

not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Parts 336, 338, and 341

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 336, 338, and 341 are amended as follows:

PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 336 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 336.50 is amended by adding paragraph (c)(8) to read as follows:

§ 336.50 Labeling of antiemetic drug products.

* * * * *

(c) * * *

(8) For products containing diphenhydramine hydrochloride identified in § 336.10(c). "Do not use [bullet]¹ with any other product containing diphenhydramine, including one used on skin".

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PART 338—NIGHTTIME SLEEP-AID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 338 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

4. Section 338.50 is amended by adding paragraph (c)(5) to read as follows:

§ 338.50 Labeling of nighttime sleep-aid drug products.

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(c) * * *

(5) "Do not use [bullet]¹ with any other product containing diphenhydramine, even one used on skin".

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¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

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

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

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

6. Section 341.72 is amended by adding paragraphs (c)(6)(iv) and (c)(7) as follows:

§ 341.72 Labeling of antihistamine drug products.

* * * * *

(c) * * *

(6) * * *

(iv) For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.12(f) and (g). "Do not use [bullet]¹ with any other product containing diphenhydramine, even one used on skin".

(7) For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.12(f) and (g). "Do not use [bullet] with any other product containing diphenhydramine, even one used on skin".

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7. Section 341.74 is amended by adding paragraphs (c)(4)(viii)(C) and (c)(4)(ix)(C) to read as follows:

§ 341.74 Labeling of antitussive drug products.

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(c) * * *

(4) * * *

(viii) * * *

(C) "Do not use [bullet]¹ with any other product containing diphenhydramine, even one used on skin".

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(ix) * * *

(C) "Do not use [bullet] with any other product containing diphenhydramine, even one used on skin".

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Dated: November 25, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01-02-136]

RIN 2115-AE47

Drawbridge Operation Regulations; Long Island, New York Inland Waterway From East Rockaway Inlet to Shinnecock Canal, NY

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Wreck Lead Bridge, mile 4.4, across Reynolds Channel at Hempstead, New York. This deviation from the regulations allows the bridge to remain in the closed position from 6:30 a.m. on December 10, 2002 through 6:30 a.m. on December 13, 2002. This deviation is necessary to facilitate scheduled maintenance at the bridge.

DATES: This deviation is effective from December 10, 2002 through December 13, 2002.

FOR FURTHER INFORMATION CONTACT: Joseph Schmied, Project Officer, First Coast Guard District, at (212) 668-7165.

SUPPLEMENTARY INFORMATION: The bridge owner, Long Island Railroad, requested a temporary deviation from the drawbridge operating regulations to facilitate necessary structural repairs, replacement of structural bracing, couplings, and deteriorated concrete, at the bridge.

Under this deviation the Wreck Lead Bridge, mile 4.4, across Reynolds Channel at Hempstead, New York, may remain in the closed position from 6:30 a.m. on December 10, 2002 through 6:30 a.m. on December 13, 2002.

There have been few requests to open this bridge during the requested time period scheduled for these structural repairs in past years. The Coast Guard and the bridge owner coordinated this closure with the facilities upstream from the bridge and no objections to this scheduled closure were received.

This deviation from the operating regulations is authorized under 33 CFR 117.35, and will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

Dated: November 22, 2002.

V.S. Crea,

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

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