That airspace extending upward from the surface to and including 2,600 feet MSL within a 4.4-mile radius of the Pitt-Greenville Airport. This control zone is effective during the specific dates and times established in advance by a Notice to Airman. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in East Point, Georgia, on April 30, 1992.

Don Cass,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 92-11187 Filed 5-12-92; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 356

[Docket No. 81N-0033]

RIN 0905-AA06

Oral Health Care Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking to amend the tentative final monograph for over-the-counter (OTC) oral health care drug products by adding a new section that will exempt oral health care drug products containing menthol in a lozenge dosage form from that part of the accidental overdose warning required by § 330.1(g) (21 CFR 330.1(g)) that states: "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The exemption from the warning is being provided because OTC oral health care drug products containing menthol in a lozenge dosage form have been determined to have a low potential for acute toxicity resulting from accidental ingestion. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by July 13, 1992; written comments on the agency's economic impact determination by July 13, 1992.

ADDRESSES: 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: 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: Under § 330.1(g), the following general warning statements are required on all orally administered OTC drug products: "Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately." Section 330.1(g) also states that FDA will grant an exemption from these general warnings where appropriate upon petition.

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 provides for menthol to be used as an antitussive in a lozenge dosage form at a dose of 5 to 10 milligrams (mg) every hour as needed (52 FR 30042 at 30055 to 30056).

Subsequently, based on data submitted in two citizen petitions, the agency proposed to provide for an exemption for menthol-containing antitussive cough drops from the required general warning statements in § 330.1(g) in the **Federal Register** of July 6, 1989 (54 FR 28442). The agency concluded that accidental ingestion of menthol lozenges marketed in the monograph dosage (5 to 10 mg) is highly unlikely to present any degree of acute oral toxicity. Because of this low potential for acute toxicity, the agency proposed to add a new section to the monograph for OTC antitussive drug products and to provide an exemption for OTC antitussive drug products and to provide an exemption from the second part of the accidental overdose warning required by § 330.1(g) for antitussive drug products containing menthol in a lozenge dosage form. The second part of this warning states: "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." However, the agency concluded that products containing menthol should continue to bear the first part of the general warning, which states: "Keep this and all drugs out of the reach of children." The agency considered this part of the warning necessary to reinforce and ensure that all drugs, regardless of potential toxicity, are treated by consumers as drugs and kept out of the reach of all children.

Final agency action on this proposal occurred with the publication of an amendment to the final monograph for OTC antitussive drug products in the **Federal Register** of July 6, 1990 (55 FR 27806). The agency provided an exemption for menthol lozenges (marketed in accordance with the monograph) from the second part of the accidental overdose warning required by § 330.1(g), which states: "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." However, the labeling must continue to bear the first part of the general warning in § 330.1(g), which states: "Keep this and all drugs out of the reach of children." (See § 341.74(f) (21 CFR 341.74(f)), 55 FR 27806 to 27808.)

In the **Federal Register** of May 25, 1982 (47 FR 22760), FDA published an advance notice of proposed rulemaking for OTC oral health care drug products. The Advisory Review Panel on OTC Oral Cavity Drug Products (the Panel) recommended that menthol be generally recognized as safe and effective (Category I) as an OTC anesthetic/analgesic in lozenges containing 2 to 20 mg menthol to be taken every 2 hours, if necessary (47 FR 22760 at 22813 to 22814). In the tentative final monographs for OTC oral health care drug products published in the **Federal Register** of January 27, 1988 (53 FR 2436 at 2458 to 2459) and September 24, 1991 (56 FR 48302 at 48344), the agency concurred with the Panel's Category I recommendation and dosage for menthol in a lozenge dosage form and proposed that it be included in the monograph for OTC oral health care drug products.

Subsequent to the publication of the September 24, 1991 tentative final monograph for OTC oral health care drug products, the agency received a comment requesting that the tentative final monograph be amended by adding a new section that would exempt oral health care drug products containing 2 to 20 mg menthol in a lozenge dosage form from that part of the accidental overdose warning required by § 330.1(g) which states: "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The comment did not request an exemption from the portion of the warning that states "Keep this and all drugs out of the reach of children."

As noted above, the agency has previously considered this type of exemption for OTC lozenge products containing menthol for antitussive use. The agency believes that it is highly unlikely that OTC lozenge products containing menthol for oral health care

anesthetic/analgesic use would present any degree of acute oral toxicity. Accordingly, the agency is proposing to amend the tentative final monograph for OTC oral health care drug products to include the same type of exemption that currently exists in the monograph for OTC antitussive drug products.

The agency has examined the economic consequences of this proposed rulemaking 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 assessment 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 proposed rule for OTC oral health care 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 for OTC oral health care drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC oral health care drug products. Types of impact may include, but are not limited to, costs associated with relabeling. There should be no adverse impact on costs because this labeling change can be implemented at the same time as any other labeling changes that become necessary when the final rule for OTC oral health care drug products is issued. Comments regarding the impact of this rulemaking on OTC oral health care drug products should be accompanied by appropriate documentation. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

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.

Interested persons may, on or before July 13, 1992, submit written comments on the proposed regulation to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before July 13, 1992. Three copies of all 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 and may be accompanied by a supporting memorandum or brief. Comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 356

Labeling, Oral health care drug products, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 356 (as proposed in the **Federal Register** of September 24, 1991 (56 FR 48302)) be amended as follows:

PART 356—ORAL HEALTH CARE DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 356 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 356.52 is amended by adding new paragraph (e) to read as follows:

§ 356.52 Labeling of anesthetic/analgesic drug products.

* * * * *

(e) *Exemption from the general accidental overdose warning.* The labeling for oral health care anesthetic/analgesic drug products containing the active ingredient identified in § 356.12(f) marketed in accordance with § 356.52(d)(6)(ii) is exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison center immediately." The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states: "Keep this and all drugs out of the reach of children."

Dated: March 18, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92–11177 Filed 5–12–92; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF TRANSPORATION

Coast Guard

33 CFR Part 165

[CGD1 92–025]

Safety Zone: Narragansett Bay, Quonset Point, RI

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on June 5, 6 and 7, 1992, at Quonset Point, North Kingstown, RI, while aerial demonstrations, including those by the USAF Thunderbirds, are performed in preparation of, and during, the "Rhode Island National Guard Open House." This action is necessary to protect spectator/pleasure craft, as well as other vessels in the vicinity, from the risks of low flying aircraft and aerial demonstrations. The USAF Thunderbirds will practice between the hours of 12 p.m. and 1 p.m. on June 5, 1992, and aerial demonstrations, including those by the USAF Thunderbirds, will be performed between the hours of 11 a.m. and 4 p.m. on June 6 and 7, 1992.

DATES: Comments must be received on or before May 28, 1992.

ADDRESSES: Comments should be mailed to the Commanding Officer, Marine Safety Office Providence, John O'Pastore Federal Building, Providence, Rhode Island, 02903–1790, or may be delivered to Room 217 at the above address between 7:30 a.m. and 4 p.m., Monday through Friday, except federal holidays. The telephone number is (401) 528–5335. The Marine Safety Office Providence maintains a public docket for the rulemaking. Comments will become part of this docket and will be available for inspection or copying at room 217, Marine Safety Office Providence.

FOR FURTHER INFORMATION CONTACT: LTJG T. Burke at (401) 528–5335.

SUPPLEMENTARY INFORMATION: .

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting