

SUPPLEMENTARY INFORMATION:

Background

On December 30, 1993, Customs published in the *Federal Register* (58 FR 69460) T.D. 94-1 to set forth interim amendments to the Customs Regulations to implement the preferential tariff treatment and other Customs-related provisions of the North American Free Trade Agreement (NAFTA) which was adopted by the United States through the enactment of the North American Free Trade Agreement Implementation Act ("the Act"), Public Law 103-182, 107 Stat. 2057. Those interim regulatory amendments took effect on January 1, 1994, to coincide with the effective date of the NAFTA.

This document corrects some errors published in T.D. 94-1. Two errors involved amended § 24.22: (1) Paragraph (g)(1), as revised in the document, failed to fully reflect the change in wording of section 13031(a)(5) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(a)(5)) effected by section 521 of the Act for fiscal years 1994 through 1997; and (2) the document failed to amend paragraph (g)(2)(iv) to avoid a conflict between that paragraph and the amended statutory and paragraph (g)(1) language. In new § 181.45, a printing error involving the text of paragraph (a) before the example is corrected by rearranging the text without any change in substance. In addition, in order to ensure coverage of all appropriate litigation contexts involving Customs and its officers or agents, at the end of new §§ 181.98(b) and 181.116(f) the word "defendant" is corrected to read "party to the action". Finally, this document corrects a number of drafting or typesetting errors of an editorial nature.

Corrections of Publication

Accordingly, the document published in the *Federal Register* as T.D. 94-1 on December 30, 1993 (58 FR 69460) is corrected as set forth below.

Correction to the Background Section

1. On page 69461, in the second column under the heading Part 24, the first paragraph is corrected to read:

Section 24.22, which was published as a final rule in T.D. 93-85 on October 21, 1993 (58 FR 54271), is amended to reflect changes to the commercial passenger arrival fee provisions of section 13031 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c) effected by section 521 of the Act. The changes involve, for fiscal years 1994 through 1997 (in effect, from January 1, 1994 through September

30, 1997), (1) replacement of the words "from a place outside the United States" by the words "from outside the customs territory of the United States", (2) an increase in the fee from \$5 to \$6.50, and (3) suspension of the fee exemption for persons whose journey involves certain specified locations outside the United States.

Corrections to the Interim Regulations

2. On page 69470, in the third column, the amendatory language and text pertaining to § 24.22 are corrected to read:

Section 24.22 is amended by revising paragraph (g)(1), the introductory text of paragraph (g)(2)(i)(A), and paragraph (g)(2)(iv) to read as follows:

§ 24.22 Fees for certain services.

* * * * *

(g) *Fee for arrival of passengers aboard commercial vessels and commercial aircraft.*

(1) *Fee.* Except as provided in paragraph (g)(2) of this section:

(i) For the period from January 1, 1994 through September 30, 1997, a fee of \$6.50 shall be collected and remitted to Customs for services provided in connection with the arrival of each passenger aboard a commercial vessel or commercial aircraft from outside the customs territory of the United States; and

(ii) Commencing on October 1, 1997, a fee of \$5 shall be collected and remitted to Customs for services provided in connection with the arrival of each passenger aboard a commercial vessel or commercial aircraft from a place outside the United States.

(2) * * *

(i)(A) Except during the period from January 1, 1994 through September 30, 1997, persons whose journey:

* * * * *

(iv) Except during the period from January 1, 1994 through September 30, 1997, persons departing from and returning to the United States without having touched a foreign port or place;

* * * * *

§ 181.12 [Corrected]

3. On page 69475, in the first column, in § 181.12(a)(3), the second sentence should be a flush paragraph.

§ 181.45 [Corrected]

4. On page 69478, in the second column, in § 181.45, the text of paragraph (a) before the example is corrected to read:

(a) *Goods originating in Canada or Mexico.* A Canadian or Mexican originating good that is dutiable and is imported into the United States is

eligible for drawback without regard to the limitation on drawback set forth in § 181.44 of this part if that originating good is:

(1) Subsequently exported to Canada or Mexico;

(2) Used as a material in the production of another good that is subsequently exported to Canada or Mexico; or

(3) Substituted by a good of the same kind and quality and used as a material in the production of another good that is subsequently exported to Canada or Mexico.

