk from Residual Epichlorohydrin and Acrylamide Monomers in Dimethylamine-Epichlorohydrin and Acrylic Acid-Acrylamide Resins, Respectively, for Use as Fixing Agents in Immobilizing Glucose Isomerase Enzyme Preparation: Use Requested in Food Additive Petition No. 9A4175 from Enzymes Bio-Systems Ltd.''

9. Memorandum dated August 7, 1997, from the Division of Product Policy to Division of Petition Control, ''FAPs 9A4175, 3B3677, 6B3940, 3B3696, 9B4131, 9B4132 and 9B4133. DPC Request to Identify and Address Unresolved Issues in the Pending Acrylamide Petitions.''

10. Konishi, Y. et al., ''Forestomach Tumors Induced by Orally Administered Epichlorohydrin in Male Wistar Rats,'' *Gann*, 71:922–923, 1980.

11. Research and Consulting Co., AG, Project 017820, Report Parts 1–4, February 24, 1986: 104-Week Chronic Toxicity and Carcinogenicity Study with 1,3-Dichloropropan-2-ol in the Rats; Food Master File 000543, Vol. 11.

12. Memorandum dated August 24, 1998, from the Executive Secretary, Cancer Assessment Committee, to the Chairman, Cancer Assessment Committee, ''FAP 9A4175: Worst-Case Cancer Risk Assessment for 1,3-dichloropropanol (DCP).''

13. Memorandum dated March 25, 1999, from Division of Health Effects Evaluation to the Executive Secretary, Cancer Assessment Committee, ''Expedited Risk Assessment for 1,3-dichloropropanol Memo of August 24, 1998. Accepting Risk Estimate for Regulation of FAP 9A4175.''

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: 21 U.S.C. 321, 342, 348.

2. Section 173.357 is amended in the table in paragraph (a)(2) by alphabetically adding entries for ''Acrylamide-acrylic acid resin'' and ''Dimethylamine-epichlorohydrin resin'' to read as follows:

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

* * * * *

(a) * * *

(2) * * *

Substances	Limitations
Acrylamide-acrylic acid resin: Complying with § 173.5(a)(1) and (b) of this chapter.	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.

Substances	Limitations
* * * * *	
Dimethylamine-epichlorohydrin resin: Complying with § 173.60(a) and (b) of this chapter.	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
* * * * *	

* * * * *

Dated: June 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–15901 Filed 6–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name and Address

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's name and address for Akey, Inc.

DATES: This rule is effective June 25, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Akey, Inc., P.O. Box 607, Lewisburg, OH 45338, has informed FDA of a change of name and address to North American Nutrition Companies, Inc., C.S. 5002, 6531 St., Rt. 503, Lewisburg, OH 45338. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Akey, Inc.'' and by alphabetically adding a new entry for ''North American Nutrition Companies, Inc.'', and in the table in paragraph (c)(2) by revising the entry for ''017790'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
North American Nutrition Companies, Inc., C.S. 5002, 6531 St., Rt. 503, Lewisburg, OH 45338	017790
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
017790	North American Nutrition Companies, Inc., C.S. 5002, 6531 St., Rt. 503, Lewisburg, OH 45338
* * * * * * *	

Dated: May 24, 2002.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–15900 Filed 6–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA28

TRICARE; Revisions to Coverage Criteria for Transplants, Cardiac and Pulmonary Rehabilitation and Ambulance Services

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule implements a number of regulatory revisions relating to TRICARE coverage for transplants and related services, cardiac and pulmonary rehabilitation and ambulance services. The revisions are clarification of TRICARE coverage and time limitations on preauthorizations for solid organ and stem cell transplantation for beneficiaries whose conditions are considered appropriate