

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

121. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1200a [Amended]

122. Section 524.1200a *Kanamycin ophthalmic ointment* is amended by removing paragraph (a)(1) and by removing the designation for paragraph (a)(2).

123. Section 524.1200b is amended by revising paragraph (a) to read as follows:

§ 524.1200b Kanamycin ophthalmic aqueous solution.

(a) *Specifications.* The drug, which is in an aqueous solution including suitable and harmless preservatives and buffer substances, contains 10 milligrams of kanamycin activity (as the sulfate) per milliliter of solution.

* * * * *

§ 524.1204 [Amended]

124. Section 524.1204 *Kanamycin sulfate, calcium amphotericin, and hydrocortisone acetate* is amended by removing paragraph (a)(1), by redesignating paragraphs (a)(2)(i) through (a)(2)(iii) as paragraphs (a)(1)(i) through (a)(1)(iii), and by redesignating paragraph (a)(3) as paragraph (a)(2).

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

125. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.360 [Amended]

126. Section 529.360 *Cephalothin discs* is amended by removing the phrase “, comply with the requirements of § 460.1 of this chapter” from paragraph (a) and adding in its place “have a uniform potency of 30 micrograms cephalothin per disc”.

PART 800—GENERAL

127. The authority citation for 21 CFR part 800 is revised to read as follows:

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360k, 361, 362, 371.

PART 801—LABELING

128. The authority citation for 21 CFR part 801 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

PART 807—ESTABLISHMENT AND REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

129. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

§ 807.25 [Amended]

130. Section 807.25 *Information required or requested for establishment registration and device listing* is amended by removing “, 507,” in paragraph (f)(3).

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

131. The authority citation for 21 CFR part 809 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

§ 809.5 [Removed]

132. Section 809.5 *Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act* is removed.

§ 809.6 [Removed]

133. Section 809.6 *Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements* is removed.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

134. The authority citation for 21 CFR part 812 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

135. The authority citation for 21 CFR part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

§ 860.84 [Amended]

136. Section 860.84 *Classification procedures for “old devices”* is amended by removing the fourth sentence in paragraph (a).

Dated: December 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 99–140 Filed 1–4–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 78N–0281]

Direct Food Substances Affirmed as Generally Recognized as Safe; Magnesium Hydroxide; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on food for human consumption to correct an error in the Chemical Abstracts Service (CAS) registry number for magnesium hydroxide. This document corrects that error.

DATES: This regulation is effective January 5, 1999.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of April 5, 1985 (50 FR 13557), the agency amended its regulations by adding § 184.1428 (21 CFR 184.1428) to affirm that magnesium hydroxide is generally recognized as safe (GRAS) as a direct human food ingredient. The CAS registry number for magnesium hydroxide was incorrectly published as “(Mg(OH)₂, CAS Reg. No. 1409–42–8)” instead of “(Mg(OH)₂, CAS Reg. No. 1309–42–8)”. Accordingly, the agency is amending § 184.1428 to correct the error.

Publication of this document constitutes final action on this change. Notice and public procedure are unnecessary because FDA is merely correcting a nonsubstantive error in its regulations.

List of Subjects in 21 CFR Part 184

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

**PART 184—DIRECT FOOD
SUBSTANCES AFFIRMED AS
GENERALLY RECOGNIZED AS SAFE**

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 184.1428 [Amended]

2. Section 184.1428 *Magnesium hydroxide* is amended in paragraph (a) by removing “(Mg(OH)₂, CAS Reg. No. 1409-42-8)” and adding in its place “(Mg(OH)₂, CAS Reg. No. 1309-42-8)”.

Dated: December 21, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-28 Filed 1-4-99; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD 08-98-079]

RIN 2115-AE47

**Temporary Drawbridge Regulations;
Mississippi River, Iowa and Illinois**

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: The Coast Guard is temporarily changing the drawbridge operation regulation governing the Burlington Railroad Drawbridge, Mile 403.1, Upper Mississippi River. The drawbridge shall open on signal if at least six (6) hours advance notice is given from 12:01 a.m. on December 31, 1998, until 12:01 a.m. on March 1, 1999. Advance notice may be given by calling (309) 345-6103 during work hours or (309) 752-5244 after hours. This arrangement is necessary to perform annual maintenance and repair work on the bridge.

DATES: This temporary rule is effective from 12:01 a.m. on December 31, 1998, until 12:01 a.m. on March 1, 1999.

ADDRESSES: The public docket and all documents referred to in this notice will be available for inspection and copying at room 2.107f in the Robert A. Young Federal Building at Director, Western Rivers Operations (ob), Eighth Coast Guard District, 1222 Spruce Street, St. Louis, MO 63101-2832, between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Roger K. Wiebusch, Bridge Administrator; Director, Western Rivers

Operations, Eighth Coast Guard District, Bridge Branch, 1222 Spruce Street, St. Louis, MO 63101-2832, telephone (314) 539-3900, extension 378.

SUPPLEMENTARY INFORMATION: On December 1, 1998, Burlington Northern Santa Fe requested a temporary change to the operation of the Burlington Railroad Drawbridge across the Upper Mississippi River, Mile 403.1 at Burlington, Iowa. The Railroad requested that the bridge be allowed to open for navigation between December 31, 1998 and March 1, 1998 upon a six (6) hour advance notice so that necessary maintenance and bridge repair activities can be performed. Advance notice may be given by calling Al Poole, (309) 345-6103 during work hours and Larry Moll, (309) 752-5244, after hours.

In accordance with 5 U.S.C. 533, a notice of proposed rulemaking has not been published and good cause exists for making this rule effective in less than 30 days from publication. Following normal rulemaking procedures would be impractical. Delaying implementation of the regulation will not benefit navigation and would result in unnecessary delays in repairing the bridge.

Background and Purpose

The Burlington Railroad Drawbridge has a vertical clearance of 21.5 feet above normal pool in the closed to navigation position. Navigation on the waterway consists of commercial tows and recreational watercraft. Presently the draw opens on signal for passage of river traffic. This temporary drawbridge operation amendment has been coordinated with the commercial waterway operators who do not object. Winter conditions on the Upper Mississippi River coupled with the closure of Army Corps of Engineer's Locks No. 11, 12, 19, 20, 24, and 25 until March 1, 1999, will preclude any significant navigation demands for the drawspan openings. The Burlington Railroad Drawbridge is located downstream of Lock 18 and upstream of Lock 19. Performing maintenance on the bridge during the winter when no vessels are impacted is preferred to bridge closures or advance notification requirements during the commercial navigation season.

Regulatory Evaluation

This temporary rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. The Office of Management and Budget has not

reviewed it under that order. It is not significant under the Regulatory Policies and Procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this temporary rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This is because river traffic will be extremely limited by lock closures and ice during this period.

Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Coast Guard must consider whether this temporary rule will have a significant economic impact on a substantial number of small entities. “Small entities” may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000. Because it expects the impact of this action to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b), that this action will not have economic impact on a substantial number of small entities.

Collection of Information

This temporary rule contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism Assessment

The Coast Guard has analyzed this proposal under the principles and criteria contained in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment Assessment

The Coast Guard considered the environmental impact of this temporary rule and concluded that this action is categorically excluded from further environmental documentation in accordance with Section 2.B.2, Figure 2-1 (32)(e) of the National Environmental Protection Act Implementing Procedures, COMDTINST M16475.1C.

List of Subjects in 33 CFR Part 117

Bridges.

Temporary Regulations

In consideration of the foregoing, Part 117 of Title 33, Code of Federal Regulations, is amended as follows: