FAP 5B4483, BASF Aktiengesellschaft, concerning exposure to methylene chloride from the use of polyaryletherketone resins, February 14, 1996.

4. ''Toxicology and Carcinogenesis Studies of Dichloromethane (methylene chloride) (CAS Reg. No. 75–09–2) in F344/N Rats and B6C3F_1 Mice'' (Inhalation Studies). National Toxicology Program Technical Report Series, No. 306 (1986).

5. Memorandum from the Quantitative Risk Assessment Committee, concerning estimation of upper-bound lifetime risk from methylene chloride for uses requested in FAP 5B4483 (BASF Aktiengesellschaft), February 20, 1996.

List of Subjects in 21 CFR Part 177

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 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. New § 177.1556 is added to subpart B to read as follows:

§ 177.1556 Polyaryletherketone resins.

The poly(oxy-1,4-phenylenecarbonyl-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylenecarbonyl-1,4-phenylene) resins (CAS Reg. No. 55088–54–5 and CAS Reg. No. 60015–05–6 and commonly referred to as polyaryletherketone resins) identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food, subject to the provisions of this section.

(a) *Identity.* Polyaryletherketone resins consist of basic resins produced by reacting 4,4′-diphenoxy benzophenone and terephthaloyl dichloride in such a way that the finished resins have a minimum weight average molecular weight of 20,000 grams per mole, as determined by light scattering measurements in sulfuric acid at room temperature.

(b) *Optional adjuvant substances.* The basic polyaryletherketone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. These adjuvants may include substances used in accordance with § 174.5 of this chapter and the following:

(1) Benzoyl chloride, poly(tetrafluoro ethylene).

(2) [Reserved]

(c) *Extractive limitations.* The finished food-contact article yields net total extractives in each extracting solvent not to exceed 0.052 milligram per square inch (corresponding to 0.008 milligram per square centimeter) of food-contact surface, when extracted at reflux temperature for 2 hours with the following solvents: Distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid (by weight) in distilled water, and *n*-heptane.

(d) In testing the finished food-contact article made of polyaryletherketone resin, use a separate test sample for each required extracting solvent.

Dated: August 2, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20852 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 93F–0385]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of May 21, 1996 (61 FR 25395). The document amended the food additive regulations to provide for the safe use of formaldehyde, polymer with 1-naphthylenol, as a release agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers intended for food-contact applications. The document was published with some errors. This document corrects those errors.

EFFECTIVE DATE: May 21, 1996.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

In FR Doc. 96–12761, appearing on page 25395 in the Federal Register of Tuesday, May 21, 1996, the following corrections are made:

1. On page 25395, in the first column, under the ''**SUMMARY**'' caption, in the fifth line, and under the ''**SUPPLEMENTARY INFORMATION**'' caption, in the first paragraph, beginning in the thirteenth line, ''1-naphthylenol'' is corrected to read ''1-naphthalenol''.

§ 178.3860 [Corrected]

2. On page 25396, in the Table, under the heading ''List of substances,'' ''1-naphthylenol'' is corrected to read ''1-naphthalenol''.

Dated: July 25, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20821 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 179

[Docket No. 94F–0125]

Irradiation in the Production, Processing, and Handling of Food

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 a source of high intensity pulsed light to control microorganisms on the surface of food. This action is in response to a food additive petition filed by Foodco Corp. (now known as PurePulse Technologies, Inc.).

DATES: Effective August 15, 1996; written objections and requests for a hearing by September 16, 1996.

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: Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3093.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of May 2, 1994 (59 FR 22673), FDA announced that a food additive petition (FAP 4M4417) had been filed by Foodco Corp., 8888 Balboa Ave., San Diego, CA 92123, proposing that the food additive regulations be amended to provide for the safe use of a source of high intensity pulsed light to control microorganisms on the surface of food. (Since the publication of the notice of filing, Foodco Corp. has changed its

name to PurePulse Technologies Inc., (PurePulse).)

II. Evaluation of Safety

Under the proposed conditions of use, foods would be exposed to broadband radiation (wavelengths covering the range 200 to 1,100 nanometers (nm)) that is emitted as high intensity pulses (flashes) by xenon flashlamps. This wavelength range covers the entire ''visible'' region of the spectrum (that range of wavelengths that is capable of being perceived by the human eye), as well as limited portions of the ultraviolet (UV) and infrared (IR) regions. Use of the proposed sources of radiation results in exposure of the surfaces of treated foods to short pulses of high intensity light. The proposed pulsed light treatment does not involve the use of a source of ionizing radiation.

The proposed pulsed light treatment is intended to reduce the numbers of microorganisms (bacteria, yeasts, and molds) on the surfaces of treated foods. PurePulse did not propose restricting the types of foods that would be treated with pulsed light. The agency has evaluated the safety of the proposed pulsed light treatment assuming that all types of foods could potentially be treated with pulsed light, while recognizing that, in actual practice, not all types are likely to be so treated.

