

a substantial number of small entities. No significant economic impact would be imposed on such entities by the interim final rule.

The Department has decided that it is in the best interests of the grantees to enact this interim final rule as quickly as possible. The Department intends to publish in the near future proposed and final regulations to implement the 1992 amendments to JTPA. It is likely, however, that final regulations will not be published in time to be implemented for the next program cycle. This interim final rule will permit grantees to make meaningful plans for the next program cycle. In the past, grantees have consistently sought this waiver provision. Members of the Council unanimously support this regulatory waiver capability as being in the best interests of the section 401 grantees. There are no mandatory requirements imposed on section 401 grantees as a result of this interim final rule. The decision to request or not request a specific waiver is up to the individual grantee, and will be considered by the Department on an individual basis. General input from the grantee community at large is strongly in favor of this interim final rule, because it will enable grantees to seek, and the Department to grant, relief from regulations which are currently not subject to waiver of any kind. It is broadly construed as being of benefit to the government and to all section 401 grantees.

Catalog of Federal Domestic Assistance Number

This program is listed in the *Catalog of Federal Domestic Assistance* at No. 17.251, "Native American Employment and Training Programs".

Paperwork Reduction

This interim final rule contains no new collection of information requirements.

List of Subjects

20 CFR Part 626

Grant programs—labor, Manpower training programs.

20 CFR Part 632

Grant programs—Indians,—Grant programs—labor, Indians Manpower training programs, Youth.

Interim Final Rule

Accordingly, 20 CFR Chapter V is amended as follows:

PART 626—INTRODUCTION TO THE REGULATIONS UNDER THE JOB TRAINING PARTNERSHIP ACT

1. The authority citation for Part 626 is revised to read as follows:

Authority: 29 U.S.C. 1579(a).

2. In § 626.4, the consolidated table of contents is amended by adding a section heading for 632.70 under Part 632 to read as follows:

§ 626.4 Table of contents for the Job Training Partnership Act regulations.

* * * * *

PART 632—INDIAN AND NATIVE AMERICAN EMPLOYMENT AND TRAINING PROGRAMS

* * * * *

Subpart E—Program Design and Management

632.70 Waiver of regulations under Parts 632 and 636.

* * * * *

3. The authority citation for Part 632 is revised to read as follows:

Authority: 29 U.S.C. 1579(a).

4. Subpart E of Part 632 is amended by adding a new § 632.70 to read as follows:

§ 632.70 Waiver of regulations under Parts 632 and 636.

(a) A Native American section 401 grantee may request, and the Assistant Secretary of Labor for Employment and Training may grant, a waiver of specific provisions of 20 CFR Parts 632 and 636, or of any applicable administrative issuance, to the extent that such request is consistent with the provision of the Act.

(b)(1) In requesting a waiver under this section, the Native American section 401 grantee shall demonstrate how it will enhance the provision of services or outcomes to participants, which may include, but are not limited to, the following purposes: improving the targeting of services to the hard-to-serve; increasing the level of basic and occupational skills training provided by the JTPA program; contributing to the provisions of academic enrichment services to youth; promoting coordination of JTPA programs with other human resources programs; or substantially improving the job placement outcomes of the JTPA program.

(2) The request shall describe the regulatory requirements to be waived and demonstrate how such requirements impede the enhancement of the services and outcomes described in paragraph (b)(1) of this section.

(3) The waiver request shall indicate how the grantee will modify its

planning documents as a result of the waiver.

(c) A waiver shall not be granted for:

(1) Any statutory requirement;
(2) The formula for allocation of funds;

(3) Eligibility requirements for services as provided in this part;

(4) Requirements for public health or safety, labor standards, civil rights, occupational safety or health, or environmental protection; or

(5) Prohibitions or restrictions relating to construction of buildings or facilities.

(d) Waivers granted shall be effective for no more than four years from the date the waiver is granted.

Signed at Washington, DC, this 13th day of November 1995.

Robert B. Reich,

Secretary of Labor.

[FR Doc. 95-28434 Filed 11-24-95; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 430, 436, and 442

[Docket No. 95N-0186]

Antibiotic Drugs; Cefpodoxime Proxetil, Cefpodoxime Proxetil Tablets, and Cefpodoxime Proxetil Granules for Oral Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to include accepted standards for a new antibiotic drug, cefpodoxime proxetil, and its use in two dosage forms, cefpodoxime proxetil tablets and cefpodoxime proxetil granules for oral suspension. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective December 27, 1995; written comments, notice of participation, and request for a hearing by December 27, 1995; data, information, and analyses to justify a hearing by January 26, 1996.

