The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an abbreviated assessment under 21 CFR 25.31a(b)(1).

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday:

1. Carr, G.M., "Carcinogenicity Testing Programs" *in* "Food Safety: Where Are We.? Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, July 1979, p. 59.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intragastric Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

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

5. Memorandum dated February 13, 1986, from Food Additive Chemistry Evaulation Branch to Indirect Additives Branch, "Exposure to Ethylene Oxide (EO) and 1,4-Dioxane (DX)."

Any person who will be adversely affected by this regulation may at any time on or before October 24, 1986, 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.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR Part 175 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. In § 175.105(c)(5) by alphabetically inserting a new item in the list of substances to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by condensation of 1 mole of nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4)	
* * * * *	

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–21562 Filed 9–23–86; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 178

[Docket No. 79F–0449]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of elemental iodine, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) of average molecular weight between 768 and 837, and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxy-poly(oxyethylene)poly(oxypropylene) of average molecular weight between 950 and 1,120, as components of a sanitizing solution used on food-contact surfaces. This action responds to a petition filed by the Diversey Wyandotte Division of the Diversey Corp.

DATES: Effective September 24, 1986; objections by October 24, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690. .

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 28, 1979 (44 FR 76862), FDA announced that a petition (FAP OB3480) had been filed by Diversey Wyandotte Division of the Diversey Corp. (formerly BASF Wyandotte Corp.), 1532 Biddle Ave., Wyandotte, MI 48192, proposing that the food additive regulations be amended to provide for the safe use of elemental iodine, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly-(oxypropylene) of average molecular weight between 768 and 837, and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly (oxyethylene) poly (oxypropylene) of average molecular weight between 950 and 1,120, as components of a sanitizing solution to be used on food-contact surfaces.

FDA reviewed the safety of the individual food additives that are the components of the sanitizing solution as well as the starting materials used to manufacture these food additives. Although iodine and the two ethoxylated emulsifiers, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly-(oxyethylene)poly (oxypropylene) and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene)poly (oxypropylene), have not been shown to cause cancer, the two ethoxylated emulsifiers may contain minute amounts of ethylene oxide and 1,4-dioxane as byproducts of their production. These chemicals have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as ethylene oxide and 1,4-dioxane, are commonly found as contaminants in all chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, 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. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the food additives amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further than no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve a use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain a carcinogenic chemical but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic constituent.

Since that decision, FDA has approved the use of other color additives on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for these decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, published in the **Federal Register** of April 2, 1982 (47 FR 14464).

The agency now believes that the Delaney anticancer clause is not applicable unless the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer, but that contains a carcinogenic constituent, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use of Additives

Sanitizing solutions are mixtures of additives in which each additive has a functional effect. The subject sanitizing solution contains one additive, iodine, that is the active sanitizing agent and two ethoxylated compounds that function as emulsifiers and aid the penetration of cells by the active ingredient.

A. Iodine

Iodine is used in this and in other currently regulated sanitizing solutions as the active ingredient. Iodine has a long history of use for this purpose. FDA finds that iodine is safe and effective at the use levels established in this regulation, based on efficacy data submitted by the petitioner and on toxicity studies on iodine that are available in the scientific literature.

B. Ethoxylated Emulisifiers

FDA estimates that the petitioned use of *alpha*-alkyl-(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) and *alpha*-alkyl-(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) will result in extremely low levels of exposure to these additives. The agency has calculated an estimated daily intake of *alpha*-alkyl-(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) and *alpha*-alkyl-(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) based on considerations such as the migration of the additives under the most severe intended use conditions and the probable concentration of the additives in the daily diet from food-contact articles that contain these substances. The estimated daily intake for these two additives is 0.4 milligram and 0.6 milligram per day 1.35 and 2.13 parts per million in the diet) for a 60 kilogram person.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2) and has not required such testing here. FDA has evaluated the safety of the ethoxylated emulsifiers under the general safety cause, considering all available data and using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemicals that may be present as impurities in the additives. Because these ethoxylated emulsifiers have not been shown to cause cancer, the anticancer clause does not apply to them. Based on its evaluation, the agency has concluded that the additives are safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that it used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see, e.g., 49 FR 13018, 13019; April 2, 1984). This risk evaluation of the carcinogenic impurities ethylene oxide and 1,4-dioxane has two aspects: (1) Assessment of the worst case exposure to the impurities from the proposed use of the sanitizing solution, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

