Section 24.12 also issued under 19 U.S.C. 1524; 46 U.S.C. 927.

2. Section 24.12(a)(2), Customs Regulations (19 CFR 24.12(a)(2)), is revised to read as follows:

§ 24.12 Customs fees; charges for storage.

(a) * * *

(2) No fee will be charged for furnishing an official certificate if the request is made to Customs at the time the entry summary is filed. However, Customs shall charge and collect a fee of $10.00 for each hour or fraction thereof for time spent by each clerical, professional or supervisor in finding the documents and furnishing an official certification if the request is made after the entry documents are filed, plus a charge of 15 cents per page for photcopying. The fee may be revised periodically by publication of a general notice in the **Federal Register** and *Customs Bulletin* setting forth the revised fee. The published revised fee shall remain in effect until changed.

* * * * *

Alfred R. De Angelus,

Acting Commissioner of Customs.

Approved: October 7, 1985.

David D. Queen,

Acting Assistant Secretary of the Treasury.

[FR Doc. 85-25888 Filed 10-29-85; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 107

[Docket No. 83N-0270]

Nutrient Requirements for Infant Formulas

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the infant formula nutrient requirements of the Infant Formula Act of 1980, based on the 1983 recommendations of the Committee on Nutrition of the American Academy of Pediatrics (CON/AAP). In developing this final rule, FDA also considered the Codex Alimentarius Commission's "Recommended International Standard for Infant Formula" (Codex standard). This final rule ensures that the nutrient levels required for infant formulas reflect the latest recommendations by CON/AAP and others and are adequate in meeting the normal infant's total nutritional needs.

EFFECTIVE DATE: This final rule will become effective on January 14, 1986, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after that date. Voluntary compliance may begin October 30, 1985.

FOR FURTHER INFORMATION CONTACT: Nicholas Duy, Center for Food Safety and Applied Nutrition (HFF-204), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-245-3117.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of April 11, 1984 (49 FR 14396), FDA published a proposed rule (21 CFR part 107, Subpart D) to codify without change most of the nutrients and nutrient levels specified in section 412(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(g)) and to revise certain nutrient requirements based on recommendations of CON/AAP, the Codex standard for infant formulas, and other sources of information. The proposed rule would have (1) raised slightly the minimum levels for calcium and phosphorus, (2) set maximum levels for iron and iodine, (3) established the minimum level for niacin in units of niacin equivalents, and (4) required that any added vitamin K be in the form of phylloquinone.

Interested persons were given until June 11, 1984, to comment on the proposal. FDA received five letters, each containing one or more comments, from a consumer, a trade organization, and manufacturers. All comments supported the proposal at least in part, and some comments made suggestions. Some of the comments addressed issues not raised by the proposal, such as the infant formula quality control regulations (21 CFR Part 106), the infant formula labeling regulations (21 CFR Part 107, Subpart B), and the adoption of the Codex Standard requirements dealing with the pesticide residues, microbiological quality, and other contaminants. These comments are not discussed herein.

The final rule is based on the proposal, with two changes suggested by the comments. FDA has raised slightly the proposed maximum level for iron, and has not adopted the proposed minimum level for niacin in units of niacin equivalents.

A summary of pertinent comments and the agency's response follows:

Vitamins

1. One comment suggested simplification and clarification of the proposed requirement for the addition of vitamin B_6 (pyridoxine). Proposed § 107.100 (a) and (d) specified a minimum level of 35 micrograms of B_6 for the first 1.8 grams of protein per 100 kilocalories and at least 15 additional micrograms of vitamin B_6 for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories. The comment suggested simply providing for B_6 at a level of at least 15 micrograms for each gram of protein.

The agency disagrees with this comment and has not made the change in the final rule, because the "simplification" would reduce the minimum level of B_6 required from 35 micrograms per 100 kilocalories to 27 micrograms per 100 kilocalories. Prior to the proposal, CON/AAP specifically reviewed the vitamin B_6 requirement and recommended to the agency that the minimum level required by the Infant Formula Act of 1980, which was not changed by the proposed requirements, "* * * is the minimum level that will provide good growth and development in healthy full term infants * * *" and that a distinct hazard may be encountered below these levels. FDA agrees with CON/AAP's recommendation and has, therefore, not reduced the minimum level proposed for vitamin B_6.

