

radius of Boone Municipal Airport and within 2.6 miles each side of the 334° bearing from the Boone NDB extending from the 6.6-mile radius to 7 miles northwest of the airport.

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Issued in Kansas City, MO on May 23, 1996.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division Central Region.

[FR Doc. 96-14762 Filed 6-10-96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 88F-0426]

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 3-aminomethyl-3,5,5-trimethylcyclohexylamine as a cross-linking agent for use in epoxy resin coatings. This action responds to a petition filed by Huels AG.

DATES: Effective June 11, 1996; written objections and requests for a hearing by July 11, 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: Julius Smith, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of January 26, 1989 (54 FR 3853), FDA announced that a food additive petition (FAP 9B4118) had been filed by Huels AG, P.O. Box 1320, D-4370 Marl, Federal Republic of Germany (currently c/o Bruce EnvivoExcel Group, Inc., 94 Buttermilk Bridge Rd., Washington, NJ 07882). 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 3-aminomethyl-3,5,5-trimethylcyclohexylamine as a cross-linking agent for use in epoxy resins complying with § 175.300(b)(3)(viii).

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 that are intended for contact with foods 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 July 11, 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.

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)(viii)(b) by alphabetically adding a new entry to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(viii) * * *

(b) Catalysts and cross-linking agents for epoxy resins:
3-Aminomethyl-3,5,5-trimethylcyclohexylamine (CAS Reg. No. 2855-13-2).

* * * * *

Dated: May 12, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-14648 Filed 6-10-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 177

[Docket No. 92F-0357]

Indirect Food Additives: Polymers

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 polysulfone resins identified as 1,1'-sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] (minimum 92 percent) and 4,4'-sulfonylbis[phenol] (maximum 8 percent) (CAS Reg. No. 88285-91-0) consisting of basic resins produced when a mixture of 4,4'-isopropylidenediphenol (minimum 92 percent) and 4,4'-sulfonylbis[phenol]

(maximum 8 percent) is made to react with 4,4'-dichlorodiphenyl sulfone in such a way that the finished resins have a minimum number average molecular weight of 26,000, as determined by osmotic pressure in dimethylformamide, as an article or component of articles for use in contact with food. This action responds to a food additive petition filed by BASF Corp.

DATES: Effective June 11, 1996; written objections and requests for a hearing by July 11, 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: Richard H. White, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3094.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 17, 1992 (57 FR 54247), FDA announced that a food additive petition (FAP 1B4262) had been filed by BASF Corp., 1609 Biddle Ave., Wyandotte, MI 48192-3799. The petition proposed to amend the food additive regulations in § 177.1655 *Polysulfone resins* (21 CFR 177.1655) to provide for the safe use of a polysulfone resin consisting of 1,1'-sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] and 4,4'-sulfonylbis[phenol], as an article or component of articles intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. Based upon its review, the agency concludes that the food additive is more appropriately identified as 1,1'-sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] (minimum 92 percent) and 4,4'-sulfonylbis[phenol] (maximum 8 percent) (CAS Reg. No. 88285-91-0). FDA is therefore adopting this name for the food additive in this final rule. The petitioner also requested an amendment to the petition to adopt a 0.01 percent (100 parts per million) limit for the residual solvent, *N*-methyl-2-pyrrolidone, in the finished basic resin. The agency agrees that this is appropriate limitation and, based upon the available data, concludes that the proposed food additive use is safe and that the additive will achieve its intended technical effect. Therefore, FDA further concludes that § 177.1655 should be amended to revise paragraph

(a), and in the table in paragraph (b) to add *N*-methyl-2-pyrrolidone and to revise the limitations.

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 July 11, 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.

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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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. Section 177.1655 is amended by revising paragraph (a) and the table in paragraph (b) to read as follows:

§ 177.1655 Polysulfone resins.

