List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701–1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

2. Section 5.80 is amended by revising paragraph (a)(1)(iii) and by removing paragraph (a)(1)(iv) to read as follows:

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) * * *

(iii) The Director, Office of Over-the-Counter Drug Evaluation, CDER, for drugs under the Director's jurisdiction.

* * * * *

Dated: November 2, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–28149 Filed 11–14–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 175

[Docket No. 95F–0064]

Indirect Food Additives: Adhesives and Components of Coatings

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 silver chloride-coated titanium dioxide as a preservative in polymer latex emulsions in resinous and polymeric coatings intended for use in contact with food. This action is in response to a petition filed by Johnson Matthey Chemicals.

DATES: Effective November 15, 1995; written objections and requests for a hearing by December 15, 1995.

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

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of April 13, 1995 (60 FR 18845), FDA announced that a food additive petition (FAP 5B4453) had been filed by Johnson Matthey Chemicals, c/o 1000 Potomac St. NW., Washington, DC 20007. The petition proposed that the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) be amended to provide for the safe use of silver chloride-coated titanium dioxide as a preservative in polymer latex emulsions used in resinous and polymeric coatings intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed use of the additive in resinous and polymeric coatings intended for use in contact with food is safe and that the regulations in § 175.300 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 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. 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.

Any person who will be adversely affected by this regulation may at any time on or before December 15, 1995, 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR 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, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 175.300 is amended in paragraph (b)(3)(xxxiii) by alphabetically adding a new entry to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(xxxiii) Miscellaneous materials:

* * * * *

Silver chloride-coated titanium dioxide for use only as a preservative in latex emulsions at a level not to exceed 2.2 parts per million (based on silver ion concentration) in the dry coating.

* * * * *

Dated: October 26, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–28216 Filed 11–14–95; 8:45 am]

BILLING CODE 4160–01–F

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2619 and 2676

Valuation of Plan Benefits in Single-Employer Plans; Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal; Amendments Adopting Additional PBGC Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulations on Valuation of Plan Benefits in Single-Employer Plans and Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal. The former regulation contains the interest assumptions that the PBGC uses to value benefits under terminating single-employer plans. The latter regulation contains the interest assumptions for valuations of multiemployer plans that have undergone mass withdrawal. The amendments set out in this final rule adopt the interest assumptions applicable to single-employer plans with termination dates in December 1995, and to multiemployer plans with valuation dates in December 1995. The effect of these amendments is to advise the public of the adoption of these assumptions.

EFFECTIVE DATE: December 1, 1995.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024 (202–326–4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: This rule adopts the December 1995 interest assumptions to be used under the Pension Benefit Guaranty Corporation's regulations on Valuation of Plan Benefits in Single-Employer Plans (29 CFR part 2619, the ''single-employer regulation'') and Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal (29 CFR part 2676, the ''multiemployer regulation'').

Part 2619 sets forth the methods for valuing plan benefits of terminating single-employer plans covered under title IV of the Employee Retirement Income Security Act of 1974, as amended. Under ERISA section 4041(c), all single-employer plans wishing to terminate in a distress termination must value guaranteed benefits and ''benefit liabilities.'' *i.e.*, all benefits provided under the plan as of the plan termination date, using the formulas set forth in part 2619, subpart C. (Plans terminating in a standard termination may, for purposes of the Standard Termination Notice filed with PBGC, use these formulas to value benefit liabilities, although this is not required.) In addition, when the PBGC terminates an underfunded plan involuntarily pursuant to ERISA section 4042(a), it uses the subpart C formulas to determine the amount of the plan's underfunding. Part 2676 prescribes rules for valuing benefits and certain assets of multiemployer plans under sections 4219(c)(1)(D) and 4281(b) of ERISA.

Appendix B to part 2619 sets forth the interest rates and factors under the single-employer regulation. Appendix B to part 2676 sets forth the interest rates and factors under the multiemployer regulation. Because these rates and factors are intended to reflect current conditions in the financial and annuity markets, it is necessary to update the rates and factors periodically.

The PBGC issues two sets of interest rates and factors, one set to be used for the valuation of benefits to be paid as annuities and one set for the valuation of benefits to be paid as lump sums. The same assumptions apply to terminating single-employer plans and to multiemployer plans that have undergone a mass withdrawal. This amendment adds to appendix B to parts 2619 and 2676 sets of interest rates and factors for valuing benefits in single-employer plans that have termination dates during December 1995 and multiemployer plans that have undergone mass withdrawal and have valuation dates during December 1995.

For annuity benefits, the interest rates will be 6.00% for the first 20 years following the valuation date and 5.75% thereafter. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 4.50% for the period during which benefits are in pay status, and 4.0% during all years preceding the benefits' placement in pay status. The above annuity interest assumptions represent a decrease (from those in effect for November 1995) of .20 percent for the first 20 years following the valuation date and are otherwise unchanged. The lump sum interest assumptions represent a decrease (from those in effect for November 1995) of .25 percent for the period during which benefits are in pay status, and are otherwise unchanged.

Generally, the interest rates and factors under these regulations are in effect for at least one month. However, the PBGC publishes its interest assumptions each month regardless of whether they represent a change from the previous month's assumptions. The assumptions normally will be published in the Federal Register by the 15th of the preceding month or as close to that date as circumstances permit.

The PBGC has determined that notice and public comment on these amendments are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest rates and factors promptly so that the rates and factors can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in single-employer plans whose termination dates fall during December 1995, and in multiemployer plans that have undergone mass withdrawal and have valuation dates during December 1995, the PBGC finds that good cause exists for making the rates and factors set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 2619

Employee benefit plans, Pension insurance, and Pensions.

29 CFR Part 2676

Employee benefit plans and Pensions.

In consideration of the foregoing, parts 2619 and 2676 of chapter XXVI, title 29, Code of Federal Regulations, are hereby amended as follows: