person" in the first sentence of paragraph (b); by revising the first sentence of the Note to paragraph (b); and adding a sentence to the end of paragraph (c); as follows:

§ 200.81 Publication of interpretative, no-action and certain exemption letters and other written communications.

(a) Except as provided in paragraphs (b) and (c) of this section, every letter or other written communication requesting the staff of the Commission to provide interpretative legal advice with respect to any statute administered by the Commission or any rule or regulation adopted thereunder, or requesting a statement that, on the basis of the facts stated in such letter or other communication, the staff would not recommend that the Commission take any enforcement action, or requesting an exemption, on the basis of the facts stated in such letter, from the provisions of the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) or any rule or regulation thereunder, where the issuance of an order granting such exemption does not require public notice and an opportunity for hearing, together with any written response thereto, shall be made available for inspection and copying by any person. Letters or other written communications with respect to rules 10b–6, 10b–7, 10b–8, 10b–13 and 13e–4 [§§ 240.10b–6, 240.10b–7, 240.10b–8, 240.10b–13 and 240.13e–4 of this chapter] under the Exchange Act, together with any response thereto, shall be made available for inspection and copying by any person 30 days after the response has been sent or given to the person requesting it. All other letters or written communications, together with the response thereto, shall be made available for inspection and copying by any person as soon as practicable after the response has been sent or given to the person requesting it.

(b) * * *

Note.—All letters or other written communications requesting interpretative advice, a no-action position, or an exemption shall indicate prominently, in a separate caption at the beginning of the request, each section of the Act and each rule to which the request relates. * * *

(c) * * * Further, this section shall not apply to applications or other written communications filed pursuant to § 240.24b–2 that relate to objections to public disclosure of information filed with the Commission or any exchange.

By the Commission.

Jonathan G. Katz,

Secretary.

April 7, 1988.

[FR Doc. 88-8241 Filed 4-13-88; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 452

[Docket No. 88N-0048]

Antibiotic Drugs; Ertythromycin Topical Gel

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 erythromycin, erythromycin topical gel. The manufacturer has supplied sufficent data and information to establish its safety and efficacy.

DATES: Effective April 14, 1988; comments, notice of participation, and request for hearing by May 16, 1988; data, information, and analyses to justify a hearing by June 13, 1988.

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: Peter A. Dionne, Center for Drug Evaluation and Research (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 erythromycin, erythromycin topical gel. 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 21 CFR Part 452 by adding a new § 452.510e to provide for the inclusion of accepted standards for the 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, notice and comment procedure and delayed effective date are found to be unnecessary and not in the public interest. This final rule, therefore, is effective April 14, 1988. However, interested persons may, on or before May 16, 1988, 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 hearing 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 May 16, 1988, a written notice of participation and request for hearing, and (2) on or before June 13, 1988, 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 fact 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 452

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 452 is amended as follows:

PART 452—MACROLIDE ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR Part 452 continues to read as follows:

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

2. Part 452 is amended by adding new § 452.510e to read as follows:

§ 452.510e Erythromycin topical gel.

(a) *Requirements for certification*—(1) *Standards of identify, strength, quality, and purity.* Erythromycin topical gel is erythromycin in a suitable and harmless gel. Each gram contains 20 milligrams of erythromycin. The erythromycin content is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain. The erythromycin used conforms to the standards prescribed by § 452.10(a)(1), except with respect to heavy metals.

(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 request shall contain:

(i) Results of tests and assays on:

(A) The erythromycin used in making the batch for potency, moisture, pH, residue on ignition, identity, and crystallinity.

(B) The batch for erythromycin content.

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

(A) The erythromycin used in making the batch: 5 packages, each containing approximately 100 milligrams.

(B) The batch: A minimum of 8 containers.

(b) *Tests and methods of assay; erythromycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place approximately 1 gram, accurately weighed, of the product into a high-speed glass blender jar containing 200 milliliters of 0.5 percent (volume by volume) polysorbate 80 in 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 of the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

Dated: April 6, 1988.

Daniel L. Michels,

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

[FR Doc. 88-8151 Filed 4-13-88; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 48

Self-Contained Self-Rescue Devices; Correction

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Final rule; correction.

SUMMARY: This notice corrects a typographical error in a final rule amending Part 48 Training and Retraining of Underground Miners, which appeared in the **Federal Register** on March 30, 1988, 53 FR 10332.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations and Variances, MSHA, phone (703) 235-1910.

The following correction is made to 30 CFR 48.6(b)(8) which appeared in the **Federal Register** on March 30, 1988 (53 CFR 10332).

§ 48.6 [Amended]

On page 10335 at the bottom of the third column, the first sentence which reads, "The course shall include instruction and demonstration in the use, care, and maintenance of self-rescue and respiratory devices and at the mine," is revised to read as follows:

"The course shall include instruction and demonstration in the use, care, and maintenance of self-rescue and respiratory devices used at the mine."

* * * * *

Dated: April 6, 1988.

Patricia W. Silvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 88-8127 Filed 4-13-88; 8:45 am]

BILLING CODE 4510-43-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-87-31]

Regatta; Barnegat Bay Classic, Toms River, NJ

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Special Local Regulations 33 CFR 100.502 for the Barnegat Bay Classic powerboat race are being amended. The location of the regulated area and effective period of the regulations are being changed along with change in the events name. This event, sponsored by the Barnegat Bay Power Boat Association, involves competition between high speed powerboats on Barnegat Bay adjacent to the Intracoastal Waterway. The purpose of this regulation is to provide for the safety of participants, spectators and passers-by on navigable waters during the event.