* * * * *

(a) For the purpose of this section, polysulfone resins are:

(1) Poly(oxy-*p*-phenylenesulfonyl-*p*-phenyleneoxy-*p*-phenyleneisopropylidene-*p*-phenylene) resins (CAS Reg. No. 25154-01-2) consisting of basic resins produced when the disodium salt of 4,4'-isopropylidenediphenol is made to react with 4,4'-dichlorodiphenyl sulfone in such a way that the finished resins have a minimum number average molecular weight of 15,000, as determined by osmotic pressure in monochlorobenzene; or

(2) 1,1'-Sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] (minimum 92 percent) and 4,4'-sulfonylbis[phenol] (maximum 8 percent) (CAS Reg. No. 88285-91-0) produced when a mixture of 4,4'-isopropylidenediphenol (minimum 92 percent) and 4,4'-sulfonylbis[phenol] (maximum 8 percent) is made to react with 4,4'-dichlorodiphenyl sulfone in such a way that the finished resin has a minimum number average molecular weight of 26,000, as determined by osmotic pressure in dimethylformamide.

* * * * *

(b) * * *

List of substances	Limitations
Dimethyl sulfoxide	Not to exceed 50 parts per million as residual solvent in finished basic resin in paragraph (a)(1) of this section.

List of substances	Limitations
Monochlorobenzene Monochlorobenzene.	Not to exceed 500 parts per million as residual solvent in finished basic resin in paragraph (a)(1) of this section.
N-methyl-2-pyrrolidone.	Not to exceed 0.01 percent (100 parts per million) as residual solvent in finished basic resin in paragraph (a)(2) of this section.

* * * * *

Dated: May 17, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-14697 Filed 6-10-96; 8:45 am]

BILLING CODE 4160-01-F

Food and Drug Administration**21 CFR Parts 200, 250, and 310**

[Docket No. 95N-0310]

Revocation of Obsolete Regulations**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking certain regulations that are obsolete or are no longer necessary to achieve public health goals. These regulations were among those identified for revocation in a page-by-page review conducted in response to the Administration's "Reinventing Government" initiative, which seeks to streamline government to ease the burden on regulated industry and consumers.

EFFECTIVE DATE: July 11, 1996.**FOR FURTHER INFORMATION CONTACT:**

Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION:**I. Background**

In the Federal Register of October 13, 1995 (60 FR 53480), FDA published a proposed rule to revoke certain regulations. This was done in response to the President's order to all Federal agencies to conduct a page-by-page review of all their regulations and to

"eliminate or revise those that are outdated or otherwise in need of reform." The proposed rule contained a section-by-section analysis of all the regulations (21 CFR parts 100, 101, et al.) that FDA intended to revoke. This final rule pertains only to those regulations (21 CFR parts 200, 250, and 310) pertaining exclusively to the Center for Drug Evaluation and Research. No comments were received in response to the proposal to revoke these regulations.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule, which is the revocation of certain regulations that are obsolete or are no longer necessary, is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule is the revocation of certain regulations that are obsolete or are no longer necessary, the agency is not aware of any adverse impact this final rule will have on any small entities, and the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(9) 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.

List of Subjects**21 CFR Part 200**

Drugs, Prescription drugs.

21 CFR Part 250**Drugs.****21 CFR Part 310**

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 200, 250, and 310 are amended as follows:

PART 200—GENERAL

1. The authority citation for 21 CFR part 200 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 515, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375).

2. Sections 200.100 and 200.101 are removed and the heading for subpart D is reserved.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

3. The authority citation for 21 CFR part 250 continues to read as follows:

Authority: Secs. 201, 306, 402, 502, 503, 505, 601(a), 602(a) and (c), 701, 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b)).

§ 250.104 [Removed]

4. Section 250.104 *Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act* is removed.

§ 250.203 [Removed]

5. Section 250.203 *Status of fluoridated water and foods prepared with fluoridated water* is removed.

PART 310—NEW DRUGS

6. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512-516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

§ 310.101 [Removed]

7. Section 310.101 *FD&C Red No. 4; procedure for discontinuing use in new drugs for ingestion; statement of policy* is removed.