individual's annuity in order to recover an overpayment of benefits. The regulation also adds a provision to explain when an actuarial adjustment in an annuity takes effect when an annuity is paid by electronic funds transfer (EFT).

DATES EFFECTIVE: July 1, 1998.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Michael C. Litt, Bureau of Law, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611, (312) 751–4929, TDD (312) 751–4701.

SUPPLEMENTARY INFORMATION: Section 255.8 of the Board's regulations (62 FR 64164) provides for recovery of an overpayment by means of an actuarial adjustment. In accordance with this provision, an overpayment may be recovered by permanently reducing the annuity payable to the individual from whom recovery is sought. The calculation of the reduction is performed using actuarial tables. Formerly, the authority for the use of these tables is contained in a Board Order which is not readily available to the public. This amendment adds language specifying that the Board will use the tables and interest rate adopted in accordance with the triennial evaluation of the railroad retirement trust funds as required by section 15(g) of the Railroad Retirement Act.

Previously, where an annuity is paid by check, an actuarial reduction takes effect, and the overpayment is recovered, upon negotiation of the first check which reflects the adjustment. The amendment adds language to provide that, in the case of an annuity paid by electronic funds transfer, the adjustment is effective when the first payment reflecting the actuarially adjusted rate is deposited.

The rule was published as a proposed rule February 12, 1998 (63 FR 7088) requesting comments on or before April 13, 1998. No comments were received.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action for purposes of Executive Order 12866. Therefore, no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR 255.8

Railroad employees, Railroad retirement.

For the reasons set out in the preamble, title 20, part 255 of the Code of Federal Regulations is amended as follows:

PART 255—RECOVERY OF OVERPAYMENTS

1. The authority citation for part 255 continues to read as follows:

Authority: 45 U.S.C. 231f(b)(5); 45 U.S.C. 231(i).

2. Section 255.8 is revised to read as follows:

§ 255.8 Recovery by adjustment in connection with subsequent payments.

(a) Recovery of an overpayment may be made by permanently reducing the amount of any annuity payable to the individual or individuals from whom recovery is sought. This method of recovery is called an actuarial adjustment of the annuity. The Board cannot require any individual to take an actuarial adjustment in order to recover an overpayment nor is an actuarial adjustment available as a matter of right. An actuarial adjustment becomes effective and the debt is considered recovered when, in the case of an individual paid by electronic funds transfer, the first annuity payment reflecting the annuity rate after actuarial adjustment is deposited to the account of the overpaid individual, or, in the case of an individual paid by check, the first annuity check reflecting the annuity rate after actuarial adjustment is negotiated.

Example. An annuitant agrees to recovery of a $5,000 overpayment by actuarial adjustment. However, the annuitant dies before negotiating the first annuity check reflecting the actuarially-reduced rate. The $5,000 is not considered recovered. If the annuitant had negotiated the check before he died, the $5,000 would be considered fully recovered.

(b) In calculating any adjustment under this section, beginning with the first day of January after the tables and long-term or ultimate interest rate go into effect under section 15(g) of the Railroad Retirement Act (the triennial evaluation), the Board shall use those tables and long-term or ultimate interest rate.

Dated: May 21, 1998.

By Authority of the Board,

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 98–14326 Filed 5–29–98; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 87F–0162]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

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 sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by the condensation of 1 mole of nonylphenol and an average of 9 to 10 moles of ethylene oxide) for use as an emulsifier in the manufacture of polyvinyl acetate and vinyl-acrylate copolymers intended for use in coatings for paper and paperboard that will contact food. This action responds to a petition filed by American Cyanamid Co.

DATES: The regulation is effective June 1, 1998; written objections and requests for a hearing by July 1, 1998.

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

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of June 4, 1987 (52 FR 21122), FDA announced that a food additive petition (FAP 6B3908) had been filed by American Cyanamid Co., One Cyanamid Plaza, Wayne, NJ 07470. The petition proposed to amend the food additive regulations in § 178.3400 *Emulsifiers and/or surface-active agents* (21 CFR 178.3400) to provide for the safe use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt for use as a surfactant in contact with food.

The agency has determined that the data submitted in the food additive petition provided information for a more specific identification of the additive as sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety

produced by the condensation of 1 mole of nonylphenol and an average of 9 to 10 moles of ethylene oxide). Therefore, FDA is using this description of the additive in the codified section of the final rule. The agency has also determined that the data submitted in the petition are adequate to support its limited use as a surfactant in the manufacture of polyvinyl acetate and vinyl-acrylate copolymers intended for use in coatings for paper and paperboard food packaging.

