(b) *Significance of calcium or calcium and vitamin D.* Adequate calcium intake, or adequate calcium and vitamin D intake, is not the only recognized risk factor in the development of osteoporosis, which is a multifactorial bone disease. Maintenance of adequate calcium and vitamin D intakes throughout life is necessary to achieve optimal peak bone mass and to reduce the risk of osteoporosis in later life. However, vitamin D is most effective in this regard when calcium intake is adequate. Increasing intake of calcium has been shown to have beneficial effects on bone health independent of dietary vitamin D.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating calcium or, when appropriate, calcium and vitamin D with a reduced risk of osteoporosis may be made on the label or labeling of a food described in paragraphs (c)(2)(ii) and (d)(1) of this section, provided that:

(A) The claim makes clear the importance of adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, throughout life, in a healthful diet, are essential to reduce osteoporosis risk. The claim does not imply that adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, is the only recognized risk factor for the development of osteoporosis;

(B) The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake, or when appropriate, an adequate dietary calcium and vitamin D intake, throughout life.

(ii) *Nature of the food.* (A) The food shall meet or exceed the requirements for a ''high'' level of calcium as defined in § 101.54(b);

(B) The calcium content of the product shall be assimilable;

(C) Dietary supplements shall meet the United States Pharmacopeia (USP) standards for disintegration and dissolution applicable to their component calcium salts, except that dietary supplements for which no USP standards exist shall exhibit appropriate assimilability under the conditions of use stated on the product label;

(D) A food or total daily recommended supplement intake shall not contain more phosphorus than calcium on a weight per weight basis.

(d) *Optional information.* (1) The claim may include the term ''vitamin D'' if the food meets or exceeds the requirements for a ''high'' level of vitamin D as defined in § 101.54(b);

(2) The claim may include information from paragraphs (a) and (b) of this section.

(3) The claim may make reference to physical activity.

(4) The claim may include information on the number of people in the United States, including the number of people in certain subpopulations in the United States, who have osteoporosis or low bone density. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or the National Osteoporosis Foundation.

(5) The claim may state that the role of adequate calcium intake, or when appropriate, the role of adequate calcium and vitamin D intake, throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase ''build and maintain good bone health'' may be used to convey the concept of optimizing peak bone mass. The claim may also state that adequate intake of calcium, or when appropriate, adequate intake of calcium and vitamin D, is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss for persons with a family history of the disease, post-menopausal women, and elderly men and women.

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between calcium and osteoporosis:

Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

(f) *Model additional health claims for calcium and vitamin D.* The following model health claims may be used in food labeling to describe the relationship between calcium, vitamin D, and osteoporosis:

Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

Dated: September 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22730 Filed 9–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA–2008–N–0341]

Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to require that the holder of a new drug application (NDA) submit certain information regarding authorized generic drugs in an annual report. We are taking this action as part of our implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA requires that FDA publish a list of all authorized generic drugs included in an annual report since 1999, and that the agency update the list quarterly. We are using direct final rulemaking for this action because the agency expects that there will be no significant adverse comment on the rule. In the proposed rule section of this issue of the **Federal Register**, we are concurrently proposing and soliciting comments on this rule. If significant adverse comments are received, we will withdraw this final rule and address the comments in a subsequent final rule. FDA will not provide additional opportunity for comment.

DATES: This direct final rule is effective February 11, 2009. Submit written or electronic comments on or before December 15, 2008. If we receive no timely significant adverse comments, we will publish a notice in the **Federal Register** before January 12, 2009, confirming the effective date of the direct final rule. If we receive any timely significant adverse comments, we will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule before February 11, 2009.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0341, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michelle D.D. Bernstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, rm. 6223, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85, 121 Stat. 823). Section 920 of FDAAA adds new section 505(t) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(t)) and requires that FDA take the following actions:

- Publish on its Internet site a complete list of all authorized generic drugs included in an annual report submitted to the agency after January 1, 1999, consisting of the drug trade name, the brand company manufacturer, and the date the authorized generic drug entered the market;
- Update the list quarterly; and
- Notify relevant Federal agencies, including the Centers for Medicare and Medicaid Services and the Federal Trade Commission, that the list has been published and will be updated quarterly.