C. 1,4-Dioxane

Based on the fraction of the daily diet that may be in contact with surfaces containing *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) and *alpha*-alkyl-($C_{12}C_{18}$)-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene), as well as the level of 1,4-dioxane that may be present in these additives (Ref. 5), FDA estimated the hypothetical worst case exposure to 1,4-dioxane from the use of these additives to be 10 nanograms per person per day. The agency used data in a carcinogenesis bioassay on 1,4-dioxane conducted for the National Cancer Intstitute (Ref. 4) to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the two ethoxylated emulsifiers in the sanitizing solution. The results of the bioassay on 1,4-dioxane indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinomas and hepatocellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The committee further concluded that an estimate of the upper bound level of lifetime human risk from potential exposure to 1,4-dioxane stemming from the proposed use of the two ethoxylated emulsifiers could be calculated from the bioassay.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the ethoxylated emulsifiers. Based on a worst case exposure of 10 nanograms per person per day, FDA estimates that the upper bound limit of individual lifetime risk from potential exposure to 1,4-dioxane from the use of the two ethoxylated emulsifiers is 4×10^{-10} or less than 4 in 10 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 1,4-dioxane is expected to be substantially less than the estimated daily intake, and therefore the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to 1,4-dioxane that results from the use of the two ethoxylated emulsifiers.

D. Ethylene Oxide

Based on the fraction of the daily diet that may be in contact with surfaces containing *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly (oxyethylene) poly (oxypropylene) and *alpha*-alkyl-(C_{12}-C_{18})-*omega*-hydroxypoly (oxyethylene)poly(oxypropylene), as well as the level of ethylene oxide that may be present in these additives (Ref. 5), FDA estimated the hypothetical worst case exposure to ethylene oxide from the use of these ethoxylated emulsifiers to be 10 nanograms per person per day.

The agency used data in a carcinogenesis bioassay on ethylene oxide conducted for the Institute for Hygiene, University of Mainz, West Germany (Ref. 3), to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the ethoxylated emulsifiers. The results of the bioassay on ethylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinoma of the forestomach and carcinoma in situ of the glandular stomach.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that this information on ethylene oxide supported the finding of carcinogenicity. The committee further concluded that an estimate of the upper bound limit of lifetime human cancer risk from potential exposure to ethylene oxide could be made from the bioassay.

Based on a worst case exposure of 10 nanograms per person per day, FDA estimates, using a linear proportional model, that the upper bound limit of individual lifetime risk from potential exposure to ethylene oxide from the use of *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)-poly(oxypropylene) and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxy-poly(oxyethylene)poly(oxypropylene) is 2×10^{-8} or less than 2 in 100 million. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to ethylene oxide is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that results from the use of *alpha*-alkyl-(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene-poly(oxypropylene).

E. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of the ethylene oxide and 1,4-dioxane impurities in the ethoxylated emulsifiers. The agency finds that a specification is not necessary for the following reasons: (1) Because of the levels at which ethylene oxide and 1,4-dioxane are used in the production of these additives, the agency would not expect these impurities to become components of food at other than small levels; and (2) The upper bound limit of lifetime risk from exposure to these impurities, even under worst case assumptions, is very low, less than 2 in 100 million.

F. Conclusion on Safety

FDA, has evaluated the available toxicity data and the exposure calculations for the components of the sanitizing solution and has determined that these food additives are safe for their proposed use.

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 (address above) by appointment with the information contact person listed above. As provided in 21 CFR 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.

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(1).

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday:

1. Carr, G.M., "Carcinogenicity Testing Program" *in* "Food Safety: Where Are We?," Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, July 1979, p. 59.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Dunkleberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intragastic Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

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

5. Memorandum dated February 13, 1986, from Food Additive Chemistry Evaluation Branch to Indirect Additives Branch, "Exposure to Ethylene Oxide (EO) and 1,4-Dioxane (DX)."

Any person who will be adversely affected by this regulation may at any time on or before October 24, 1986, 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.

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, 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: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. In § 178.1010 by adding new paragraphs (b)(31) and (c)(26) to read as follows:

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(31) An aqueous solution containing elemental iodine, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly-(oxypropylene) of average molecular weight between 768 and 837, and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene) poly(oxypropylene) of average molecular weight between 950 and 1,120. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(c) * * *

(26) The solution identified in paragraph (b)(31) of this section shall provide, when ready to use, at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

* * * * *

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–21564 Filed 9–23–86; 8:45 am]
BILLING CODE 4160–01–M

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21 CFR Part 178

[Docket No. 83F–0156]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aqueous dispersion of polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, polyoxyethylene (minimum (min.) 3 moles ethylene oxide) cetyl alcohols, and polyoxyethylene (min. 20 moles ethylene oxide) oleyl ether, for use in aqueous dispersions of vinylidene chloride copolymers intended for use in contact with food. This action responds to a petition filed by Morton Thiokol, Inc.