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:

James Timper, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6714.

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, cefpodoxime proxetil, and its use in two dosage forms, cefpodoxime proxetil tablets and cefpodoxime proxetil granules for oral suspension. 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 430, 436, and 442 to include 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 December 27, 1995. However, interested persons may, on or before December 27, 1995, submit written 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 December 27, 1995, a

written notice of participation and request for a hearing, and (2) on or before January 26, 1996, 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**21 CFR Part 430**

Administrative practice and procedure, Antibiotics.

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 430, 436, and 442 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. The authority citation for 21 CFR part 430 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 357, 371); secs. 215, 301, 351 of the Public Health Service Act (42 U.S.C. 216, 241, 262).

2. Section 430.4 is amended by adding new paragraph (a)(70) to read as follows:

§ 430.4 Definitions of antibiotic substances.

(a) * * *

(70) Cefpodoxime proxetil.

Cefpodoxime proxetil is an antibiotic substance having the chemical structure described by the following name: (±)-1-Hydroxyethyl(+)-(6*R*,7*R*)-7-[2-(2-amino-4-thiazolyl)glyoxylamido]-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate, 7²-(*Z*)-(O-methyloxime), isopropyl carbonate (ester).

* * * * *

3. Section 430.5 is amended by adding new paragraphs (a)(105) and (b)(107) to read as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(105) *Cefpodoxime proxetil*. The term "cefpodoxime proxetil master standard" means a specific lot of the (R) isomer of cefpodoxime proxetil that is designated by the Commissioner as the standard of comparison in determining the potency of the cefpodoxime proxetil working standard.

(b) * * *

(107) *Cefpodoxime proxetil*. The term "cefpodoxime proxetil working standard" means a specific lot of a homogeneous preparation of cefpodoxime proxetil.

4. Section 430.6 is amended by adding new paragraph (b)(107) to read as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

* * * * *

(b) * * *

(107) *Cefpodoxime proxetil*. The term "microgram" applied to cefpodoxime proxetil means the cefpodoxime (potency) contained in 1.304 micrograms of the cefpodoxime proxetil master standard when dried.

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

5. 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).

6. Section 436.215 is amended by alphabetically adding a new entry to the table in paragraph (b) and by adding new paragraph (c)(19) to read as follows:

§ 436.215 Dissolution test.

* * * * *

(b) * * *

Dosage form	Dissolution medium	Rotation rate ¹	Sampling times(s)	Apparatus
* * * Cefpodoxime proxetil tablets	* * * 900 mL pH 3.0 glycine buffer	* * * 75	* * * 30 min	* * * 2

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

(c) * * *

(19) *Cefpodoxime proxetil*—(i) *Dissolution fluid: 0.04 molar glycine buffer, pH 3.0*—(A) *Stock solution.* Dissolve 54.5 grams of glycine (aminoacetic acid) and 42.6 grams of sodium chloride in about 500 milliliters of deionized water in a 1-liter volumetric flask. Add cautiously, and with swirling, 14.2 milliliters of concentrated hydrochloric acid. Cool to room temperature. Dilute to volume with deionized water and mix. Check the pH of the solution obtained by diluting 50 milliliters of the stock solution to 900 milliliters with deionized water. The pH should be 3.0±0.1. If necessary, adjust the pH of the stock solution with 50 percent sodium hydroxide or concentrated hydrochloric acid. Recheck that the pH of the working solution is 3.0±0.1.

(B) *Working solution.* Dilute 50 milliliters of stock solution to 900 milliliters with deionized water.

(ii) *Preparation of the working standard solutions.* Accurately weigh approximately 28 milligrams for the 100-milligram tablets and 56 milligrams for the 200-milligram tablets of the cefpodoxime proxetil working standard and dissolve in 10 milliliters of methanol. Dilute to 200 milliliters with dissolution fluid. Prepare fresh daily.

(iii) *Sample solutions.* Filter the sample solutions through a 0.45-micron filter before use. Use the sample solution as it is removed from the dissolution vessel without further dilution.

