

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 2. Section 314.3 is amended in paragraph (b) by adding the following definition for *authorized generic drug* in alphabetical order:

§ 314.3 Definitions.

* * * * *

(b) * * *

Authorized generic drug means a listed drug, as defined in this section, that has been approved under section 505(c) of the act and is marketed, sold, or distributed directly or indirectly to retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark that differs from that of the listed drug.

* * * * *

■ 3. Section 314.81 is amended by redesignating paragraph (b)(2)(ii) as paragraph (b)(2)(ii)(a) and by adding new paragraph (b)(2)(ii)(b) as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(b) *Authorized generic drugs.* If applicable, the date each authorized generic drug (as defined in § 314.3) entered the market, the date each authorized generic drug ceased being distributed, and the corresponding trade or brand name. Each dosage form and/or strength is a different authorized generic drug and should be listed separately. The first annual report submitted on or after February 11, 2009, must include the information listed in this paragraph for any authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999. If information is included in the annual report with respect to any authorized generic drug, a copy of that portion of the annual report must be sent to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, 10903 New Hampshire Ave., Bldg. 51, rm. 4183, Silver Spring, MD 20993-0002 and marked “Authorized Generic Submission” or, if FDA has required that annual reports be submitted in an electronic format, the information required by this section must also be submitted in the electronic format.

* * * * *

Dated: September 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-22833 Filed 9-26-08; 8:45 am]

BILLING CODE 4160-01-S

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Parts 2200 and 2203

Rules of Procedure; Regulations Implementing the Government in the Sunshine Act; Corrections and Technical Amendments

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Final rule; corrections and technical amendments.

SUMMARY: The Occupational Safety and Health Review Commission (OSHRC) is making corrections and technical amendments to its rules and regulations, which include revisions to its address and regularly scheduled meeting time, as well as corrections of erroneous cross-references and a typographical error.

DATES: Effective on September 29, 2008.

FOR FURTHER INFORMATION CONTACT: Ron Bailey, Attorney-Advisor, Office of the General Counsel, by telephone at (202) 606-5410, by e-mail at rbailey@oshrc.gov, or by mail at: 1120—20th Street, NW., Ninth Floor, Washington, DC 20036-3457.

SUPPLEMENTARY INFORMATION:

I. Background

OSHRC is making several corrections and technical amendments to its Rules of Procedure found at 29 CFR part 2200, and its Regulations Implementing the Government in Sunshine Act found at 29 CFR part 2203.

As to 29 CFR part 2200, OSHRC is correcting a typographical error in § 2200.63(b) by removing “zequestenç” and adding in its place “requested.” Also, in §§ 2200.57(a) and 2200.96, OSHRC is amending the reference to its nine-digit ZIP code, which has been changed from 20036-3419 to 20036-3457. Finally, OSHRC is correcting cross-references that should have been amended when OSHRC revised its Rules of Procedure on July 3, 1997 (62 FR 35961). In that revision, OSHRC reduced the period specified in § 2200.90(b)(2) for transmitting a judge’s decision to the Executive Secretary from 20 days to 10 days. This 20-day period was previously cross-referenced in §§ 2200.91(c) and 2200.209(g), but was

inadvertently left unchanged. Therefore, § 2200.91(c), which refers to “the 20 days provided by § 2200.90(b),” is corrected to read “the 10 days provided by § 2200.90(b)” and § 2200.209(g), which refers to the “21 day period provided for in rule § 2200.90(b)(2),” is corrected to read the “11-day period provided for in rule § 2200.90(b)(2).”

As to 29 CFR part 2203, OSHRC is amending the time of its regularly-scheduled meetings. Sections 2203.2 (definition of “Regularly-scheduled meetings”) and 2203.4(c) presently state that such meetings are held at 10 a.m. every Thursday, except for legal holidays. In both sections, this meeting time is being amended to “10:30 a.m.” every Thursday, except for legal holidays. Also, in §§ 2203.4(c) and 2203.7(b), OSHRC is amending the reference to its nine-digit ZIP code from 20036-3419 to 20036-3457.

II. Statutory and Executive Order Reviews

Waiver of Proposed Rulemaking: For good cause, OSHRC finds that prior notice and opportunity for comment on these changes are unnecessary pursuant to 5 U.S.C. 553(b)(3)(B), because the amendments and corrections to the affected sections are merely technical in nature and propose no substantive changes on which public comment could be solicited.

Waiver of 30-Day Delayed Effective Date Requirement: OSHRC finds that good cause exists for the final rule to be exempt from the 30-day delayed effective date requirement of 5 U.S.C. 553(d) because a delay in clarifying these rules would be contrary to the public interest.

