Any person who decides to seek a hearing must file (1) on or before November 2, 1990, a written notice of participation and request for hearing, and (2) on or before December 3, 1990, 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 (address above).

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 333

First aid antibiotic drug products, Labeling, Over-the-counter drugs.

21 CFR Part 448

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, subchapter D of chapter I of title 21 of the Code of Federal Regulations is amended in parts 333 and 448 as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 333 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 333.120 is amended by revising paragraph (a)(7) to read as follows:

§ 333.120 Permitted combinations of active ingredients.

* * * * *

(a) * * *

(7) Bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each gram, 120 units of bacitracin and 2,350 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases: *Provided,* That is meets the tests and methods of assay in § 448.513e(b) of this chapter.

* * * * *

PART 448—PEPTIDE ANTIBIOTIC DRUGS

3. The authority citation for 21 CFR part 448 continues to read as follows:

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

4. Section 448.513e is amended by revising paragraph (a)(1) to read as follows:

§ 448.513e Bacitracin zinc-polymyxin B sulfate topical aerosol.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin zinc-polymyxin B sulfate topical aerosol is bacitarcin zinc, polymyxin B sulfate in a suitable and harmless vehicle, packaged in a pressurized container with suitable and harmless inert gases. Each gram contains 120 units of bacitracin and 2,350 units of polymyxin B. Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of bacitracin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. Its moisture content is not more than 0.5 percent. It contains not more than an average of 10 microorganisms per container. The bacitracin zinc used conforms to the standards prescribed by § 448.13(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1).

* * * * *

Dated: September 3, 1990

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90–23347 Filed 10–2–90; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 341

[Docket No. 89N–0411]

RIN 0905–AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph for OTC Antitussive Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph for over-the-counter (OTC) antitussive drug products in 21 CFR part 341. As amended, only the term "lozenge" is used to describe a solid dosage form oral antitussive drug product intended for dissolution in the mouth. Also, the final monograph is amended to clarify that a systemically acting antitussive drug product can be marketed in a lozenge dosage form. This amendment of the final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: October 3, 1990.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 295–8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 12, 1987 (52 FR 30042), FDA issued a final monograph for OTC antitussive drug products (21 CFR part 341) that established conditions under which these products are generally recognized as safe and effective and not misbranded. The monograph currently provides for menthol to be used in a "lozenge" or "compressed tablet" dosage form (See §§ 341.3(c) and 341.74(d)(2)(iii).)

After publication of the antitussive final monograph, the United States Pharmacopeia (U.S.P.) (Ref. 1) added a definition for "lozenges." This definition, which became official in January 1990, is as follows:

Lozenges are solid preparations containing one or more medicaments, usually in a flavored, sweetened base which are intended to dissolve or disintegrate slowly in the mouth. They can be prepared by molding (gelatin and/or fused sucrose or sorbitol base) or by compression of sugar based tablets. Molded lozenges are sometimes referred to as pastilles while compressed lozenges are often referred to as troches. They are usually intended for treatment of

local irritation or infections of the mouth or throat but may contain active ingredients intended for systemic absorption after swallowing.

The new U.S.P. definition of "lozenge" includes "compressed tablet" dosage forms. Accordingly, to make the antitussive final monograph consistent with the U.S.P. definition, FDA proposed an amendment to the final monograph in the **Federal Register** of October 2, 1989 (54 FR 40412). The proposal stated that only the term "lozenge" would be used to describe a solid dosage form to be dissolved in the mouth for a local effect. Thus, the term "compressed tablet" would be deleted from §§ 341.3(c) and 341.74(d)(2)(iii). In addition, FDA proposed to amend the definition of an "oral antitussive drug" in § 341.3(b) to clarify that such drugs may also be formulated as lozenges.

As mentioned, these revisions were proposed so that the monograph would conform to the U.S.P. definition of lozenges. Also, the agency was aware that antitussive drug products intended for systemic use were currently being marketed as lozenges (Ref. 2). The agency concluded that the revised definition of an oral antitussive drug would also be consistent with the new U.S.P. definition of lozenges.

