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
* *	* * *
Oxidized bis(hydrogenated tallow alkyl)amines.	For use only at levels not to exceed 0.05 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, or 1.3: The finished polymers may be used in contact with food types I, II, IV–B, VII–B, and VIII described in Table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, and with food types III, IV–A, V, VI, VII–A, and IX described in Table 1 of § 176.170(c) of this chapter, under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter.

Dated: September 13, 1995.

Janice F. Oliver,

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

[FR Doc. 95–23776 Filed 9–25–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 453

[Docket No. 95N–0081]

Antibiotic Drugs; Clindamycin Phosphate Vaginal Cream

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, clindamycin phosphate vaginal cream. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

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

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 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: 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, clindamycin phosphate vaginal cream. 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 453 (21 CFR part 453) to provide for the inclusion of accepted standards for this product.

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 October 26, 1995. However, interested persons may, on or before October 26, 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 October 26, 1995, a written notice of participation and request for a hearing, and (2) on or before November 27, 1995, 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 Part 453

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 453 is amended as follows:

PART 453—LINCOMYCIN ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 453 continues to read as follows:

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

2. New § 453.522d is added to subpart F to read as follows:

§ 453.522d Clindamycin phosphate vaginal cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin phosphate vaginal cream contains clindamycin phosphate in a suitable and harmless cream vehicle. Each gram contains clindamycin phosphate equivalent to 20 milligrams of clindamycin activity. Its clindamycin content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of clindamycin that it is represented to contain. Its pH is not less than 3.0 and not more than 6.0. It passes the identity test. The clindamycin phosphate used conforms to the standards prescribed by § 453.22(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 clindamycin phosphate used in making the batch for clindamycin content, microbiological activity, moisture, pH, crystallinity, and identity.

(B) The batch for clindamycin content, pH, and identity.

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

(A) The clindamycin phosphate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(B) The batch: a minimum of six immediate containers.

(b) *Tests and methods of assay* —(1) *Clindamycin content (high performance liquid chromatography assay).* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 210 nanometers, a 25-centimeter long x 4.6 millimeter ID column packed with microparticulate (5 to 10 micrometers in diameter) reverse phase octylsilane hydrocarbon bonded silica packing material, a flow rate of 1.0 milliliter per minute, and a known injection volume of 20 microliters. The retention time of clindamycin phosphate, and clindamycin are approximately 6 and 9 minutes, respectively. Reagents, working standards and sample solutions, resolution test solution, system suitability requirements, and calculations are as follows:

(i) *Reagents*—(A) *0.1M Potassium phosphate monobasic buffer.* Dissolve 13.61 grams of potassium phosphate monobasic in 775 milliliters of water. Adjust the pH to 2.5 with phosphoric acid. Further dilute with water to a volume of 1,000 milliliters.

(B) *Mobile phase.* Mix 225 milliliters of acetonitrile and 775 milliliters of 0.1*M* potassium phosphate, pH 2.5 buffer (225:775). Filter through a suitable filter capable of removing particulate matter greater than 0.5 micron in diameter. Degas the mobile phase just prior to its introduction into the chromatograph.

(ii) *Preparation of working standard, sample, and resolution test solutions*—(A) *Working standard solution.* Dissolve an accurately weighed portion of the clindamycin phosphate working standard in sufficient mobile phase (prepared as directed in paragraph (b)(1)(i)(B) of this section) to obtain a solution containing 200 micrograms of clindamycin activity per milliliter.

(B) *Sample solutions.* Accurately weigh and transfer approximately 1.0 gram of the sample into a 125-milliliter Erlenmeyer flask. Add 100.0 milliliters of mobile phase (prepared as directed in paragraph (b)(1)(i)(B) of this section), accurately measured, and 8 to 10 glass beads (4 to 5 millimeters). Close the flask securely using a plastic stopper and shake vigorously by mechanical means for 1 hour at 50 °C. Cool in an ice bath for approximately 20 minutes. Centrifuge a portion of the mixture. Use the lower cloudy solution for chromatographic analysis. Filter a few milliliters of the centrifuged solution through an appropriate 2 micron filter.

(C) *Resolution test solution.* Place 15 milligrams each of clindamycin phosphate and clindamycin hydrochloride in a 25-milliliter volumetric flask and dissolve and dilute to volume with mobile phase and mix well. Use this solution to determine the resolution factor.

(iii) *System suitability requirements*—(A) *Asymmetry factor.* Calculate the asymmetry factor (A_S), measured at a point 5 percent of the peak height from the baseline as follows:

$$A_s = \frac{a + b}{2a}$$

where:

a = Horizontal distance from point of ascent to point of maximum peak height; and

b = Horizontal distance from point of maximum peak height to point of descent.

The asymmetry factor (A_s) is satisfactory if it is not less than 1.0 and not more than 1.3.

(B) *Efficiency of the column.* From the number of theoretical plates (*n*) calculated as described in § 436.216(c)(2) of this chapter, calculate the reduced plate height (h_r) as follows:

$$h_r = \frac{(L)(10{,}000)}{(n)(d_p)}$$

where:

L = Length of the column in centimeters;

n = Number of theoretical plates; and

d_p = Average diameter of the particles in the analytical column packing in micrometers.