For purposes of publishing the list, section 505(t)(3) of the act defines the term ''authorized generic drug'' as a ''listed drug (as that term is used in [section 505(j) of the act]) 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 under a different 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 than the listed drug.''

Currently, there is no requirement that an NDA holder specifically report that it is marketing an ''authorized generic drug.'' NDA holders are required to include information about distribution or certain changes to manufacturing or labeling in annual reports, which may indicate that an authorized generic is being marketed. However, annual reports may not include all the information necessary for FDA to publish the list required by FDAAA. For example, sponsors rarely include the date the authorized generic entered the market.

To allow FDA to accurately report a complete list of all authorized generic drugs included in annual reports and to update the list in a timely fashion, we are adding a requirement that annual reports specifically and clearly include the information we are required to report. In addition, we are requiring that the NDA holder report the date the authorized generic drug ceased being distributed to ensure that the list is as accurate and up-to-date as possible. The first annual report submitted after implementation of this regulation must provide information regarding any authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999.

There are currently 15 divisions in FDA that receive annual reports for over 2,200 active NDAs. When information is included in an annual report about an authorized generic drug, we are requiring that a copy of that portion of the annual report be sent to a central office in the agency that will compile the list and update it quarterly.

II. Direct Final Rulemaking

We have determined that the subject of this rulemaking is suitable for a direct final rule. FDA expects this amendment to be noncontroversial, and the agency does not anticipate receiving any significant adverse comments on this rule. We have determined that publishing a direct final rule is the most appropriate method to meet the requirement, under section 505(t) of the act, that the agency publish a list of all authorized generic drugs.

If we receive no significant adverse comment, we will publish a document in the **Federal Register** confirming the effective date of the direct final rule. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change. If timely significant adverse comments are received, we will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule within 30 days after the comment period ends.

Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule, identical in substance to this direct final rule, that provides a procedural framework from which to proceed with standard notice-and-comment rulemaking in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule, and we will consider those comments in developing a final rule. We will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to part of this rule and that part may be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment. A full description of our policy on direct final

rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Description of the Direct Final Rule

We are defining the term ''authorized generic drug'' as a listed drug (as defined in § 314.3 (21 CFR 314.3)) 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 either 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.

We are amending our regulations in § 314.81 (21 CFR 314.81) to require that an NDA holder specifically report that it has marketed an authorized generic drug during the applicable time period. Section 314.81(b)(2) requires that an NDA holder submit an annual report within 60 days of the anniversary date of approval of an NDA for every NDA it holds. We are amending § 314.81 by redesignating paragraph (b)(2)(ii) regarding distribution data, as paragraph (b)(2)(ii)(*a*), and adding a new paragraph (b)(2)(ii)(*b*) regarding marketing of authorized generic drugs. This new paragraph states that, if an authorized generic drug was marketed under an NDA, or ceased to be marketed, during the reporting year, the annual report must list the date each authorized generic drug 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 after implementation of this regulation must include the required marketing information 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 the portion of the annual report with that information 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.'' This final rule assumes that the copy of the relevant portion of the annual report may currently be submitted in any number of formats (e.g., a paper copy, a PDF document on a computer disc). Current capabilities do not permit direct electronic submission through a Web-based system. However, FDA is committed to adapting its business practices to evolving technology, including using the significant advancements in Web-based, electronic systems. We anticipate that, in future rulemakings, Web-based submission of annual reports will eventually be required. In anticipation of that future change, this final rule provides that once an electronic submission format is adopted for annual reports, the submission to the agency of the information required under this regulation will also be required in that electronic format. We anticipate that when such a change is implemented, future guidance will address any technical questions related to such submissions.