DATES: Effective September 24, 1986; objections by October 24, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 3, 1983 (48 FR 24984), FDA announced that a petition (FAP 3B3707) had been filed by Morton Chemical Division of Morton Thiokol, Inc., Two North Riverside Plaza, Chicago, IL 60606, proposing that the food additive regulations be amended to provide for the safe use of an aqueous dispersion of polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, poly(oxyethylene) (min. 3 moles ethylene oxide) cetyl alcohols, and poly(oxyethylene) (min. 20 moles ethylene oxide) oleyl ethers for use in aqueous dispersions of polyvinylidene chloride copolymers intended for use in contact with food.

The aqueous dispersion that is subject of this petition is a blend of three substances, each of which has a functional effect when the dispersion is used in polyvinylidene chloride polymers. No adverse toxic effects were observed in a 2-year rat feeding study of the aqueous dispersion. Because the dispersion is merely a blend and not a compound or polymer, however, the dispersion is not a food additive, but its component substances are. Therefore, in acting on this petition, FDA has evaluated the safety of each of the food additives that made up the dispersion. This evaluation includes a review of the safety of each additive and of the starting materials used to manufacture the additives.

Two of three additives, polyoxyethylene (min. 3 moles ethylene oxide) cetyl alcohol and polyoxyethylene (min. 20 moles oxyethylene) oleylether (sometimes referred to as "the ethoxylated additives"), although not shown to cause cancer, may contain minute amounts of ethylene oxide and 1,4-dioxane as byproduct of their production. These chemicals have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as these chemicals, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, 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. The concept of safety embodied in the Food Additives

Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4, 1958.) This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409 (c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve a use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole has not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain a carcinogenic chemical but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6 published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic constituent.

Since that decision, FDA has approved the use of other color additives and food additives on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for those decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, published in the **Federal Register** of April 2, 1982 (47 FR 14464).

The agency now believes that the Delaney anticancer clause is not applicable unless the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer, but that contains a carcinogenic constituent, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use of Additives

A. Diesters of Oxidatively Refined Montan Wax Acids

The first additive, polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids is safe and effective for the use established in this regulation. This finding is based upon the data presented in the petition and other available data.

B. Ethoxylated Additives

FDA estimates that the petitioned use of the polyoxyethylene (min. 3 moles ethylene oxide) cetyl alcohols and polyethylene (min. 20 moles ethylene oxide) will result in extremely low levels of exposure to these additives. The agency has calculated an estimated daily intake of polyoxyethylene cetyl alcohols and polyoxyethylene oleyl ether based on considerations such as the migration of the additives under the most severe intended use conditions and the probable concentration of the additives in the daily diet from food-contact articles that contain these substances. The estimated daily intake for these two additives is less than 20 parts per billion each in the diet.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2) and has not required such testing here. Evaluation of the safety of the exthoxylated emulsifiers was based upon the data in the petition and other available information. Because these ethoxylated additives have not been shown to cause cancer, the anticancer clause does not apply to them.

FDA has evaluated the safety of the ethoxylated emulsifiers under the general safety clause, using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemicals that may be present as impurities in the additive. Based on this evaluation, the agency has concluded that these additives are safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that it has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see, e.g., 49 FR 13018, 13019; April 2, 1984). This risk evaluation of the carcinogenic impurities ethylene oxide and 1,4-dioxane, has two aspects: (1) Assessment of the worst case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

C. 1,4-Dioxane

Based on the fraction of the daily diet that may be in contact with surfaces containing polyoxyethylene (min. 3 moles oxyethylene) cetyl alcohols and polyoxyethylene (min. 20 moles oxyethylene) oleyl ether, as well as the level of 1,4-dioxane that may be present in these additives (Ref. 5), FDA estimated the hypothetical worst case exposure to 1,4-dioxane from the use of these additives to be 0.7 nanogram per person per day. The agency used data in a carcinogenesis bioassay on 1,4-dioxane conducted from the National Cancer Institute (Ref. 4) to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of polyoxyethylene (min. 3 moles oxyethylene) cetyl alcohols and polyoxyethylene (min. 20 moles ethylene oxide) oleyl ether. The results of the bioassay on 1,4-dioxane indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinomas and hepatocellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The committee further concluded that an estimate of the upper bound limit of lifetime human cancer risk from potential exposure to 1,4-dioxane stemming from the proposed use of the ethoxylated additives could be made from the bioassay.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed contitions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent

with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the food additives. Based on a worst case exposure of 0.7 nanogram per person per day, FDA estimates that the upper bound limit of individual lifetime risk from potential exposure to 1,4-dioxane from use of polyoxyethylene (min. 3 moles oxyethylene) cetyl alcohols and polyoxyethylene (min. 20 moles oxyethylene) oleyl ether is 3×10^{-11} or less than 3 in 100 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 1,4-dioxane is expected to be substantially less than the estimated daily intake, and therefore the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to 1,4-dioxane that results from the use of poly(oxyethylene) (min. 3 moles ethylene oxide) cetyl alcohols and poly(oxyethylene) (min. 20 moles ethylene oxide) oleyl ether.

D. Ethylene Oxide

Based on the fraction of the daily diet that may be in contact with surfaces containing polyoxyethylene (min. 3 moles ethylene oxide) cetyl alcohols and polyoxyethylene (min. 20 moles oxyethylene) oleyl ether, as well as the level of ethylene oxide that may be present in the additive (Ref. 5), FDA estimated the hypothetical worst case exposure to ethylene oxide from the use of these additives to be 0.7 nanogram per person per day. The agency used data in a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, West Germany (Ref. 3), to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of these additives. The results of the bioassay on ethylene oxide demonstrated that this material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinoma of the forestomach and carcinoma in situ of the glandular stomach.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that this information on ethylene oxide supported the finding of carcinogenicity. The committee further concluded that an estimate of the upper bound of lifetime human cancer risk from potential exposure to ethylene oxide could be made from the bioassay.

Based on a worst case exposure of 0.7 nanogram per person per day, FDA estimates, using a linear proportional model, that the upper bound limit of individual lifetime risk from potential exposure to ethylene oxide from the use of these two ethoxylated additives is 1×10^{-9} or less than 1 in 1 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to ethylene oxide is expected to be substantially less than the estimated daily intake. Therefore, the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that results from the use of these ethoxylated additives.

E. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of the ethylene oxide and 1,4-dioxane impurities in the ethoxylated food additives. The agency finds that a specification is not necessary for the following reasons: (1) Because of the levels at which ethylene oxide and 1,4-dioxane are used in production of these additives, the agency would not expect these impurities to become components of food at other than extremely small levels; and (2) the upper bound limit of lifetime risk from exposure to these impurities, even under worst case assumptions, is very low, less than 1 in 1 billion.

F. Conclusion of Safety

FDA has evaluated the available toxicity data and the exposure calculation for the additive and has determined that these additives are safe for their proposed use.

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 (address above) by appointment with the information contact person listed above. As provided in 21 CFR 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.

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(1).

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. Carr, G.M., "Carcinogenicity Testing Programs" *in* "Food Safety: Where Are We?," Committee on Agriculture, Nutrition, and Forestry, United States Senate, July 1979, p. 59.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intragastric Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

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

5. Memorandum dated February 13, 1986, from Food Additive Chemistry Evaluation Branch to Indirect Additives Branch, "Exposure to Ethylene Oxiode (EO) and 1,4-Dioxane (DX)."

Any person who will be affected by this regulation may at any time on or before October 24, 1986 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.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Production aids.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10, 4.61.

2. In § 178.3770 by adding a new paragraph (c) to read as follows:

§ 178.3770 Polyhydric alcohol diesters or oxidatively refined (Gersthoffen process) montan wax acids.

* * * * *

(c) The polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, identified in paragraph (a) or (b) of this section, may also be used as a component of an aqueous dispersion of vinylidene chloride copolymers, subject to the conditions described in paragraphs (c)(1) and (2) of this section.

(1) The aqueous dispersion of the additive contains not more that 18 percent polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, not more than 2 percent poly(oxyethylene) (minimum 20 moles of ethylene oxide) oleyl ether (CAS Reg. No. 9005–98–2), and not more than 1 percent poly(oxyethylene) (minimum 3 moles ethylene oxide) cetyl alcohols (CAS Reg. No. 9004–95–9).

(2) The aqueous dispersion described in paragraph (c)(1) of this section is used as an additive to aqueous dispersions of vinylidene chloride copolymers, regulated in §§ 175.300, 175.320, 175.360, 176.170, 176.180, and 177.1630 of this chapter, at levels not to exceed 1.5 percent (solids basis) in the finished coating.

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–21563 Filed 9–23–86; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 184

[Docket No. 82N–0103]

Gras Status of Glucono Delta-Lactone

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that glucono delta-lactone is generally recognized as safe (GRAS) for use as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective October 24, 1986.

The Director of the **Federal Register** approves the incorporation by reference of certain publications in 21 CFR 184.1318 effective on October 24, 1986.

FOR FURTHER INFORMATION CONTACT: Damon Larry, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 17, 1982 (47 FR 35778), FDA published a proposal to affirm that glucono delta-lactone is GRAS for use as a direct human food ingredient. FDA published this proposal in accordance with its review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review, mutagenic and teratology reports, and the report of the Select Committee on GRAS Substances (the Select Committee) on glucono delta-lactone are available for public review in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents are also available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of glucono delta-lactone, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of this ingredient recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for glucono delta-lactone were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of this ingredient under conditions different from those set forth in this final rule has been waived.

FDA received three comments in response to the agency's proposal on glucono delta-lactone. One comment was from a manufacturer of the substance, a second was from an importer of glucono delta-lactone, and the third was from a user of glucono delta-lactone. The comments and the agency's responses to them follow.

1. The first two comments requested that FDA modify the description of the manufacturing process for glucono delta-lactone in proposed § 184.1318(a). The comments asserted that the method for producing gluconic acid (an initial step in the production of glucono delta-lactone) that is included in § 184.1318(a) (oxidation of *D*-glucose with bromine water) is not the common method for commercially producing this substance. The comments stated that the more widely used method is to produce gluconic acid by oxidizing food-grade glucose in the presence of suitable strains of microorganisms that are non-pathogenic and non-toxicogenic to man or animals or in the presence of enzymes derived from such microorganisms. One comment identified the microorganisms used in the manufacture of gluconic acid from glucose as *Aspergillus niger* and *Acetobacter suboxydans*.

The agency has carefully evaluated these comments. The agency agrees that the comments describe the method that is currently used to produce food-grade glucono delta-lactone. This method is used by the major producer of gluconic acid and glucono delta-lactone in the United States and also by the supplier for a major importer into the United States of food-grade glucono delta-lactone. Glucono delta-lactone prepared for food use by the procedure described in the comments meets the specifications of the Food Chemicals Codex, which are being adopted by the agency. Because the product meets the specifications of the Food Chemicals Codex and is prepared using strains of

nonpathogenic and nontoxicogenic microorganisms that are safe and suitable, the agency concludes that the product is GRAS. The agency has modified the final rule to include the current methods of manufacture of glucono delta-lactone in response to these comments.

The agency is not, however, listing specific organisms or enzymes in § 184.1318(a). Such a listing is unnecessary and would merely introduce an element of rigidity that is not needed to ensure the safety of the product. The two microorganisms mentioned in the comments, *Aspergillus niger* and *Acetobacter suboxydans*, are well recognized by the scientific community as not presenting a toxicogenic or pathogenic concern. The agency believes that there may be other microorganisms that are suitable for the production of gluconic acid and that do not present such concerns. Therefore, a listing of specific microorganisms is unnecessary.

2. The third comment requested that FDA affirm that glucono delta-lactone is GRAS for use as a pH control agent in fats and oils. The comment included no current information on this use and no data on the effectiveness of this use of glucono delta-lactone. A contact by telephone with the company that submitted the comment revealed that the use of glucono delta-lactone in fats and oils was the subject of active research, and that if this food category was not included in the regulation, the company would consider discontinuing this research.

In this final rule, FDA is taking actions that, in essence, grant this request. FDA proposed to affirm that glucono delta-lactone is GRAS for use as a pH control agent and, in the absence of information that raises questions about the safety of this use, is adopting that aspect of the proposal. Moreover, the agency is deleting the food categories that were listed in the proposal from the regulation. Both the Select Committee and the agency have concluded that a large margin of safety exists for the use of this ingredient, and that a reasonably foreseeable increase in the level of consumption of this ingredient will not adversely affect human health. Further, this ingredient is used in a large number of food categories.