2. Several comments objected to establishing the minimum level for niacin in terms of niacin equivalents. The present minimum level is expressed in terms of micrograms of niacin. The reasons for the objections are: (1) Manufacturers would have to analyze for the two components that comprise niacin equivalents, niacin and tryptophan, rather than just analyzing for niacin which is sufficient to meet present requirements; (2) analyses for tryptophan would require procedures that are laborious and unreliable; (3) CON/AAP recommendations specified a minimum requirement of either 250 micrograms of niacin *or* 0.8 milligram niacin equivalents; and (4) CON/AAP considers the protein level in infant formulas as providing "* * * the tryptophan that supplies the [necessary] niacin equivalents. The Committee (CON/AAP) feels a specific recommendation for niacin is desirable."

The agency agrees and has eliminated this proposed requirement from the final rule. The requirement of this final rule with respect to expression of the minimum level of niacin, therefore, does

not revise the requirements of the Infant Formula Act of 1980.

Minerals

3. Several comments suggested a maximum level of 3 milligrams of iron per 100 kilocalories in lieu of the proposed maximum level of 2.5 milligrams per 100 kilocalories. The comments indicated that the amount of iron presently added to infant formulas will result in levels that occasionally exceed the proposed 2.5-milligram maximum level. Consequently, the comments stated that, if a 2.5-milligram per 100 kilocalorie maximum were imposed, manufacturers would be required to lower the fortification rate of infant formulas when no safety concerns have been identified at the existing level of fortification.

The agency agrees and has made this change in § 107.100(a) of the final rule.

4. Two comments suggested that the proposed maximum level for iodine of 75 micrograms per 100 kilocalories be postponed until a joint FDA/industry study of analytical methods is completed and it is shown that appropriate methodology exists for iodine. The comments indicated that available analytical methods, especially when applied to soy-based infant formulas, do not have the necessary accuracy and precision to determine the level of iodine present.

The agency disagrees with the contention that the proposed maximum level for iodine of 75 micrograms per 100 kilocalories should be postponed until the completion of a joint FDA/industry study of the analytical methods for iodine. It is agency policy to take into consideration the accuracy and precision of the methodology used before any regulatory action is recommended. The accuracy and precision of available methods are always taken into account whenever maximum or minimum levels for substances are set. In this case, a minimum level for iodine (5 micrograms per 100 kilocalories) has been in effect since 1971. Agency experience for these years has shown the methodology to be sufficiently precise and accurate to make the determination that an infant formula meets or does not meet the minimum level of iodine required. There is no indication that any additional difficulties are involved in determining that a product does or does not exceed a maximum level over those encountered in determining the presence of a minimum level. In addition, the joint FDA/industry study referred to in the comments is a review of methodology used for determining all nutrients required for infant formulas, not just iodine. The purpose of the review is to identify methodology that can be applied uniformly by industry and FDA. Although the review may result in the identification of better methodologies across-the-board, in the interim, it is necessary to set standards under the Infant Formula Act based on the best currently available information.

5. One comment suggested that the requirement for iodine (I_2) be expressed as iodide (I^-) because (1) the nutrient is primarily present in infant formulas in the form of iodide, (2) manufacturers generally test for iodide, and (3) this change in nomenclature would be consistent with the nomenclature used for chloride.

The agency disagrees with this comment. FDA has required, for many years, that this nutrient be declared by the name iodine for all foods with nutrition labeling (21 CFR 101.9(c)(7)(iv)), and for infant formula (21 CFR 107.10 and former 21 CFR 105.65(c)(5)). Consequently, consumers have become accustomed to this nutrient being declared as iodine and any change would be both confusing to the consumer and inconsistent with the nomenclature required for other foods. Therefore, the agency has retained the requirement that this nutrient be declared as iodine (I_2).

Proposed Effective Date

6. One comment suggested that the agency set one effective date for all labeling changes currently under consideration in this final rule and in the final rule for infant formula labeling (21 CFR Part 107, Subpart B).

The agency agrees and has provided for an effective date of January 14, 1986, which is the effective date for the infant formula labeling regulations (21 CFR Part 107, Subpart B).

FDA does not believe that this effective date will pose problems for the infant formula industry, as information available to the agency indicates that all currently marketed products are already in compliance with the final rule. If any manufacturer believes that it will be unable to comply with the final rule by the effective date, it may petition the agency for a specific period of additional time. FDA will consider such requests on a case-by-case basis.