EFFECTIVE DATE: These regulations are effective May 16, 1988.

FOR FURTHER INFORMATION CONTACT: Mr. Billy J. Stephenson, Chief, Boating Affairs Branch, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, (804-398-6204).

SUPPLEMENTARY INFORMATION: On April 2, 1987, the Commander, Third Coast Guard District published a notice of proposed rulemaking in the **Federal Register** for these regulations (Vol. 52, No. 63 FR 10593-10594).

Interested persons were requested to submit comments and one comment was received. These regulations are being made effective in less than 30 days from the date of publication. There was not sufficient time remaining in advance of the event to provide for a delayed effective date.

Drafting Information

The drafters of these regulations are Mr. Lucas A. Dlhopolsky, project officer, Chief, Boating Affairs Branch, Boating

Safety Division, Fifth Coast Guard District, and Commander Robert J. Reining, project attorney, Fifth Coast Guard District Legal Staff.

Discussion of Regulations

Since the publication of the notice of proposed rulemaking the Coast Guard has gone through an organization realignment. The Commander, Fifth Coast Guard District assumed responsibility for the waters of Barnegat Bay south of Toms River, New Jersey on April 30, 1987. On July 6, 1987, a rule was published that redesignated § 100.302 of title 33 Code of Federal Regulations as § 100.502 and amended paragraph (b) of that section to delete the reference to the Third Coast Guard District's Local Notice to Mariners. One comment was received in response to the Notice of Proposed Rulemaking. The commenter wrote to commend the sponsors of the Barnegat Bay Classic for cooperating with the commenter's yacht club by moving the powerboat race course location further south on Barnegat Bay. In so doing a conflict with an already scheduled annual sailboat regatta was avoided.

Economic Assessment and Certification

These regulations are considered to be nonmajor under Executive Order 12291 on Federal Regulation and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1987). The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary. This event will draw a large number of spectator craft into the area for the duration of the race. This should have a favorable impact on commercial facilities providing services to the spectators. This area is used primarily by recreational boaters; any impact on commercial traffic in the area will be negligible. Since the impact of thse regulations is expected to be minimal the Coast Guard certifies that they will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water).

Final Regulation

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations is amended as follows:

PART 100—[AMENDED.]

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. Part 100 is amended by revising the section heading and paragraphs (a) and (b) of § 100.502 to read as follows:

§100.502 Barnegat Bay Classic, Toms River, New Jersey.

(a) *Regulated Area.* Barnegat Bay, New Jersey in the areas bounded by latitude 39°54′00″ North on the north, latitude 36°49′00″ North on the south, the Intracoastal Waterway (ICW) on the west and Island Beach on the east.

(b) *Effective Dates.* These regulations will be effective annually on the fourth Saturday in August unless otherwise specified in the Coast Guard Local Notice to Mariners and a **Federal Register** Notice. In case of postponement due to weather, the approved rain date is the following day and these regulations are effective for the same time period.

* * * * *

Dated: July 26, 1987.

A. D. Breed,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 88-8197 Filed 4-13-88; 8:45 am]

BILLING CODE 4910-14-M

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33 CFR Part 117

[CGD8-87-14]

Drawbridge Operation Regulations; Gulf Intracoastal Waterway, Louisiana

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the St. Mary Parish Council and the Louisiana Department of Transportation and Development, the Coast Guard is changing the regulation governing the operation of the swing span bridge on State Route 319 over the Gulf Intracoastal Waterway, mile 134.0 near Cypremort, St. Mary Parish, Louisiana, by permitting the draw to remain closed to navigation from 6:55 to 7:10 a.m. and 3:50 to 4:05 p.m. Monday through Friday, except holidays, from 15 August to June 5. This change is being made to allow school buses to pass without delays because of bridge openings. This action should accommodate the needs of vehicular traffic and still provide for the reasonable needs of navigation.

EFFECTIVE DATE: This regulation becomes effective on May 16, 1988.

FOR FURTHER INFORMATION CONTACT: Mr. John Wachter, Bridge Administration Branch, Eighth Coast Guard District, Telephone (504) 589-2965.

SUPPLEMENTARY INFORMATION: On 24 December 24, 1987, the Coast Guard published a proposed rule (52 FR 48717) concerning this amendment. The Commander, Eighth Coast Guard District, also published the proposal as a Public Notice dated 6 January 1988. In each notice interested parties were given until 8 February 1988 to submit comments.

Drafting Information

The drafters of this regulation are Mr. John Wachter, project officer, and Lieutenant Commander James Vallone, project attorney.

Discussion of Comments

Five letters of comment were received about the proposed rule change. The National Marine Fisheries Service offered no objection. Three letters received from residents whose small children ride the school buses expressed appreciation and verified the need for the proposed rule. One letter writer objected to the proposal as creating an unsafe condition when a tow pushing an empty barge must stand by for the bridge to open. The Coast Guard has carefully considered the comments. A review of the bridge logs indicates that the bridge opens about once every two days on average during both the proposed 15-minute morning closure period and the proposed 15-minute afternoon closure period. Due to the very short periods that the bridge will be closed to navigation, mariners should be able to adjust their speed when approaching the bridge to avoid the 15-minute closure periods and any hazards that may occur due to full stoppage of their vessels. Therefore, the final rule is unchanged from the proposed rule as published in (52 FR 48717) on 24 December 1987.

Economic Assessment and Certification

This regulation is considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact of this regulation is expected to be so minimal that a full regulatory evaluation is unnecessary. The basis for this conclusion is that the closure periods are so abbreviated that they are not considered to be significant. Since the economic impact of this regulation is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.