(iv) *Procedure.* Using a suitable spectrophotometer and water as the blank, determine the absorbance of each standard and sample solution at the absorbance peak at approximately 259 nanometers. Determine the exact position of the absorption peak for the particular instrument used.

(v) *Calculations.* Determine the percent of label dissolved as follows:

$$\text{Percent dissolved} = (A_{sam}/A_{std}) \times (C_s/L) \times V \times P \times F1$$

where:

A_{sam} = Absorbance of the sample at 259 nanometers;

A_{std} = Absorbance of the working standard solution at 259 nanometers;

C_s = Concentration of the working standard preparation in milligrams per milliliter;

L = Tablet strength, in milligrams per tablet;

P = Purity of the reference standard in percent;

V = Volume of dissolution fluid used in milliliters (900); and

$F1$ = 0.7666 (conversion factor to free acid equivalents).

PART 442—CEPHA ANTIBIOTIC DRUGS

7. 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).

8. New § 442.54 is added to subpart A to read as follows:

§ 442.54 Cefpodoxime proxetil.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefpodoxime proxetil is (±)-1-hydroxyethyl(+)-(6*R*,7*R*)-7-[2-(2-amino-4-thiazolyl)glyoxyamido]-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate,7*Z*-(*O*-methyloxime), isopropyl carbonate (ester). It is so purified and dried that:

(i) Its potency is not less than 690 micrograms and not more than 804 micrograms of cefpodoxime activity per milligram, on an anhydrous basis.

(ii) The ratio of its *R*-epimer to total cefpodoxime is not less than 0.5 and not more than 0.6.

(iii) Its moisture content is not more than 3 percent.

(iv) It gives a positive identity test.

(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 cefpodoxime potency, isomer ratio, moisture, and identity.

(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.* Proceed as directed in § 436.216 of this chapter, using a suitable thermostatted column heating mechanism to maintain a column temperature of 40 °C, an ultraviolet detection system operating at a wavelength of 254 nanometers, a 15 centimeter X 4.6 millimeter (i.d.) column packed with microparticulate (5 micrometers in diameter) reversed phase packing material such as octadecyl silane bonded to silicas, a flow rate of 0.8 milliliter per minute, and a known injection volume of 2 microliters. The retention time for the *S*-epimer is approximately 22 minutes and the retention time for *R*-epimer is approximately 28 minutes. The internal standard (propylparaben) has a retention time of 34 minutes. Mobile phase, dilution solvent, resolution solution, internal standard solution, working standard and sample solutions, system suitability requirements, and calculations are as follows:

(i) *Mobile phase.* The mobile phase consists of 420 milliliters of methanol, 580 milliliters of deionized water, and 230 milligrams of *L*-histidine hydrochloride. The pH is adjusted to 2.5±0.1 using 2*N* sulfuric acid. The mobile phase must be at room temperature for a correct pH measurement. The methanol concentration may be adjusted to achieve comparable retention times from column to column. Increasing methanol reduces retention times. Filter the mobile phase through a suitable filter capable of removing particulate matter 0.5 micron in diameter and degas it just before its introduction into the chromatograph.

(ii) *Dilution solvent.* Prepare a solvent for dilution by thoroughly mixing 495 milliliters of deionized water, 495 milliliters of acetonitrile, and 10 milliliters of acetic acid in an appropriate container.

(iii) *Resolution solution.* Prepare a 1 milligram per milliliter solution of any bulk containing ANTI-A in dilution solvent. Use this solution to determine the resolution between ANTI-A and the

later-eluting drug epimer (R-epimer). Alternately, the resolution factor can be determined between the R and S isomers.

(iv) *Internal standard solution.*

Prepare a solution of propylparaben in dilution solvent at a concentration of 10 milligrams per milliliter.

(v) *Preparation of working standard solutions.* Accurately weigh approximately 42 milligrams of the cefpodoxime proxetil working reference standard add 3 milliliters of internal standard solution and 25 milliliters of dilution solvent. The standard solution is stable for at least 48 hours.

Refrigeration is not recommended.

(vi) *Sample solution.* Accurately weigh approximately 42 milligrams of the sample, add 3 milliliters of internal

standard and 25 milliliters of dilution solvent. The sample solution is stable for at least 48 hours. Refrigeration is not recommended.

(vii) *System suitability requirements—*

(A) *Asymmetry factor.* The asymmetry factor (A_s) is satisfactory if it is not less than 0.8 and not more than 1.1 for the R-epimer of cefpodoxime peak.

(B) *Efficiency of the column.* The absolute efficiency (h_p) is satisfactory if it is not more than 5 for the R-epimer peak.

(C) *Resolution factor.* The resolution factor (R) between the peak for ANTI-A and the peak for the R-epimer is satisfactory if it is not less than 1.3. Alternately, the resolution factor (R) between the peak for the R-epimer and

the peak for the S-epimer of cefpodoxime is not less than 11.

(D) *Coefficient of variation (Relative standard deviation).* The coefficient of variation (S_R in percent of 5 replicate injections) is satisfactory if it is not more than 2 percent.

(E) *Capacity factor (k').* The capacity factor (k') for the R-epimer of cefpodoxime is satisfactory if it is not less than 10.4 and not more than 15.6.

(F) If the system suitability parameters in this paragraph (b)(1)(iv) have been met, then proceed as described in § 436.216(b) of this chapter.

(viii) *Calculations.* Calculate the micrograms of cefpodoxime proxetil per milligram of sample on an anhydrous basis as follows:

Micrograms of cefpodoxime proxetil per milligram

$$= \frac{R_u \times P_s \times 100}{R_s \times C_u \times (100 - m)}$$

where:

R_u = Ratio of cefpodoxime proxetil peaks area (sum of both epimers) to the internal standard peak response in the sample solution;

R_s = Ratio of cefpodoxime proxetil peaks area (sum of both epimers) to the internal standard peak response in the working standard solution;

P_s = Cefpodoxime proxetil activity of the working standard solution in micrograms per milliliter;

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

m = Percent moisture content of the sample.

(2) *Isomer ratio.* Using the procedure described in paragraph (b)(1) of this section, calculate the ratio of the R-epimer (Ab) to the sum of the S-epimer and R-epimer (Aa and Ab), by the equation

$$\text{Isomer Ratio} = \text{Ab}/(\text{Aa} + \text{Ab})$$

where:

Aa = Area of the early eluting S-epimer peak; and

Ab = Area of the late eluting R-epimer peak.

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter, except use 30 milliliters of solvent C instead of 20 milliliters of solvent A.

(4) *Identity.* Proceed as directed in § 436.211 of this chapter, using the mineral oil mull prepared as described in paragraph (b)(2) of that section.

9. New §§ 442.154, 442.154a, and 442.154b are added to subpart B to read as follows:

§ 442.154 Cefpodoxime proxetil oral dosage forms.

§ 442.154a Cefpodoxime proxetil tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefpodoxime proxetil tablets are composed of cefpodoxime proxetil and one or more suitable and harmless diluents, binders, lubricants, colorings, and coating substances. Each tablet contains cefpodoxime proxetil equivalent to either 100 milligrams or 200 milligrams of cefpodoxime. Its cefpodoxime proxetil content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of cefpodoxime that it is represented to contain. Its loss on drying is not more than 5 percent. It passes the dissolution test. It passes the identity test. The cefpodoxime proxetil used conforms to the standards prescribed by § 442.54(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 cefpodoxime proxetil used in making the batch for potency, isomer ratio, moisture, and identity.

(B) The batch for content, loss on drying, dissolution, and identity.

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

(A) The cefpodoxime proxetil 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) Cefpodoxime content.* Proceed as directed in § 442.54(b)(1), preparing the sample solution and calculating the cefpodoxime content as follows:

(i) *Preparation of sample solution.* Obtain the average tablet weight of at least 20 tablets. Grind the tablets using a mortar and pestle. Weigh approximately 660 milligrams into a suitable container. Add 30 milliliters of internal standard solution. Shake for 30 minutes using a horizontal platform shaker or equivalent. Centrifuge for about 10 minutes at 3,000 revolutions per minute until the particulate matter has settled. Withdraw a 1 milliliter aliquot of the supernatant and dilute with 9 milliliters of dilution solvent. The sample solutions are stable for at least 48 hours. Refrigeration is not recommended.