Accordingly, the agency has concluded that it is not necessary to list food categories of use to ensure its safe use of this ingredient. Therefore, the agency has modified § 184.1318 by deleting the food categories and is affirming that glucono delta-lactone is GRAS when used in accordance with current good manufacturing practice under § 184.1(b)(1) (21 CFR 184.1(b)(1). To make clear, however, that the affirmation of the GRAS status of Glucono delta-lactone is based on the evaluation of currently known uses, the regulations set forth the technical effects that FDA has evaluated.

Finally, FDA has concluded that the description of glucono delta-lactone in the proposal could be misleading because it does not fully describe glucono delta-lactone as a crystalline material. FDA, therefore, has modified the description in § 184.1318(a) to include the crystallization step and to describe the crystalline material as the GRAS ingredient. The agency concludes that this change in the regulation is not significant because the proposed regulation has referenced the Food Chemicals Codex specifications for the ingredient, which describe glucono delta-lactone as a "crystalline powder."

The agency has previously determined under 21 CFR 25.24(d)(7) 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. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. FDA has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

2. Part 184 is amended by adding new § 184.1318, to read as follows:

§ 184.1318 Glucono delta-lactone.

(a) Glucono delta-lactone ($C_6H_{10}O_6$, CAS Reg. No. 90–80–2), also called *D*-gluconic acid delta-lactone or *D*-glucono-1,5-lactone, is the cyclic 1,5-intramolecular ester of *D*-gluconic acid. It is prepared by direct crystallization from the aqueous solution of gluconic acid. Gluconic acid may be produced by the oxidation of *D*-glucose with bromine water, by the oxidation of *D*-glucose by microorganisms that are nonpathogenic and nontoxicogenic to man or other animals, or by the oxidation of *D*-glucose with enzymes derived from these microorganisms.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 134, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a curing and pickling agent as defined in § 170.3(o)(5) of this chapter, leavening agent as defined in § 170.3(o)(17) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and sequestrant as defined in § 170.3(o)(26) of this chapter.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: September 17, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-21565 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 433

[Docket No. 894N-0373]

Antibiotic Drug Products for Over-the-Counter Human Use; Exemption From Certification; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that amended the antibiotic drug regulations to specifically exempt from batch certification antibiotic drug products for over-the-counter (OTC) human use (51 FR 25523; July 15, 1986). This document corrects a typographical error.

FOR FURTHER INFORMATION CONTACT: Robert J. Meyer, Center for Drugs and Biologics (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION: In FR Doc. 86-15850 appearing on page 25523, in the issue of Tuesday, July 15, 1986, the following correction is made on page 25523: In the second column, under "Background", the second paragraph, line 2, "(21 CFR 443.1)" is corrected to read "(21 CFR 433.1)".

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-21557 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 510 and 558

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADA's) from Abbott Laboratories to Fleming Laboratories, Inc.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc. P.O. Box 34384, Charlotte, NC 28234, informed FDA of acquiring two NADA's from Abbott Laboratories. Fleming is now sponsor of NADA's 8-019 (Pro-Gen Arsanilic Acid) and 8-966 (Pro-Gen Sodium Arsanilate). Abbott confirmed the change. Fleming will assume all responsibilities for the cited NADA's as required by 21 CFR 510.300 and 21 CFR Part 514. The NADA's and the regulations are amended to reflect the new sponsor.

List of Subjects

21 CFR Part 510

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

21 CFR Part 558

Animal drugs, Animal Feeds.

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, Parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

2. Section 510.600 is amended by adding a new entry alphabetically in paragraph (c)(1) and numerically in paragraph (c)(2), 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
* * * * *	
Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234	015565
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
015565	Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234.
* * * * *	

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

§ 558.60 [Amended]

4. Section 558.60 *Arsanilate sodium* is amended in paragraph (a) by removing the sponsor number "043731" and replacing it with "015565."

§ 558.62 [Amended]

5. Section 558.62 *Arsanilic acid* is amended in paragraph (a) by removing the sponsor number "043731" and replacing it with "015565."

Dated: September 18, 1986.

Marvin A. Norcross,

Associate Director for New Animal Drug Evaluation.

[FR Doc. 86-21558 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Pyrantel Tartrate

AGENCY: Food and Drug Administration.

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 for Furst-McNess Co., providing for the use of a 48-gram-per-pound pyrantel tartrate Type A medicated article in making 9.6- and 19.2-gram-per-pound pyrantel tartrate Type A medicated articles. The pyrantel tartrate Type A medicated articles subject to this approval are subsequently used to make Type C medicated feeds for swine.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: Furst-McNess Co., Freeport, IL 61032, is sponsor of NADA 140-825 submitted on