Executive Orders 12866 and 13132, and the Unfunded Mandates Reform Act of 1995: OSHRC is an independent regulatory agency, and, as such, is not subject to the requirements of E.O. 12866, E.O. 13132, or the Unfunded Mandates Reform Act, 2 U.S.C. 1501 *et seq.*

Regulatory Flexibility Act: OSHRC has determined that this rulemaking is exempt from the requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), because, as noted, a general notice of proposed rulemaking is not required under 5 U.S.C. 553(b).

Paperwork Reduction Act of 1995: OSHRC has determined that the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, is not applicable here because this final rule contains no information collection requirements that require the approval of OMB.

Congressional Notification: OSHRC has determined that the Congressional Review Act, 5 U.S.C. 801, is not

applicable here because, pursuant to 5 U.S.C. 804(3)(C), this final rule “does not substantially affect the rights or obligations of non-agency parties.”

List of Subjects

29 CFR Part 2200

Administrative practice and procedure.

29 CFR Part 2203

Sunshine Act.

Signed at Washington, DC, on the 23rd day of September, 2008.

Horace A. Thompson III,
Chairman.

Thomasina V. Rogers,
Commissioner.

■ Accordingly, 29 CFR parts 2200 and 2203 are corrected by making the following amendments:

PART 2200—RULES OF PROCEDURE

■ 1. The authority citation for part 2200 continues to read as follows:

Authority: 29 U.S.C. 661(g), unless otherwise noted. Section 2200.96 is also issued under 28 U.S.C. 2112(a).

- 2. In § 2200.57, paragraph (a), in the third sentence, remove the ZIP code suffix “3419” and add, in its place, “3457”.
- 3. In § 2200.63, paragraph (b), correct “zequestenø” to read “requested”.
- 4. In § 2200.91, paragraph (c), in the fourth sentence, remove the number “20” and add, in its place, “10”.
- 5. In § 2200.96, in the first sentence, remove the ZIP code suffix “3419” and add, in its place, “3457”.
- 6. In § 2200.209, paragraph (g), in the last sentence, remove the phrase “21 day” and add, in its place, “11-day”.

PART 2203—REGULATIONS IMPLEMENTING THE GOVERNMENT IN THE SUNSHINE ACT

■ 7. The authority citation for part 2203 continues to read as follows:

Authority: 29 U.S.C. 661(g); 5 U.S.C. 552b(d)(4); 5 U.S.C. 552b(g).

- 8. In § 2203.2, in the definition of “Regularly-scheduled meetings,” remove the time “10:00 a.m.” and add, in its place, “10:30 a.m.”
- 9. In § 2203.4, paragraph (c), in the first sentence, remove the time “10:00 a.m.” and add, in its place, “10:30 a.m.”
- 10. In § 2203.4, paragraph (c), in the first sentence, remove the ZIP code suffix “3419” and add, in its place, “3457”.
- 11. In § 2203.7, paragraph (b), in the third sentence, remove the ZIP code

suffix “3419” and add, in its place, “3457”.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[Docket No. USCG–2004–19621]

RIN 1625–AA89

Dry Cargo Residue Discharges in the Great Lakes

AGENCY: Coast Guard, DHS

ACTION: Interim rule; request for comments.

SUMMARY: The Coast Guard is amending its regulations to allow the discharge of bulk dry cargo residue (DCR) in limited areas of the Great Lakes by self-propelled vessels and by any barge that is part of an integrated tug and barge unit. DCR is the residue of non-toxic and non-hazardous bulk dry cargo like limestone, iron ore, and coal. These regulations also add new recordkeeping and reporting requirements and encourage carriers to adopt voluntary control measures for reducing discharges. Discharges are now prohibited in certain protected and sensitive areas where, previously, they were allowed. The Coast Guard also requests public comments on the need for and feasibility of additional conditions that might be imposed on discharges in the future, such as mandatory use of control measures, or further adjustments to the areas where discharges are allowed or prohibited.

DATES: This interim rule takes effect September 29, 2008. Initial reports under amended 33 CFR 151.66(c)(4) are due January 15, 2009. Comments and related material submitted in response to the request for comments must reach the Docket Management Facility on or before January 15, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2004–19621 and are available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also

find this docket on the Internet at <http://www.regulations.gov>.

We encourage you to submit comments identified by Coast Guard docket number USCG–2004–19621 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act system of records notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

FOR FURTHER INFORMATION CONTACT: If you have questions on this interim rule, call LT Heather St. Pierre, U.S. Coast Guard, telephone 202–372–1432 or e-mail Heather.J.St.Pierre@uscg.mil. If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

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I. Acronyms

APA Administrative Procedure Act
DCR Dry Cargo Residue