(ii) *Calculations.* Calculate the cefpodoxime content as follows:

Milligrams of cefpodoxime per tablet

$$= (R_{sam}/R_{std}) \times (W_{std}/W_{sam}) \times (F_1/F_3) \times F_2 \times F_4 \times P$$

where:

R_{sam} = Ratio of cefpodoxime proxetil peaks area (sum of both epimers) to the internal standard peak area in the sample preparation;

R_{std} = Ratio of cefpodoxime proxetil peaks area (sum of both epimers) to the internal standard peak area in the standard preparation;

W_{std} = Weight of cefpodoxime proxetil reference standard, in milligrams;

W_{sam} = Weight of sample, in milligrams;

F_1 = Volume of internal standard used in the sample preparation, in milliliters;

F_2 = 0.766; The ratio of molecular weight for free-acid cefpodoxime over the molecular weight of cefpodoxime proxetil (427.46/557.61);

F_3 = Volume of internal standard used in the standard preparation, in milliliters;

F_4 = Average tablet weight, i.e., weight of tablets used in sample preparation divided by the number of tablets; and

P = Purity of the cefpodoxime proxetil reference standard, expressed as a decimal.

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter, except dry the sample at a temperature of 80 °C and a pressure of 5 millimeters of mercury or less for 16 hours.

(3) *Dissolution test.* Proceed as directed in § 436.215 of this chapter. The quantity Q (the amount of cefpodoxime activity dissolved) is 70 percent within 30 minutes.

(4) *Identity.* Using the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section, the retention times for the peaks of the active ingredients must be within 2 percent of the retention

times for the peaks of the corresponding reference standards.

§ 442.154b Cefpodoxime proxetil granules for oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefpodoxime proxetil granules for oral suspension is cefpodoxime proxetil and one or more suitable and harmless preservatives, sweeteners, suspending agents, buffers, and flavorings. When constituted as directed in the labeling, each milliliter contains the equivalent of either 10 or 20 milligrams cefpodoxime activity. Its cefpodoxime proxetil content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of cefpodoxime that it is represented to contain. Its loss on drying is not more than 0.5 percent. When constituted as described in the labeling, the pH of the suspension is not less than 4 and not more than 5.5. It passes the identity test. The cefpodoxime proxetil used conforms to the standards prescribed by § 442.54(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 cefpodoxime proxetil used in making the batch for potency, isomer ratio, moisture, and identity.

(B) The batch for content, loss on drying, pH, and identity.

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

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

(B) The batch: A minimum of 10 intermediate containers.

(b) *Tests and methods of assay—(1) Cefpodoxime content.* Proceed as directed in § 442.54(b)(1), preparing the sample solution and calculating the cefpodoxime content as follows:

(i) *Preparation of sample solution.* Reconstitute as directed in the labeling. Immediately before sampling the suspension, shake vigorously for several seconds. Into a suitable container, accurately weigh out 6 grams of the 50 milligrams per 5 milliliters suspension, or 3 grams of the 100 milligrams per 5 milliliters suspension. Add 5 milliliters of internal standard solution and 25 milliliters of dilution solvent. Shake for 30 minutes using a horizontal platform shaker or equivalent. Centrifuge for about 10 minutes at 3,000 revolutions per minute until the particulate matter has settled. Withdraw a 1 milliliter aliquot of the supernatant and dilute with 1 milliliter of dilution solvent. The sample solutions are stable for at least 48 hours. Refrigeration is not recommended.

(ii) *Calculations.* Calculate the cefpodoxime content as follows:

$$\text{Milligrams of cefpodoxime per 5 milliliters of suspension} = (R_{sam}/R_{std}) \times (W_{std}/W_{sam}) \times (F_1/F_3) \times (F_2/F_4) \times F_5 \times P$$

where:

R_{sam} = Ratio of cefpodoxime proxetil peaks area (sum of both epimers) to the internal standard peak area in the sample preparation;

R_{std} = Ratio of cefpodoxime proxetil peaks area (sum of both epimers) to the internal standard peak area in the standard preparation;

W_{std} = Weight of cefpodoxime proxetil reference standard, in milligrams;

W_{sam} = Weight of sample, in grams;

F_1 = Volume of internal standard used in the sample; preparation, in milliliters;

F_2 = 0.766; The ratio of molecular weight for free-acid cefpodoxime over the molecular weight of cefpodoxime proxetil (427.46/557.61);

F_3 = Volume of internal standard used in the standard preparation, in milliliters;

F_4 = 0.2; Factor to convert to 5 milliliters;

F_5 = Specific gravity of suspension for milligram per 5 milliliter calculated on the air-free basis (specific gravity is determined on a sample of suspension that has been shaken gently on a platform shaker under vacuum for 2 hours); and

P = Purity of the cefpodoxime proxetil reference standard, expressed as a decimal.

