Substances	Limitations
* * *	* * * * * * *
3,9-Bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane (CAS Reg. No. 90498–90–1).	For use only: 1. At levels not to exceed 0.2 percent by weight of polypropylene complying with § 177.1520(c), item 1.1 of this chapter. The finished polymer is to be used in contact with food only under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.3 percent by weight of polyethylene complying with § 177.1520(c) of this chapter, item 2.1, provided that the polymer has a minimum density of 0.94 grams per cubic centimeter and is used in contact with food only under conditions of use D through G described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * * * * *

Dated: June 15, 1995.

Janice F. Oliver,

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

[FR Doc. 95–15922 Filed 6–28–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 442

[Docket No. 94N–0132]

Antibiotic Drugs; Cefotetan and Cefotetan Disodium Injection; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is technically amending a final rule that appeared in the **Federal Register** of May 25, 1994 (59 FR 26939). The document amended the antibiotic drug regulations to provide for the inclusion of accepted standards for a new bulk form of cefotetan. The agency received a comment on the final rule that pointed out, among other things, that the correct name of the antibiotic is cefotetan disodium. This document corrects those errors.

EFFECTIVE DATE: June 29, 1995.

FOR FURTHER INFORMATION CONTACT: James M. Timper, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6714.

SUPPLEMENTARY INFORMATION: As published, the final regulation contains errors that may prove to be misleading and are in need of clarification. The name of the antibiotic is ''cefotetan disodium'' not ''cefotetan sodium.'' The calculation for determining cefotetan concentration in the finished dosage form was published incorrectly, and an additional sample preparation, potassium bromide discs, can be used also. Accordingly the agency is amending 21 CFR 442.52 to correct those errors.

List of Subjects in 21 CFR Part 442

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR 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 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

2. Section 442.52 is amended by revising paragraphs (b)(1)(iv) and (b)(3) to read as follows:

§ 442.52 Cefotetan.

(b) * * *

(1) * * *

(iv) *Calculation*. Calculate the micrograms of cefotetan per milligram of sample as follows:

$$\text{Micrograms of cefotetan per milligram} = \frac{A_U \times P_S \times V_f \times 1{,}000}{A_S \times V_s}$$

where:

A_U = Area of the cefotetan peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the cefotetan peak in the chromatogram of the cefotetan working standard;

P_S = Cefotetan activity in the cefotetan working standard solution in micrograms per milliliter;

V_f = Volume of flask used to dilute standard; and

V_s = Volume of sample diluted.

* * * * *

(3) *Identity*. Proceed as directed in § 436.211 of this chapter using the potassium bromide discs prepared as described in § 436.211(b)(1) of this chapter or the mineral oil mull prepared as described in § 436.211(b)(2) of this chapter.

Dated: May 9, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95–15923 Filed 6–28–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 637

[FHWA Docket No. 94–13]

RIN 2125–AD35

Quality Assurance Procedures for Construction

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is revising its regulations that establish general