References

(1) "The United States Pharmacopeia XXII—The National Formulary XVII," The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1692, 1989.

(2) "Physicians' Desk Reference—For Nonprescription Drugs," 9th Ed., Medical Economics Co., Inc., Oradell, NJ, pp. 512, 515, 651, and 652, 1988.

One comment from a manufacturer was submitted in response to the proposal. A copy of the comment is on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. In proceeding with this amendment to the final monograph, the agency has considered the issues raised in the comment.

The comment expressed no objection to the proposed amendment to the antitussive final monograph provided that the following assumptions were correct:

1. A term other than lozenge could be used in the product's trade name or in the directions for use in § 341.74(d)(2)(iii). The comment stated that the terms "drop" and "cough drops" are the most widely used terms for this type of antitussive drug product.

In the proposal, the agency stated that various types of lozenges such as compressed tablets, troches, or pastilles would not be described in final monographs. However, these terms could continue to be used in labeling (54 FR 40412). Thus, the terms "drop" and "cough drop" can be used in a product's directions and as part of its trade name.

2. A term other than lozenge may be used in connection with the appropriate statement of identity.

The statement of identity for this type of product in § 341.74 (a) is "cough suppressant" or "antitussive (cough suppressant)" only. The monograph does not allow use of the term "lozenge," or any similar term, as part of the statement of identity. However, as noted above, terms other than lozenge may be used as part of the product's trade name.

3. The term "drop" or "cough drop" may be used in lieu of "lozenge" and will not affect the right to use the language "FDA Approved Information," as permitted by 21 CFR 330.1(c), where otherwise all other language has been stated as it appears exactly in the monograph.

The designation "FDA Approved Information" can be used under the terms of § 330.1(c)(2)(i) under certain conditions. If indication information appears in the boxed area, it must be stated in the exact language of the monograph. Other information that appears within the boxed area also must be stated in exact language where exact language has been established and identified by quotation marks in the final monograph. Regarding use of the term "drop" or "cough drop" in the boxed area, none of the indications or warnings information appearing in quotation marks in the final monograph contains the word "lozenge;" therefore, there would be no need to substitute the term "drop" or "cough drop" in these portions of the labeling. The word "lozenge" does appear in the directions information in the final monograph, but not in quotation marks. Thus, appropriate alternate words, such as "drop" or "cough drop," may be used in the boxed area in place of the word "lozenge" that appears in the monograph directions for such products.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking on OTC antitussive drug products (54 FR 40412 at 40413). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessments determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this amendment of the monograph for OTC antitussive drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking amending the final monograph for OTC antitussive drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

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.

List of Subjects in 21 CFR Part 341

Antitussive drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act, subchapter D of chapter I of title 21 of the Code of Federal Regulations is amended in part 341 as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 341.3 is amended by revising paragraphs (b) and (c) to read as follows:

§ 341.3 Definitions.

* * * * *

(b) *Oral antitussive drug.* A drug that either is taken by mouth or is dissolved in the mouth in the form of a lozenge and acts systemically to relieve cough.

(c) *Topical antitussive drug.* A drug that relieves cough when inhaled after being applied topically to the throat or chest in the form of an ointment or from a steam vaporizer, or when dissolved in the mouth in the form of a lozenge for a local effect.

* * * * *

3. Section 341.74 is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 341.74 Labeling of antitussive drug products.

* * * * *

(d) * * *

(2) * * *

(iii) *For products containing menthol identified in § 341.14(b)(2) in a lozenge.* The product contains 5 to 10 milligrams menthol. Adults and children 2 to under 12 years of age: Allow lozenge to dissolve slowly in the mouth. May be repeated every hour as needed or as directed by a doctor. Children under 2 years of age: Consult a doctor.