§ 181.47 [Corrected]

5. On page 69479, in the second column, the second sentence in § 181.47(a) is corrected by removing the word "existing".

§ 181.53 [Corrected]

6. On page 69482, in the second column, in § 181.53(e)(2), the second sentence of the example is corrected by adding the word "have" after the word "would" within the parentheses.

§ 181.94 [Corrected]

7. On page 69491, in the third column, in § 181.94, the reference "thirty (30)" in the second sentence is corrected to read "30".

§ 181.98 [Corrected]

8. On page 69492, in the second column, in § 181.98(b), the word "defendant" at the end of the last sentence is corrected to read "party to the action".

§ 181.100 [Corrected]

9. On page 69493, in the third column, in § 181.100(a)(2)(iii), the text is corrected by adding the word "value" after the word "regional".

§ 181.116 [Corrected]

10. On page 69496, in the third column, in § 181.116(f), the word "defendant" at the end of the last sentence is corrected to read "party to the action".

Dated: February 17, 1994.

Karen J. Hiatt,

Acting Assistant Commissioner, Office of Commercial Operations.

[FR Doc. 94-4148 Filed 2-23-94; 8:45 am]

BILLING CODE 4820-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 92F-0061]

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 trimethylolpropane as a pigment dispersant in resinous and polymeric coatings in contact with food. This action is in response to a petition filed by SCM Chemicals.

DATES: Effective February 24, 1994; written objections and requests for a hearing by March 28, 1994.

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 Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of April 13, 1992 (57 FR 12831), FDA announced that a food additive petition (FAP 2B4316) had been filed by SCM Chemicals, c/o 1001 G St. NW., suite 500 West, Washington, DC 20001. 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 trimethylolpropane as a pigment dispersant in resinous and polymeric coatings in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive 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 March 28, 1994, 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:

* * * * *

Trimethylolpropane (CAS Reg. No. 77-99-6).

For use as a pigment dispersant at levels not to exceed 0.45 percent by weight of the pigment.

* * * * *

Dated: February 15, 1994.

Janice F. Oliver,

Acting Director, Center for Food Safety and Applied Nutrition

[FR Doc. 94-4081 Filed 2-23-94; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 178

[Docket No. 93F-01801]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant in the manufacture of polypropylene and styrene block polymers that contact food. This action is in response to two petitions filed by Sumitomo Chemical America, Inc.

DATES: Effective February 24, 1994; written objections and requests for a hearing by March 28, 1994.

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 Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 23, 1993 (58 FR 34058), FDA announced that two food additive petitions (FAP's 3B4357 and 3B4359) had been filed by Sumitomo Chemical

America, Inc., 345 Park Ave., New York, NY 10154, proposing that food additive regulations be amended in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant in the manufacture of polypropylene and styrene block polymers that contact food.

FDA has evaluated data in the petitions and other relevant material. The agency concludes that the proposed uses of the additive are safe and that the regulations in § 178.2010 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 petitions 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 March 28, 1994, 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

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

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

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

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *
(b) * * *

Substances	Limitations
2,4-Di- <i>tert</i> -pentyl-6-[1-(3,5-di- <i>tert</i> -pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate (CAS Reg. No. 123968-25-2).	For use only: 1. At levels not to exceed 0.2 percent by weight of polypropylene complying with § 177.1520 of this chapter. The additive is used under conditions of use D through G described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.5 percent by weight of styrene block polymers complying with § 177.1810 of this chapter. The additive is used under conditions of use D through G described in Table 2 of § 176.170(c) of this chapter.

Dated: February 15, 1994.
Janice F. Oliver,
Acting Director, Center for Food Safety and Applied Nutrition.
[FR Doc. 94-4079 Filed 2-23-94; 8:45 am]
BILLING CODE 4160-01-F

21 CFR Parts 436 and 442

[Docket No. 93N-0328]

Antibiotic Drugs; Cefadroxil Hemihydrate; Cefadroxil Hemihydrate Capsules and Cefadroxil Hemihydrate Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

antibiotic drug regulations to provide for the inclusion of accepted standards for a new antibiotic drug, cefadroxil hemihydrate, and the use of the antibiotic drug in two dosage forms, cefadroxil hemihydrate capsules and cefadroxil hemihydrate tablets. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective March 28, 1994; written comments, notice of participation, and request for a hearing by March 28, 1994;

data, information, and analyses to justify a hearing by April 25, 1994.

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

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0335.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new antibiotic drug, cefadroxil hemihydrate, and its use in two dosage forms, cefadroxil hemihydrate capsules and cefadroxil hemihydrate tablets. The agency has concluded that the data supplied by the manufacturer concerning these antibiotic drugs are adequate to establish their safety and efficacy when used as directed in the labeling and that the regulations should be amended in 21 CFR parts 436 and 442 to provide for the inclusion of accepted standards for these products.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for

approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, is effective March 28, 1994. However, interested persons may, on or before March 28, 1994, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before March 28, 1994, a written notice of participation and request for a hearing, and (2) on or before April 25, 1994, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for a hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings

and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this document and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for a hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Parts 436 and 442

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 436 and 442 are amended as follows:

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

1. The authority citation for 21 CFR part 436 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

2. Section 436.215 is amended by alphabetically adding two new entries to the table in paragraph (b) and by adding new paragraph (c)(17) to read as follows:

§ 436.215 Dissolution test.

* * * * *
(b) * * *

Dosage form	Dissolution medium	Rotation rate ¹	Sampling time(s)	Apparatus
Cefadroxil hemihydrate capsules	900 mL distilled water	100	45 min	1
Cefadroxil hemihydrate tablets	900 mL distilled water	50	30 min	2

¹Rotation rate of basket or paddle stirring element (revolutions per minute).

(c) * * *
(17) *Cefadroxil hemihydrate*. Proceed as directed in paragraph (c)(1) of this section, except use the cefadroxil working standard and measure the

absorbance at the absorption peak of approximately 264 nanometers.

* * * * *

PART 442—CEPHA ANTIBIOTIC DRUGS

3. The authority citation for 21 CFR part 442 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

4. New § 442.7 is added to subpart A to read as follows:

§ 442.7 Cefadroxil hemihydrate.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefadroxil hemihydrate is 7-[D-2-amino-2-(p-hydroxyphenyl)acetamido]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid hemihydrate. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms and not more than 1,050 micrograms of cefadroxil activity per milligram on an anhydrous basis.

(ii) [Reserved]

(iii) Its moisture content is not less than 2.4 percent and not more than 4.5 percent.

(iv) The pH of an aqueous solution containing 50 milligrams per milliliter is not less than 4.0 and not more than 6.0.

(v) When calculated on an anhydrous basis, its absorptivity at 264 nanometers is not less than 95 percent and not more than 104 percent of that of the cefadroxil standard similarly treated and corrected for potency.

(vi) It passes the identity test.

(vii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for cefadroxil potency, moisture, pH, absorptivity, identity, and crystallinity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay—(1) Potency.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 20 micrograms of cefadroxil per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay for cefadroxil.* Proceed as directed in § 442.40(b)(1)(ii), except prepare the working standard and sample solutions

and calculate the potency of the sample as follows:

(A) *Preparation of working standard solutions.* Dissolve and dilute an accurately weighed portion of the cefadroxil working standard in sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter.

(B) *Preparation of sample solutions.* Dissolve an accurately weighed portion of the sample in sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter (estimated).

(C) *Calculations.* Calculate the potency of the sample in micrograms per milligram as follows:

$$\text{Micrograms of cefadroxil per milligram} = \frac{A_U \times P_o \times 100}{A_S \times W_U \times (100-m)}$$

where:

A_U = Absorbance of sample solution;

A_S = Absorbance of working standard solution;

P_o = Potency of working standard solution in micrograms per milliliter;

W_U = Milligrams of sample per milliliter of sample solution; and

m = Percent moisture content of the sample.

(2) [Reserved]

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 50 milligrams per milliliter.