Subsequent to the filing of the petition, American Cyanamid Co. was acquired by Cytec Industries, Inc., Five Garret Mountain Plaza, West Paterson, NJ 07424. As a result of this change in ownership, FDA was informed in a letter dated September 20, 1995, that the petition and all related records be amended to reflect this change in ownership for this food additive petition.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted ethylene oxide and minute amounts of 1,4-dioxane as impurities resulting from its manufacture. These chemicals have been shown to cause cancer in test animals. Residual amounts of impurities are commonly found as constituents of chemical products, including food additives.

II. Determination of Safety

Under the so-called ''general safety clause'' 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 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 (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

III. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by the condensation of 1 mole of nonylphenol and an average of 9 to 10 moles of ethylene oxide) as an emulsifier/surfactant in the manufacture of polyvinyl acetate and vinyl-acrylate copolymers intended for use in coatings for paper and paperboard food packaging, will result in exposure of no greater than 120 parts per billion (ppb) of the additive in the daily diet (3 kilograms (kg)), or an estimated daily intake (EDI) of 0.36 milligrams per person per day (mg/p/d) (Refs. 1 and 2).

FDA concludes that the currently regulated use of the additive in adhesives (21 CFR 175.105) and the petitioned use in polyvinyl acetate and vinyl-acrylate copolymers intended for use as coatings for paper and paperboard will result in a cumulative exposure no greater than 148 ppb, or an EDI of 0.44 mg/p/d.

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 3), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small dietary exposure resulting from the proposed use of this additive is safe.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by ethylene oxide and 1,4-dioxane, the carcinogenic chemicals that may be present as impurities in the additive. The risk evaluation of ethylene oxide and 1,4-dioxane has two aspects: (1) Assessment of exposure to the impurities from the petitioned use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. Ethylene Oxide

FDA has estimated the cumulative exposure to ethylene oxide from both the regulated use of the additive in adhesives and the petitioned use of the additive as an emulsifier/surfactant in the manufacture of polyvinyl acetate and vinyl-acrylate copolymers intended for use in paper and paperboard coatings that will contact food to be no more than 1.5 parts per trillion (pptr) in the daily diet (3 kg) or 4.5 nanograms (ng)/person/day (Ref. 2). The agency used data from a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Germany (Ref. 4) to estimate the upper-bound limit of lifetime human risk from the cumulative exposure to this chemical resulting from the currently regulated use and the proposed use of the additive. The results of the bioassay on ethylene oxide demonstrated that ethylene oxide was carcinogenic for female rats under the conditions of the study. The author reported that the rodent bioassay showed that the test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinomas in situ of the glandular stomach.

Based on the agency's estimate that the cumulative exposure to ethylene oxide will not exceed 4.5 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the regulated and proposed uses of the subject additive is 8.4×10^{-9} or 8.4 in one billion (Refs. 2 and 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to ethylene oxide is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to ethylene oxide would result from the proposed use of the additive.

B. 1,4-Dioxane

FDA has estimated the cumulative exposure to 1,4-dioxane from both the regulated use of the additive in adhesives and the petitioned use of the additive as an emulsifier/surfactant for paper and paperboard coatings in contact with food to be no more than 0.15 pptr of the daily diet (3 kg), or 0.45 ng/person/day (Refs. 2 and 5). The agency used data from a carcinogenesis bioassay on 1,4-dioxane, conducted by the National Cancer Institute (Ref. 6) to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the regulated use of the additive in adhesives and the proposed use of the additive. The results of the bioassay on

1,4-dioxane demonstrated that the material was carcinogenic for female rats under the conditions of the study. The authors reported that the rodent bioassay showed that the test material caused a significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

Based on the agency's estimate that exposure to 1,4-dioxane will not exceed 0.45 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from both the regulated and proposed uses of the subject additive is 1.6×10^{-11}, or 1.6 in 100 billion (Refs. 2 and 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 1,4-dioxane is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to 1,4-dioxane would result from the proposed use of the additive.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of ethylene oxide and 1,4-dioxane present as impurities in the food additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which ethylene oxide and 1,4-dioxane may be expected to remain as impurities following production of the additive, the agency would not expect the impurities to become components of food at other than extremely low levels; and (2) the upper-bound limits of lifetime human risk from exposure to ethylene oxide and 1,4-dioxane are very low, 8.4 in 1 billion and 1.6 in 100 billion, respectively.