In assessing the safety of foods treated with radiation, including pulsed light, the agency considers changes in chemical composition of the food that may be induced by the proposed treatment, including any potential changes in nutrient levels. The agency also considers potential differences in the microbial populations found on treated versus untreated foods.

PurePulse submitted data and information regarding the nature and extent of photochemical change expected to occur in foods treated with the proposed high intensity pulsed light treatment. PurePulse also submitted data regarding the nature and extent of the changes in microbial populations on the surfaces of a representative variety of foods treated with pulsed light under the proposed conditions of use.

Having evaluated the data in the petition and other relevant material in its files, the agency finds that treated foods will not sustain significant reduction in nutrients and, thus, will retain their nutritional qualities (Ref. 1). FDA also finds that the types and amounts of photoproducts that might be produced and subsequently consumed, are not of any toxicological significance (Refs. 2 and 3).

From a microbiological standpoint, the agency concludes that the proposed treatment is effective in reducing the numbers of microorganisms on the surface of treated foods and that treated foods will be at least as safe, from a microbiological standpoint, as untreated foods that are currently marketed (Refs. 4 and 5).

III. Conclusions

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of a source of high intensity pulsed light is safe, that the additive will achieve its intended technical effect, and that therefore, the regulations in 21 CFR part 179 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.

IV. 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.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before September 16, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

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

1. Memorandum from S. Carberry, Chemistry Review Branch, to P. Hansen, Biotechnology Policy Branch, dated February 1, 1995.

2. Memorandum from S. Carberry, Chemistry Review Branch, to P. Hansen, Biotechnology Policy Branch, dated May 17, 1994.

3. Memorandum from A. Chang, Additives Evaluation Branch #1, to P. Hansen, Division of Product Policy, dated June 28, 1994.

4. Memorandum from J. Madden, Strategic Manager for Microbiology, to P. Hansen and G. Pauli, Division of Product Policy, dated August 9, 1994.

5. Memorandum from J. Madden, Strategic Manager for Microbiology, to P. Hansen, dated June 15, 1995.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

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, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: Secs. 201, 402, 403, 409, 703, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 348, 373, 374).

2. New § 179.41 is added to subpart B to read as follows:

§ 179.41 Pulsed light for the treatment of food.

Pulsed light may be safely used for treatment of foods under the following conditions:

(a) The radiation sources consist of xenon flashlamps designed to emit broadband radiation consisting of wavelengths covering the range of 200 to 1,100 nanometers (nm), and operated so that the pulse duration is no longer than 2 milliseconds (msec);

(b) The treatment is used for surface microorganism control;

(c) Foods treated with pulsed light shall receive the minimum treatment reasonably required to accomplish the intended technical effect; and

(d) The total cumulative treatment shall not exceed 12.0 Joules/square centimeter (J/cm^2.)

Dated: July 30, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–20853 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Florfenicol Solution

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 Schering-Plough Animal Health. The NADA provides for use of florfenicol injectable solution for cattle for the treatment of bovine respiratory disease.

EFFECTIVE DATE: August 15, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health, Schering-Plough Corp., P.O. Box 529, Kenilworth, NJ 07033, has filed NADA 141–063 Nuflor® Injectable Solution (300 milligrams florfenicol per milliliter) for intramuscular treatment of cattle for bovine respiratory disease (BRD) associated with *Pasteurella haemolytica, P. multocida,* and *Haemophilus somnus.* The NADA is approved as of May 31, 1996, and the regulations are amended by adding new § 522.955 to reflect the approval. The regulations are also amended to provide for a tolerance for florfenicol residues in cattle in new § 556.283. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval for use in food-producing animals qualifies for 5 years of marketing exclusivity beginning May 31, 1996, because the application is for a new animal drug, no active ingredient of which has been approved in any other application.

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.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.955 is added to read as follows:

§ 522.955 Florfenicol solution.

(a) *Specifications.* Each milliliter of sterile solution contains 300 milligrams of florfenicol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.283 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 20 milligrams per kilogram body weight (3 milliliters per 100 pounds). A second dose should be given 48 hours later.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica, P. multocida,* and *Haemophilus somnus.*

(iii) *Limitations.* For intramuscular use only. Do not inject more than 10 milliliters at each site. Injection should be given only in the neck musculature. Do not slaughter within 28 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. Not for use in veal calves, calves under 1 month of age, or calves being fed an all milk diet. Use may cause violative tissue residues to remain beyond the withdrawal time. Not for use in cattle of breeding age. The effect of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.283 is added to read as follows:

§ 556.283 Florfenicol.

The safe concentrations for total florfenicol-related residues in cattle are 2.0 parts per million (ppm) in muscle, 6.0 ppm in liver, and 12.0 ppm in kidney and fat. A tolerance of 3.7 ppm for the marker residue, florfenicol amine, has been established in cattle liver.

Dated: July 25, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–20854 Filed 8–14–96; 8:45 am]

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