(5) *Absorptivity.* Determine the absorbance of the sample and standard solutions in the following manner: Dissolve accurately weighed portions of approximately 50 milligrams each of the sample and standard in 250 milliliters of distilled water. Transfer a 10-milliliter aliquot to a 100-milliliter volumetric flask and dilute to volume with distilled water. Using a suitable spectrophotometer and distilled water as the blank, determine the absorbance of each solution at 264 nanometers. Determine the percent absorptivity of the sample relative to the absorptivity of the standard using the following calculations:

$$\text{Percent relative absorptivity} = \frac{[\text{Absorbance of sample X milligrams standard X potency of standard in micrograms per milligram X 10}]}{[\text{Absorbance of standard X milligrams sample X (100-m)}]}$$

where:

m = Percent moisture in the samples.

(6) *Identity.* Using the sample and working standard solutions prepared as described in paragraph (b)(5) of this section and a suitable spectrophotometer, record the ultraviolet spectrum from 220 to 340 nanometers. The spectrum of the sample compares qualitatively with that of the cefadroxil working standard.

(7) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

5. New §§ 442.107, 442.107a, and 442.107b are added to subpart B to read as follows:

§ 442.107 Cefadroxil hemihydrate oral dosage forms.

§ 442.107a Cefadroxil hemihydrate capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefadroxil hemihydrate capsules are composed of cefadroxil hemihydrate and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains cefadroxil hemihydrate equivalent to 500 milligrams of cefadroxil. Its cefadroxil content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefadroxil that it is represented to contain. Its moisture content is not more than 7.0 percent. It passes the dissolution test. The cefadroxil hemihydrate used conforms to the standards prescribed in § 442.7(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefadroxil hemihydrate used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(B) The batch for content, moisture, and dissolution.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The cefadroxil hemihydrate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 100 capsules.

(b) *Tests and methods of assay—(1) Cefadroxil content.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105

of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 20 micrograms of cefadroxil per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay for cefadroxil*. Proceed as directed in § 442.40(b)(1)(ii), except prepare the working standard and sample solutions and calculate the potency of the sample as follows:

(A) *Preparation of working standard solutions*. Dissolve and dilute an accurately weighed portion of the cefadroxil working standard in sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter.

(B) *Preparation of sample solutions*. Blend a representative number of capsules in a high-speed glass blender jar with sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter (estimated).

(C) *Calculations*. Calculate the cefadroxil content as follows:

$$\text{Milligrams of cefadroxil per capsule} = \frac{A_U \times P_S \times d}{A_S \times 1,000 \times n}$$

where:

A_U = Absorbance of sample solution;

A_S = Absorbance of working standard solution;

P_S = Potency of working standard solution in micrograms per milliliter;

d = Dilution factor of the sample;

n = Number of capsules in the sample assayed.

(2) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(3) *Dissolution*. Proceed as directed in § 436.215 of this chapter. The quantity Q (the amount of cefadroxil dissolved) is 75 percent within 45 minutes.

§ 442.107b Cefadroxil hemihydrate tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Cefadroxil hemihydrate tablets are composed of cefadroxil hemihydrate and one or more suitable and harmless binders and lubricants, with or without coloring and film-coating substances. Each tablet contains cefadroxil hemihydrate equivalent to 1,000 milligrams of cefadroxil. Its cefadroxil content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefadroxil that it is represented to contain. Its moisture content is not more than 8.0 percent. It passes the dissolution test. The cefadroxil hemihydrate used conforms to the standards prescribed in § 442.7(a)(1).

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples*. In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefadroxil hemihydrate used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(B) The batch for content, moisture, and dissolution.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The cefadroxil hemihydrate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 100 tablets.

(b) *Tests and methods of assay—(1) Cefadroxil content*. Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric assay shall be conclusive.

(i) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105

of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 20 micrograms of cefadroxil per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay for cefadroxil*. Proceed as directed in § 442.40(b)(1)(ii), except prepare the working standard and sample solutions and calculate the potency of the sample as follows:

(A) *Preparation of working standard solutions*. Dissolve and dilute an accurately weighed portion of the cefadroxil working standard in sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter.

(B) *Preparation of sample solutions*. Blend a representative number of tablets in a high-speed glass blender jar with sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cefadroxil per milliliter (estimated).