Economic Considerations

In accordance with Executive Order 12291, FDA has examined the economic impacts of this final rule. In a previous action the agency determined that the economic impacts of the regulations governing quality control and labeling of exempt and nonexempt infant formula were not major as defined by the order. The agency has also considered the cumulative economic effects of these various documents. The combined effects of these regulations do not constitute a major rule under any of the criteria specified by Executive Order 12291.

Furthermore, in accordance with the Regulatory Flexibility Act, the agency has considered the effect that this final rule and the regulations on quality control, labeling of infant formulas, and exempt infant formula would have on small entities, including small businesses, and has concluded that it is unlikely that any small firm will bear excessive or unreasonable burdens as a result of the combined effects of each of these regulations. Therefore, the agency certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will result from this action.

Environmental Considerations

The agency has previously considered the potential environmental effects of this rule as announced in the proposed rule (April 11, 1984; 49 FR 14396). The agency is not aware of any new information that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required. The agency has, however, amended its environmental assessment and finding of no significant impact to reflect changes in the proposed rule resulting from comments submitted to the agency. The agency's amended environmental assessment and finding of no significant impact may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 107

Food labeling, Infant formula, Nutrition requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 107 is amended as follows:

PART 107—INFANT FORMULA

1. The authority citation for 21 CFR Part 107 is revised to read as follows:

Authority: Secs. 201 (n) and (aa), 403(a) and (j), 412, 701, 52 Stat. 1041 as amended, 1047–1048 as amended, 1055–1056 as amended, 94 Stat. 1190–1193 (21 U.S.C. 321 (n) and (aa), 343 (a) and (j), 350a, 371); 31 CFR 5.11; § 107.100 issued only under secs. 201(aa), 412, 701(a) 52 Stat. 1055, 94 Stat. 1190–1193 (21 U.S.C. 321(aa), 350a, 371(a)); 21 CFR 5.11.

2. By adding new Subpart D to read as follows:

Subpart D—Nutrient Requirements

§ 107.100 Nutrient specifications.

(a) An infant formula shall contain the following nutrients at a level not less than the minimum level specified and not more than the maximum level specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container:

Nutrients	Unit of measurement	Minimum level	Maximum level
Protein	Grams	1.8	4.5
Fat	do	3.3	6.0
	Percent calories	30	54
Linoleic acid	Milligrams	300	
	Percent calories	2.7	
Vitamins			
Vitamin A	International Units	250	750
Vitamin D	do	40	100
Vitamin E	do	0.7	
Vitamin K	Micrograms	4	
Thiamine (vitamin B_1)	do	40	
Riboflavin (vitamin B_2)	do	60	
Vitamin B_6	do	35	
Vitamin B_{12}	do	0.15	
Niacin[1]	do	250	
Folic acid (folacin)	do	4	
Pantothenic acid	do	300	
Biotin [2]	do	1.5	
Vitamin C (ascorbic acid)	Milligrams	8	
Choline[2]	do	7	
Inositol [2]	do	4	
Minerals			
Calcium	do	60	
Phosphorus	do	30	
Magnesium	do	6	
Iron	do	0.15	3.0
Zinc	do	0.5	
Manganese	Micrograms	5	
Copper	Micrograms	60	
Iodine	do	5	75
Sodium	Milligrams	20	60
Potassium	do	80	200
Chloride	do	55	150

[1] The generic term "niacin" includes niacin (nicotinic acid) and niacinamide (nicotinamide).
[2] Required only for non-milk-based infant formulas.

In addition to the specifications established in the table in this paragraph for vitamins and minerals, the following also apply:

(b) Vitamin E shall be present at a level of at least 0.7 International Unit of vitamin E per gram of linoleic acid.

(c) Any vitamin K added shall be in the form of phylloquinone.

(d) Vitamin B_6 shall be present at a level of at least 15 micrograms of vitamin B_6 for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container.

(e) The ratio of calcium to phosphorus in infant formula in the form prepared for consumption as directed on the container shall be no less than 1.1 and not more than 2.0.

(f) Protein shall be present in an amount not to exceed 4.5 grams per 100 kilocalories regardless of quality, and not less than 1.8 grams per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container when its biological quality is equivalent to or better than that of casein. If the biological quality of the protein is less than that of casein, the minimum amount of protein shall be increased proportionately to compensate for its lower biological quality. For example, an infant formula containing protein with a biological quality of 75 percent of casein shall contain at least 2.4 grams of protein (1.8/0.75). No protein with a biological quality less than 70 percent of casein shall be used.