IV. Conclusion

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive as an emulsifier/surfactant for use in polyvinyl acetate and vinyl-acrylate copolymers intended for use as coatings for paper and paperboard food packaging is safe, and that the additive will achieve its intended technical effect. Therefore, the agency concludes that the regulations in § 178.3400 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 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.

V. Environmental Impact

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.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 1, 1998, 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.

VII. Paperwork Reduction Act of 1995

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

VIII. 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. Memorandum dated September 3, 1986, from the Regulatory Food Chemistry Branch (HFF–458), to the Indirect Additives Branch (HFF–335), entitled ''FAP 6B3908—American Cyanamid Co. Undated submission received July 18, 1986. Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether disodium salt.''

2. Memorandum dated June 26, 1997, from the Division of Product Policy, Scientific Support Branch (HFS–207), Chemistry and Environmental Review Team (CERT), to the Regulatory Policy Branch (HFS–206), entitled ''FAP 6B3908 (MATS #223, M2.10)-Cytec Industries, Inc. (through Keller & Heckman). Update of exposure estimates for Aerosol A–103. Regulatory Policy Branch (RPB) request dated 3–31–97 and Division of Health Effects Evaluation (DHEE) memorandum dated 3–27–97.''

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

4. Dunkelburg, H., ''Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46, pp. 924–933, 1982.

5. Memorandum dated July 16, 1997, from the Regulatory Policy Branch (HFS–206), to Sara H. Henry, Executive Secretary, Quantitative Risk Assessment Committee (HFS–308), entitled ''Re-evaluate Estimation of the Upper-Bound Lifetime Risk of Ethylene Oxide and 1,4-Dioxane in Sulfosuccinic Acid 4-Ester With Polyethylene Glycol Nonylphenyl Ether, Disodium Salt as an Emulsifier for Latex Coatings for Food-Contact Applications: Subject of Food Additive Petition FAP 6B3908 (Cytex Industries, Inc.)''.

6. ''Bioassay of 1,4-Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–80, 1978.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3400 is amended in the table in paragraph (c) by alphabetically adding a new entry under the headings

''List of substances'' and ''Limitations'' to read as follows:

§ 178.3400 Emulsifiers and/or surface active agents.

* * * * *

(c) * * *

List of substances	Limitations
* * *	* * * *
Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by condensation of 1 mole nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4).	For use only at levels not to exceed 5 percent by weight of the total coating monomers used in the emulsion polymerization of polyvinyl acetate and vinyl-acrylate copolymers intended for use as coatings for paper and paperboard.
* * *	* * * *

* * * * *

Dated: May 15, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14296 Filed 5–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Animal Drugs, Feeds, and Related Products; 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 the change of sponsor for an approved new animal drug application (NADA) from Deprenyl Animal Health, Inc., to Pfizer, Inc.

EFFECTIVE DATE: June 1, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Deprenyl Animal Health, Inc., 7101 College Blvd., suite 580, Overland Park, KS 66210, has informed FDA that it has transferred the ownership of, and all rights and interests in, the approved NADA 141–080 (selegiline hydrochloride tablets) to Pfizer, Inc., 235 East 42d St., New York, NY 10017. The agency is amending 21 CFR 510.600(c)(1) and (c)(2) to remove the sponsor name for Deprenyl Animal Health, Inc., because the firm no longer is the holder of any approved NADA's. The agency is also amending 21 CFR 520.2098 to reflect the change of sponsor.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520

Animal drugs.

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 parts 510 and 520 are 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.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Deprenyl Animal Health, Inc.''; and in the table in paragraph (c)(2) by removing the entry for ''063248''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2098 [Amended]

4. Section 520.2098 *Selegiline hydrochloride tablets* is amended in paragraph (b) by removing ''063248'' and by adding in its place ''000069''.

Dated: May 12, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–14299 Filed 5–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Lufenuron Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for subcutaneous use of lufenuron suspension in cats for control of flea populations.

EFFECTIVE DATE: June 1, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 26402, Greensboro, NC 27404–6402, is the sponsor of NADA 141–105 that provides for the subcutaneous use of Program™ (lufenuron) 10 percent sterile suspension for cats for the control of flea populations. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of March 13, 1998, and the regulations are amended by adding § 522.1289 to reflect the approval. The basis of