

February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as these routine matters will only affect air traffic procedures and air navigation. It is certified that these proposed rules will not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

#### PART 71—[AMENDED]

■ 1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p.389.

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

#### Subpart E—Class E Airspace

\* \* \* \* \*

*Paragraph 6003 Class E airspace areas designated as an extension to a Class C surface area*

\* \* \* \* \*

#### ANE CT E3 Windsor Locks, CT [Revised]

Windsor Locks, Bradley International Airport, CT

(Lat. 41°56'20"N, long. 72°41'00"W)

CHUPP NDB

(Lat. 41°52'39"N, long. 72°45'58")

That airspace extending upward from the surface within 2.9 miles on each side of the 225° bearing from the CHUPP NDB extending from the 5-mile radius of the Bradley International Airport to 8.6 miles southwest of the airport. This Class E airspace area is effective during 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 Burlington, MA, on April 10, 2003.

**Thomas R. Davidson,**

Manager, Air Traffic Division, New England Region.

[FR Doc. 03–9506 Filed 4–16–03; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 201

[Docket Nos. 93N–0182 and 82N–0166]

RIN 0910–AA01

#### Labeling for Oral and Rectal Over-the-Counter Drug Products Containing Aspirin and Nonaspirin Salicylates; Reye's Syndrome Warning

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule to amend its regulations to revise the Reye's syndrome warning required for oral and rectal over-the-counter (OTC) human drug products containing aspirin and to require a warning on OTC drug products containing nonaspirin salicylates as active ingredients. The revised warning will inform consumers of the symptoms of Reye's syndrome and advise that aspirin and nonaspirin salicylate drug products should not be given to children or teenagers who have or are recovering from chicken pox or flu-like symptoms. This final rule also finalizes FDA's notice of proposed rulemaking to require a Reye's syndrome warning for orally administered OTC drug products for relief of symptoms associated with overindulgence in food and drink (overindulgence drug products) that contain bismuth subsalicylate that published in the **Federal Register** of May 5, 1993 (58 FR 26886). FDA is issuing this final rule after considering public comment on the agency's notices of proposed rulemaking and all relevant data and information that have come to the agency's attention.

#### DATES:

**Effective Date:** This final rule is effective April 19, 2004.

**Compliance Dates:** The compliance date for OTC antidiarrheal and overindulgence drug products that contain bismuth subsalicylate as an active ingredient and have annual sales greater than \$25,000 is April 19, 2004. The compliance date for OTC antidiarrheal and overindulgence drug products that contain bismuth subsalicylate as an active ingredient and have annual sales less than \$25,000 is April 18, 2005. The compliance date for OTC drug products containing aspirin and nonaspirin salicylates as an active ingredient and marketed under a new drug application (NDA) or abbreviated

new drug application (ANDA) is October 18, 2004. The compliance dates for all other OTC drug products containing aspirin and nonaspirin salicylates as an active ingredient and marketed under an OTC drug monograph (for internal analgesic, antipyretic, and antirheumatic drug products, or for menstrual drug products) will be established when the final monographs for those drug products are published in a future issue of the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Ida I. Yoder, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of May 5, 1993 (58 FR 26886), FDA published a notice of proposed rulemaking to require a Reye's syndrome warning for OTC overindulgence drug products that contain bismuth subsalicylate (the May 1993 proposed rule). The proposed warning stated: "Children and teenagers who have or are recovering from chicken pox, flu symptoms, or flu should NOT use this product. If nausea, vomiting, or fever occur, consult a doctor because these symptoms could be an early sign of Reye syndrome, a rare but serious illness." The agency did not propose this warning for OTC antidiarrheal drug products that contain bismuth subsalicylate because bismuth subsalicylate was not a proposed monograph ingredient for that use at that time.

This warning was intended to inform consumers of the earliest recognizable symptoms of Reye's syndrome and advise that OTC overindulgence drug products containing bismuth subsalicylate should not be used during the period when children or teenagers have, or are recovering from, the flu or chicken pox. The agency mentioned that it was considering revising the Reye's syndrome warning currently required for products containing aspirin in § 201.314(h)(1) (21 CFR 201.314(h)(1)) to be the same as the proposed warning for products containing bismuth subsalicylate.

In the **Federal Register** of October 20, 1993 (58 FR 54228), FDA published a notice of proposed rulemaking to revise the Reye's syndrome warning required for OTC drug products containing aspirin to be consistent with the proposed warning for OTC overindulgence drug products containing bismuth subsalicylate (the October 1993 proposed rule). The