Dated: October 7, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85-25875 Filed 10-29-85; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Part 442

[Docket No. 85N-0466]

Antibiotic Drugs; Cefotaxime Sodium Injection

AGENCY: Food and Drug Administration.

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 dosage form of cefotaxime sodium, cefotaxime sodium injection. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective October 30, 1985; comments, notice of participation, and request for hearing by November 29, 1985; data, information, and analyses to justify a hearing by December 30, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joan M. Eckert, Center for Drugs and Biologics (HFN-815), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

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 dosage form of cefotaxime sodium, cefotaxime sodium injection. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in Part 442 (21 CFR Part 442) to provide for the inclusion of accepted standards for the product.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) (April 26, 1985; 50 FR 16636) 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, notice and comment procedure and delayed effective date are found to be unnecessary and not in the public interest. The final rule, therefore, is effective October 30, 1985. However, interested persons may, on or before November 29, 1985, 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 November 29, 1985, a written notice of participation and request for hearing, and (2) on or before December 30, 1985, 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 hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for 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 order and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for 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 Part 442

Antibiotics, Cepha.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 442 is amended as follows:

PART 442—CEPHA ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR Part 442 continues to read as follows:

Authority: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357); 21 CFR 5.10.

2. By adding new § 443.13 to read as follows:

§ 442.13 Cefotaxime sodium.

(a) *Requirements for certifications*—(1) *Standards of identity, strength, quality, and purity.* Cefotaxime sodium is the sodium salt of 5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[(acetyloxy)methyl]-7-[[(2-amino-4-thiazolyl) (methoxyimino)acetyl]amino]-8-ox-o, [6*R*-[6α,7#(*Z*)]]-. It is so purified and dried that:

(i) Its potency is not less than 855 micrograms and not more than 1,002 micrograms of cefotaxime per milligram on an anhydrous basis.

(ii) Its moisture content is not more than 6.0 percent.

(iii) Its pH in an aqueous solution is not less than 4.5 and not more than 6.5.

(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 potency, moisture, pH, and identity.

(ii) Samples, if required by the Director, Center for Drugs and Biologics: 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 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 2.0 micrograms of cefotaxime per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* 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 the working standard solution.* Dissolve and dilute an accurately weighed portion of the cefotaxime working standard in sufficient distilled water to obtain a concentration of 1 milligram of cefotaxime per milliliter.

(*b*) *Preparation of sample solution.* Dissolve and dilute an accurately weighed portion of the sample in sufficient distilled water to obtain a concentration of 1 milligram of cefotaxime per milliliter (estimated).

(*c*) *Calculation.* Calculate the cefotaxime content in micrograms per milligram as follows:

$$\text{Micrograms of cefotaxime per milligram of sample} = \frac{A_u \times P_s}{A_s \times W_u}$$

where:

A_u = Absorbance of sample solution;
P_s = Potency of working standard solution in micrograms per milliliter;
A_s = Absorbance of working standard solution; and
W_u = Milligrams of sample per milliliter of sample solution.

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

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 100 milligrams per milliliter.

(4) *Identity.* Proceed as directed in § 436.323 of this chapter, except prepare spotting solutions as follows: Prepare solutions of the sample and working standard, each containing 1 milligram of cefotaxime per milliliter in distilled water.

3. By redesignating § 442.213 as § 442.213a and by adding new §§ 442.213 and 442.213b to read as follows:

§ 442.213 Cefotaxime injectable dosage forms.

§ 442.213a Sterile cefotaxime sodium.

* * * * *

§ 442.213b Cefotaxime sodium injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefotaxime sodium injection is a frozen aqueous solution of cefotaxime sodium with one or more suitable and harmless buffer substances in an isosmotic diluent. Each milliliter contains cefotaxime sodium equivalent to either 20 milligrams or 40 milligrams of cefotaxime per milliliter. Its cefotaxime content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of cefotaxime that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 5.0 and not more than 7.5. It passes the identity test. The cefotaxime sodium used conforms to the standards prescribed by § 442.13(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 cefotaxime sodium used in making the batch for potency, moisture, pH, and identity.

(*b*) The batch for potency, sterility, pyrogens, pH, and identity.

(ii) Samples, if required by the Director, Center for Drugs and Biologics:

(*a*) The cefotaxime sodium used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Test and methods of assay.* Thaw the sample as directed in the labeling. The sample solution used for testing must be at room temperature.

(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: Using a suitable hypodermic needle and syringe, remove an accurately measured representative portion from each container and dilute with 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 or 2.0 micrograms of cefotaxime per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter, preparing the sample as follows: Using a suitable hypodermic needle and syringe, remove an accurately measured representative portion from each container and dilute with distilled water to give a stock solution of convenient concentration. Further dilute with distilled water to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, except inject a sufficient volume of the undiluted solution to deliver 50 milligrams of cefotaxime per kilogram.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

(5) *Identity.* Proceed as directed in § 436.323 of this chapter, except prepare spotting solutions as follows: Prepare solutions of the sample and working standard, each containing 1 milligram of cefotaxime per milliliter in distilled water.

Dated: October 23, 1985.

Sammie R. Young,

Deputy Director, Office of Compliance.

[FR Doc. 85-25809 Filed 10-29-85; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

Approval of Permanent Program Amendments From the State of Illinois Under the Surface Mining Control and Reclamation Act of 1977

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

ACTION: Final rule.

SUMMARY: OSM is announcing the approval of amendments to the Illinois permanent regulatory program (hereinafter referred to as the Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

By letter dated December 23, 1983, Illinois submitted to OSM proposed requirements for the training and certification of blasters working in surface coal mining operations. Revised rules were provided on March 29, 1985 and a policy statement was provided on August 16, 1985. OSM published notices in the **Federal Register** on January 25, 1984, May 1, 1985 and September 12, 1985, announcing receipt of the amendments and inviting public comment on the adequacy of the proposed amendments (49 FR 3093), (50 FR 18536), and (50 FR 37318). The final comment period closed September 27, 1985.

After providing opportunity for public comment and conducting a thorough review of the program amendments, the Director of OSM has determined that the amendments meet the requirements of SMCRA and the Federal regulations. Accordingly, the Director is approving the program amendments. The Federal regulations at 30 CFR Part 913 which codify decisions on the Illinois program are being amended to implement this action.

This final rule is being made effective immediately in order to expedite the State program amendment process and encourage States to bring their programs into conformity with the Federal standards without undue delay; consistency of the State and Federal Standards is required by SMCRA.

EFFECTIVE DATE: October 30, 1985.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Fulton, Director, Springfield Field Office, Office of Surface Mining, 600 East Monroe Street, Room 20, Springfield, Illinois 62701; Telephone: (217) 492-4495.

SUPPLEMENTARY INFORMATION:

I. Background

The Illinois program was conditionally approved by the Secretary of the Interior on June 1, 1982. Information pertinent to the general background, revisions, modifications, and amendments to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval of the Illinois program, can be found in the June 1, 1982 **Federal Register** (47 FR 23858).

At the time of the Secretary's approval of the Illinois program, OSM had not yet promulgated Federal rules governing the training and certification of blasters. Therefore, the State was not required to include such requirements in its program. However, in the notice announcing conditional approval of the Illinois program, the Secretary specified that Illinois would be required to adopt such provisions following promulgation of the Federal Standards (47 FR 23858, June 1, 1982). On March 4, 1983, OSM issued final rules effective April 14, 1983, establishing the Federal standards for the training and certification of blasters at 30 CFR Chapter VII Subchapter M (48 FR 9486).

II. Discussion of the Amendment

By letter dated December 23, 1983, Illinois submitted proposed regulations which would establish requirements for the training and certification of blasters working in surface coal mining operations. The new requirements were set forth under Part 1850—Training, Examination and Certification of Blasters.

OSM announced receipt of the amendments and initiated a public comment period on January 25, 1984 (49 FR 3093). The comment period ended February 24, 1984.

During review of the amendments, OSM identified three concerns:

(1) The proposed Illinois rules do not provide that the regulatory authority may require periodic re-examination, training or other demonstration of continued blaster competency;

(2) Illinois' proposed rules do not contain counterparts to all of the courses required for blaster training in 30 CFR 850.13(b); and

(3) The proposed Illinois' rules do not require the blaster to take every reasonable precaution to protect his certificate from loss, theft or unauthorized duplication.

OSM notified Illinois about these concerns by letter dated April 25, 1984. On May 25, 1984, Illinois responded by