The absolute efficiency (h_r) is satisfactory if it is not more than 15.

(C) *Resolution factor.* The resolution factor (R) between the peak for clindamycin phosphate and the peak for clindamycin (hydrochloride) in the chromatogram of the resolution test solution is satisfactory if it is not less than 6.0.

(D) *Coefficient of variation (relative standard deviation*). The coefficient of variation (S_R in percent) of 5 replicate injections of the working standard solution is satisfactory if it is not more than 2.5 percent. If the system suitability parameters have been met, then proceed as described in § 436.216(b) of this chapter.

(iv) *Calculation*. Calculate the clindamycin content as follows:

$$\text{Milligrams of clindamycin per gram} = \frac{A_u \times P_s \times d}{A_s \times 1{,}000}$$

where:

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

A_s = Area of the clindamycin phosphate peak in the chromatogram of the clindamycin phosphate working standard;

P_s = Clindamycin activity in the clindamycin phosphate working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

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

(3) *Identity*. The high-pressure liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the clindamycin phosphate working standard.

Dated: September 5, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95–23737 Filed 9–25–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 126 and 127

[CGD 88–049]

RIN 2115–AD06

Waterfront Facilities Handling Liquefied Hazardous Gas

AGENCY: Coast Guard, DOT.

ACTION: Correcting Amendments.

SUMMARY: This document contains correcting amendments to the final rule in CGD 88–049, published on Thursday, August 3, 1995, at 60 FR 39788.

EFFECTIVE DATE: These amendments are effective on September 26, 1995.

FOR FURTHER INFORMATION CONTACT: CDR Dennis J. Haise, Operating and Environmental Standards Division (G–MOS–2), by telephone (202) 267–6451 or fax (202) 267–4570.

SUPPLEMENTARY INFORMATION: The final rule that is the subject of these amendments regulates transfers of liquefied hazardous gas, in bulk, to and from vessels and waterfront facilities.

Need for Correction

As published, the final rule contains errors that may prove to be misleading and that therefore need correction.

Substance of Correction

Accordingly, the final rule published on August 3, 1995 [CGD 88–049], is corrected as follows:

Discussion of the Comments on and Changes to the NPRM [Corrected]

1. Page 39789, in the second column, paragraph 9, in the last sentence the phrase ''Section 127.110(c)'' is corrected to read ''Section 127.1101(c)''.

2. Page 39790, in the first column, paragraph 18, in the last sentence the word ''possible'' is corrected to read ''possibly''.

3. Page 39790, in the third column, paragraph 22, in the first sentence the phrase ''when a facility has fire or medical department of the facility'' is corrected to read ''when a facility has a fire or medical department on the facility''.

4. Page 39791, in the first column, in the third full sentence from the top of the page the letters ''LHG'' are corrected to read ''LNG''.

Collection of Information [Corrected]

5. Page 39793, at the bottom of the second column, in the table noting ''Section'' and ''Topic'' the words ''Decelaration of Inspection'' are corrected to read ''Declaration of Inspection''.

6. Page 39793, in the third column, under the heading DOT No: 2115, OMB Control No. ''0052'' is corrected to read ''0552'' and OMB Control No. ''0013'' is corrected to read ''0054''.

PART 127—WATERFRONT FACILITIES HANDLING LIQUEFIED NATURAL GAS AND LIQUEFIED HAZARDOUS GAS

§ 127.003 Incorporation by reference [Corrected]

7. Page 39794, in the second item under the title The American National Standards Institute (ANSI) the words ''ANSI S12.13, Part 1'' are corrected to read ''ANSI S12.13, Part I''.

§ 127.1203 Gas detection [Corrected]

8. Page 39797, in the third column, in paragraph (a) in the last sentence the words ''ANSI S12.13, Part 1'' are corrected to read ''ANSI S12.13, Part I''.

§ 127.1205 Emergency shutdown [Corrected]

9. Page 39798, in the first column, in paragraph (b)(4) the words ''105°(C 221°F)'' are corrected to read ''105°C (221°F)''.

§ 127.1207 Warning alarms [Corrected]

10. Page 39798, also in the first column, in paragraph (b), in the first line the word ''are'' is corrected to read ''area''.

§ 127.1301 Persons in charge of transfers for the facility; Qualifications and Certification [Corrected]

11. Page 39798, in the second column, paragraph (a)(2) the word ''Knowing'' is corrected to read ''Knows''.

§ 127.1307 Emergency Manual [Corrected]

12. Page 39799, in the first column, in paragraph (b) the words ''fire-prevention required'' are corrected to read ''fire-prevention plan required''.

Dated: September 15, 1995.

G.N. Naccara,

Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 95–23799 Filed 9–25–95; 8:45 am]

BILLING CODE 4910–14–M

33 CFR Part 165

[CGD01–95–147]

RIN 2115–AA97

Safety Zone: Deepavali Fireworks Festival, East River, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.