(C) *Calculations*. Calculate the cefadroxil content as follows:

$$\text{Milligrams of cefadroxil per tablet} = \frac{A_U \times P_S \times d}{A_S \times 1,000 \times n}$$

where:

A_U = Absorbance of sample solution;

A_S = Absorbance of working standard solution;

P_S = Potency of working standard solution in micrograms per milliliter;

d = Dilution factor of the sample; and

n = Number of tablets in the sample assayed.

(2) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(3) *Dissolution*. Proceed as directed in § 436.215 of this chapter. The quantity Q (the amount of cefadroxil dissolved) is 75 percent within 30 minutes.

Dated: February 9, 1994.

Stephanie R. Gray,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

Amendment of the Fee Exemption for Federal, State and Local Government Employees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This final rule limits the exemption from payment of application fees for registration or reregistration to Federal, state, or local government operated hospitals or institutions. This will eliminate the need for DEA to dedicate manpower or other resources to controlling abuse of the fee exempt status.

EFFECTIVE DATE: March 28, 1994.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION: On June 1, 1993, a notice of proposed rulemaking was published in the *Federal Register* (58 FR 31180). DEA proposed to limit the exemption from payment of registration or reregistration application fees to Federal, state or local government operated hospital/clinics.

A total of three comments were received, all opposed to the proposed changes. Two of the comments concerned state certified euthanasia technicians. The commenters objected to the changes on the grounds that the change would impose a financial burden on the euthanasia technicians and the animal shelters at which they work, due to the extremely high turnover rate the industry experiences. This will not be the case. The euthanasia technicians are employees of animal control facilities or shelters. They may not engage in their activities other than as employees of the facilities or shelters. Under such circumstances, DEA has traditionally issued the

registrations for such activities under the facility or shelter name with the euthanasia technician's name appearing thereafter. It is appropriate under such circumstances for the Federal, state or local government facility or shelter to request and receive the exemption from the fee. In light of the fact that DEA registers these activities as other than a hospital or clinic, the original language of the proposal with respect to Federal, state or local hospitals or clinics has been changed to Federal, state or local hospitals or other institutions.

The third commentor objected to the changes on the grounds that the proposed changes, if implemented, would prevent public sector employees from using their exempt status to obtain registrations for use in private practice. That is the exact intent of the proposal. Any individual who engages in private practice utilizing a DEA registration must pay the required fee for that registration. Individuals who engage in public practice as agents or employees of Federal, state or local hospitals or institutions would not be required to obtain a registration; they would conduct their controlled substances activities under the registration of the hospital or institution. Although this has been a longstanding policy, DEA will clarify the provisions for such activities in light of the impact that the limiting of the fee exemption will have. A proposal to amend § 1301.24 has been drafted to clarify the exemption from the registration requirement of individual practitioners who act as agents or employees of other individual practitioners and of hospitals or other institutions. That proposal will be published in the *Federal Register* in the near future.

There are approximately 44,000 active DEA registrations which were issued under the fee exempt status. Over 35,000 of the registrations are for practitioners and the remainder are for Federal, state or local hospitals or institutions. By restricting the fee exempt status to the hospitals or institutions and allowing the practitioners to carry out their official duties under the hospital or institution registrations, DEA will eliminate the need to dedicate manpower or other resources to controlling the misuse of the fee exempt status.

The limiting of the fee exemption will not affect those law enforcement analytical laboratories which are described in § 1301.26.

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this final rule will have no significant impact upon entities whose interests must be considered under the

Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* Any financial or regulatory burdens that practitioners may experience are existing burdens which the practitioners have heretofore avoided by inappropriate use of the fee exemption.

This final rule is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, security measures.

For reasons set out above, 21 CFR part 1301 is amended as follows:

PART 1301—[AMENDED]

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.13 is amended by revising paragraphs (a) and (b) to read as follows:

§ 1301.13 Persons exempt from fee.

(a) The Administrator shall exempt from payment of an application fee for registration or reregistration any hospital or other institution which is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(b) In order to claim exemption from payment of a registration or reregistration application fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's officer certifies to the status and address of the registrant.

* * * * *

Dated: February 14, 1994.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control.

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