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter, except dry the sample at a temperature of 80 °C and a pressure of 5 millimeters of mercury or less for 16 hours.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the drug constituted as directed in the labeling.

(4) *Identity*. Using the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section, the retention times for the peaks of the active ingredients must be within 2 percent of the retention times for the peaks of the corresponding reference standards.

Dated: November 13, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95-28893 Filed 11-24-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8600]

RIN 1545-AE86

Definition of an S Corporation; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains a correction to final regulations [TD 8600] which were published in the Federal Register for Friday, July 21, 1995 (60 FR 37578). The final regulations relate to the definition of an *S corporation*.

EFFECTIVE DATE: July 21, 1995.

FOR FURTHER INFORMATION CONTACT: Laura Howell, (202) 622-3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this correction are under section 1361 of the Internal Revenue Code.

Need for Correction

As published, TD 8600 contains a typographical error that is in need of correction.

Correction of Publication

Accordingly, the publication of the final regulations which is the subject of FR Doc. 95-17914, is corrected as follows:

§ 1.1361-1 [Corrected]

On page 37587, column 1, § 1.1361-1 (which was corrected at 60 FR 49976, Sept. 27, 1995), paragraph (k)(1), paragraph (ii) of *Example 1*, in the last sentence of the paragraph, the date "July

27, 1997" is corrected to read "July 28, 1997".

Cynthia E. Grigsby,
Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 95-28801 Filed 11-24-95; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 916

[SPATS No. KS-016-FOR]

Kansas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Kansas regulatory program (hereinafter referred to as the "Kansas program") under the Surface Mining Control and Reclamation Act of 1977. Kansas proposed revisions to its approved revegetation success guidelines pertaining to an additional measurement technique that could be used to determine woody stem density. The amendment is intended to improve operational efficiency.

EFFECTIVE DATE: November 27, 1995.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

- I. Background on the Kansas Program
- II. Submission of the Proposed Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

I. Background on the Kansas Program

On January 21, 1981, the Secretary of the Interior conditionally approved the Kansas program. General background information on the Kansas program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the January 21, 1981, Federal Register (46 FR 5892). Subsequent actions concerning Kansas' program and program amendments can be found at 30 CFR 916.10, 916.12 and 916.15.

II. Submission of the Proposed Amendment

By letter dated August 9, 1995 (Administrative Record No. KS-600), Kansas submitted a proposed amendment to its program pursuant to SMCRA. Kansas submitted the proposed amendment at its own initiative to improve its program efficiency. Kansas proposes to modify its requirements for determining the productivity success of trees and shrubs by amending its approved revegetation success guidelines entitled "Revegetation Standards for Success and Statistically Valid Sampling Techniques for Measuring Revegetation Success" to include an alternative sampling method for determining woody stem density.

OSM announced receipt of the proposed amendment in the September 12, 1995, Federal Register (60 FR 47314), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (Administrative Record No. KS-603). The public comment period ended on October 12, 1995.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment.

Woody Stem Density

Kansas proposes to amend its revegetation success guidelines by adding an alternative method for measurement of woody stem density. This would apply to any land use where trees or shrubs would be required to be planted as part of the approved reclamation and revegetation plan. The approved guidelines currently only allow for a 100 percent count of trees and shrubs in the proposed release area. The proposed amendment would still require that 100 percent counts are necessary when the reclamation plan calls for less than 300 stems per acre and less than 10 acres. When the reclamation plan calls for more than 300 stems per acre or the release area is larger than 10 acres, the permittee has the option of either doing a 100 percent count or collecting a statistically valid sample utilizing randomly selected 1/50th acre circular plots.

The Kansas program regulations concerning statistically valid sampling methods for measuring revegetation success are found at Kansas Administrative Regulation (KAR) 47-9-1(c)(42) and adopt by reference 30 CFR 816.116, as in effect on July 1, 1990.