* * * * *

Dated: September 4, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90-23345 Filed 10-2-90; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 110

[CGD1-87-038]

Special Anchorage Area; Perth Amboy, NJ

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is redesignating Anchorage Ground 45-A as a special anchorage. This anchorage is located in the waters contigous to the City of Perth Amboy, New Jersey. Raritan Yacht Club has requested the redesignation because the anchorage has historically been utilized solely by small recreational vessels. These vessels are currently required to be lighted at night. Raritan Bay is currently experiencing a resurgence of recreational boating during the summer months. This regulation will provide a safe anchorage well away from fairways where vessels less than 65 feet in length can safely remain unlighted at night. There are no such anchorages currently available in the immediate area.

EFFECTIVE DATE: November 2, 1990.

FOR FURTHER INFORMATION CONTACT: Lieutenant (junior grade) C. W. Jennings, Waterways Management Officer, Captain of the Port, New York, at (212) 668-7933.

SUPPLEMENTARY INFORMATION: On December 1, 1989 the Coast Guard published a notice of proposed rulemaking in the **Federal Register** for these regulations (54 FR 49776). Interested persons were requested to submit comments and no comments were received.

Drafting Information

The drafters of these regulations are LTJG C.W. Jennings, project officer, Captain of the Port, New York and LT J.B. Gately, project attorney, First Coast Guard District Legal Office.

Discussion of Comments

As previously stated no comments regarding the NPRM were received. This regulation is issued pursuant to 33 U.S.C. 2030, 2035, and 2070 as set out in the authority citation for all of part 110.

Economic Assessment and Certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary. Establishment of this proposed special anchorage area will not require dredging or result in increased cost to any segment of the public.

Since the impact of these 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.

Lists of Subjects in 33 CFR Part 110

Anchorage grounds.

Final Regulations

In consideration of the foregoing, part 110 of title 33, Code of Federal Regulations, is amended as follows:

PART 110—[AMENDED]

1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 2030, 2035 and 2071; 49 CFR 1.46 and 33 CFR 1.05-1(g). Section 110.1a and each section listed in 110.1a are also issued under 33 U.S.C. 1223 and 1231.

2. Section 110.60 paragraph (aa) is added to read as follows:

§ 110.60 Port of New York and vicinity.

* * * * *

(aa) South of Perth Amboy, New Jersey. The waters bounded by a line connecting the following points:

Latitude	Longitude
40°30'19.0"	74°15'46.0"
40°30'17.0"	74°15'39.0"
40°30'02.8"	74°15'45.0"
40°29'36.0"	74°16'09.2"
40°29'30.8"	74°16'22.0"
40°29'47.2"	74°16'52.0"
40°30'02.0"	74°16'43.0"

and thence along the shoreline to the point of beginning.

§ 110.155 [Amended]

3. Section 110.155 is amended by removing and reserving paragraph (j)(3).

Dated: August 29, 1990.

R.I. Rybacki,

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

[FR Doc. 90-23296 Filed 10-2-90; 8:45 am]

BILLING CODE 4910-14-M

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33 CFR Part 165

[CGD1 90-172]

Safety Zone Regulations; Americas Cup Restaurant Octoberfest Fireworks Display

AGENCY: Coast Guard, DOT.

ACTION: Emergency rule.

SUMMARY: The Coast Guard is establishing a safety zone on the Connecticut River between Middletown, CT and Portland, CT. This safety zone is needed to protect marine traffic from the safety hazard associated with a fireworks display in a narrow channel. Entry into this zone is prohibited unless authorized by the Captain of the Port, Long Island Sound.

EFFECTIVE DATES: This regulation becomes effective at 9:15 p.m. October 13, 1990, 15 minutes prior to the display. It terminates upon completion of the display at approximately 10 p.m. October 13, 1990, unless terminated sooner by the Captain of the Port. Rain date for this event will be 14 October 1990 at the same times.

FOR FURTHER INFORMATION CONTACT: Lt. David Skewes (203) 468-4464 or Captain of the Port, Long Island Sound duty watchstander at (203) 468-4464.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** Publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to protect any marine traffic from the potential hazards involved.