IV. Legal Authority

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA), provides authority for FDA to issue this direct final rule. Section 505(t) of the act (21 U.S.C. 355(t); FDAAA section 920) requires that FDA publish a complete list of all authorized generic drugs included in an annual report submitted to the agency after January 1, 1999, and to update that list quarterly. In addition, section 701(a) of the act (21 U.S.C. 371(a)) provides general authority for FDA to issue regulations for the efficient enforcement of the act. This direct final rule would amend FDA's existing regulations regarding annual reports in order to ensure that the information necessary for the agency to fulfill its obligation under section 505(t) is clearly reported.

V. Environmental Impact

We have carefully considered, under 21 CFR part 25, the potential environmental effects of this action. We have concluded that this action will not have a significant impact on the human environment and that an environmental impact statement is not required.

VI. Analysis of Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this direct final rule imposes only minimal regulatory obligations, the agency certifies that the direct rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this direct final rule to result in any 1-year expenditure that would meet or exceed this amount.

The only costs of this direct final rule are associated with the Paperwork Reduction Act burden, described in section VII of this document. If we assume an average hourly wage plus benefits of $56 for the reporting personnel, the annual cost is about $29,000 ($56 per hour x 520 hours).

VII. The Paperwork Reduction Act of 1995

This direct final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown with an estimate of the annual reporting and recordkeeping burden in Table 1 of this document. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Applications for FDA Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs.

Description: This rulemaking requires the holder of an NDA to notify the

agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central office. We are taking this action as part of our implementation of FDAAA, which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the agency update the list quarterly. We plan to publish this list on the Internet and to notify relevant Federal agencies that the list has been published and will be updated.

Description of Respondents: Current holders of an NDA under which an authorized generic drug was marketed during the time period covered by an annual report submitted after January 1, 1999.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR 314.81(b)(2)(ii)(*b*)	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Authorized generic drug information in the first annual report submitted after the implementation of § 314.81(b)(2)(ii)(*b*)	60	6.7	400	1 hour	400
Authorized generic drug information submitted in each subsequent annual report	60	6.7	400	15 minutes	100
The submission of a copy of that portion of each annual report containing authorized generic drug information	60	6.7	400	3 minutes	20

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

During the past several years, FDA has reviewed a small sample of annual reports it has received under § 314.81(b)(2) to discern whether an authorized generic drug is being marketed by the NDA holder. Based on information learned from this review and based on the number of annual reports the agency currently receives under § 314.81(b)(2),[1] we estimate that, after the implementation of § 314.81(b)(2)(ii)(*b*), we will receive approximately 400 annual reports containing the information required under § 314.81(b)(2)(ii)(*b*) for authorized generic drugs that were marketed during the time period covered by an annual report submitted after January 1, 1999. Based on the number of sponsors that currently submit all annual reports, we estimate that approximately 60 sponsors will submit these 400 annual reports with authorized generics. As indicated in Table 1 of this document, we are estimating that the same number of annual reports will be submitted each subsequent year from the same number of sponsors containing the information required under § 314.81(b)(2)(ii)(*b*), and that the same number of copies of that portion of each annual report containing the authorized generic drug information will be submitted from the same number of sponsors. Concerning the hours per response, based on our estimate of 40 hours to prepare each annual report currently submitted under § 314.81(b)(2),[2] we estimate that sponsors will need approximately 1 hour to prepare the information required under § 314.81(b)(2)(ii)(*b*) for each authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999; approximately 15 minutes to prepare the information required under § 314.81(b)(2)(ii)(*b*) for each subsequent annual report; and approximately 3 minutes to submit to FDA a copy of that portion of each annual report containing the authorized generic drug information.

[1] During fiscal year 2006, the Center for Drug Evaluation and Research received 2,569 annual reports under § 314.81(b)(2) from 374 sponsors.

[2] See the **Federal Register** of January 4, 2008 (73 FR 865).

VIII. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

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 ''zequestenȼ'' 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