

programs. Absent attention to these issues, it will be difficult for any proposal to place generation and demand response on a precisely level playing field.

Until then, this Commission must review what options it has available without resorting to policies that would adversely enable the short-term development of demand response at the expense of its longer-term success. In closing, I believe that demand response programs have great potential to enhance the organized energy markets and I look forward to their continued development. I am concerned, however, that a one-size-fits-all approach could result in uneconomic outcomes that ultimately set back the future development of demand response.

Philip D. Moeller,
Commissioner.

[FR Doc. 2010-6478 Filed 3-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM09-13-000]

Time Error Correction Reliability Standard

March 18, 2010.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Pursuant to section 215 of the Federal Power Act, the Commission proposes to remand the proposed revised Time Error Correction Reliability Standard developed by the North American Electric Reliability Corporation (NERC) in order for NERC to develop several modifications to the proposed Reliability Standard. The proposed action ensures that any modifications to Reliability Standards will be just, reasonable, not unduly discriminatory or preferential, and in the public interest.

DATES: Comments are due April 28, 2010.

ADDRESSES: Interested persons may submit comments, identified by Docket No. RM09-13-000, by any of the following methods:

- *eFiling:* Comments may be filed electronically via the eFiling link on the Commission's Web site at <http://www.ferc.gov>. Documents created electronically using word processing software should be filed in the native

application or print-to-PDF format and not in a scanned format. The Commission accepts most standard word processing formats and commenters may attach additional files with supporting information in certain other file formats. Attachments that exist only in paper form may be scanned. Commenters filing electronically should not make a paper filing. Service of rulemaking comments is not required.

- *Mail/Hand Delivery:* Commenters that are not able to file comments electronically must mail or hand deliver an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT: Mindi Sauter (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-6830.

Scott Sells (Technical Information), Office of Electric Reliability, Division of Reliability Standards, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-6664.

SUPPLEMENTARY INFORMATION:

Notice of Proposed Rulemaking

March 18, 2010

1. Pursuant to section 215 of the Federal Power Act (FPA),¹ the Commission proposes to remand the Time Error Correction Reliability Standard (BAL-004-1) developed by the North American Electric Reliability Corporation (NERC) in order for NERC to develop several modifications to the proposed Reliability Standard, as discussed below.²

I. Background

A. EPA Act 2005 and Mandatory Reliability Standards

2. Section 215 of the FPA requires a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Specifically, the Commission may approve, by rule or order, a proposed Reliability Standard or modification to a Reliability Standard if it determines that

the Standard is just, reasonable, not unduly discriminatory or preferential, and in the public interest.³ Once approved, the Reliability Standards may be enforced by the ERO, subject to Commission oversight, or by the Commission independently.⁴

3. Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO⁵ and, subsequently, certified NERC as the ERO.⁶ On April 4, 2006, NERC submitted a petition seeking approval of 107 proposed Reliability Standards, including BAL-004-0.⁷ On March 16, 2007, the Commission issued Order No. 693 approving 83 of these 107 Reliability Standards, including BAL-004-0, and directing other actions related to 56 of the approved Reliability Standards.

1. Time Error Correction Generally

4. Time Error occurs when a synchronous Interconnection operates at a frequency (number of cycles per second) that is different from the Interconnection's Scheduled Frequency. Interconnections control to 60 Hz (60 cycles per second), however, the control is imperfect and over time will result in the average frequency being either above 60 Hz or below 60 Hz. This discrepancy between actual frequency and Scheduled Frequency results from an imbalance between generation and interchange and load and losses, which also results in Inadvertent Interchange.⁸ Time Error Correction is the procedure Reliability Coordinators and Balancing Authorities follow to reduce Time Error and regulate the average frequency closer to 60 Hz. The Time Error Correction Reliability Standard sets forth the process that Reliability Coordinators and Balancing Authorities follow to offset their Scheduled

³ 18 U.S.C. 824o(d)(2).

⁴ *Id.* 824o(e)(3).

⁵ *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards*, Order No. 672, FERC Stats. & Regs. ¶ 31,204, *order on reh'g*, Order No. 672-A, FERC Stats. & Regs. ¶ 31,212 (2006).

⁶ *North American Electric Reliability Corp.*, 116 FERC ¶ 61,062 (ERO Certification Order), *order on reh'g & compliance*, 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa, Inc. v. FERC*, 564 F.3d 1342 (D.C. Cir. 2009).

⁷ *See Petition of the North American Electric Reliability Council and North American Electric Reliability Corporation for Approval of Reliability Standards*, April 4, 2006 at 28-29, Docket No. RM06-16-000.

⁸ Inadvertent Interchange occurs when unplanned energy transfers cross Balancing Authority boundaries, typically where a Balancing Authority experiences an operational problem that prevents its net actual interchange of energy from matching its net scheduled interchange with other Balancing Authorities within the Interconnection.

¹ 16 U.S.C. 824o.

² The Commission is not proposing any new or modified text to its regulations. Rather, as provided in 18 CFR part 40, a proposed Reliability Standard will not become effective until approved by the Commission, and the Electric Reliability Organization must post on its website each effective Reliability Standard.

Frequency to reliably correct for the accumulated Time Error. The efficiency of Time Error Corrections is determined by the participation of all Balancing Authorities within the Interconnection. Coordination and oversight by all Balancing Authorities and Reliability Coordinators is necessary to ensure that Time Error Corrections are performed reliably.

2. NERC's Proposed Time Error Correction Reliability Standard Revisions

5. On March 16, 2007, the Commission issued Order No. 693, which, among other things, approved the currently effective Time Error Correction Reliability Standard, BAL-004-0.⁹ On March 11, 2009, NERC filed a petition for Commission approval of the revised Time Error Correction Reliability Standard, designated BAL-004-1. The petition states that the proposed Reliability Standard would supersede the existing Reliability Standard, and is intended to ensure that Interconnection Time Monitors will continue to volunteer for that role during an interim time period during which NERC and the industry will consider significant changes in how to manage Time Error Correction. NERC states that a potential more permanent solution already is incorporated in the scope of its ongoing Project 2007-05—Balancing Authority Controls.

6. The Time Error Correction Reliability Standard applies to Reliability Coordinators and Balancing Authorities. NERC states that, while in NERC's view Time Error itself is not a reliability issue, correcting for Time Error can affect reliability, and therefore the methods used for Time Error Correction must be carried out by the Balancing Authorities and Reliability Coordinators within each Interconnection in accordance with NERC Reliability Standards.

7. NERC indicates that designating an Interconnection Time Monitor is primarily an issue for the Eastern Interconnection. The Midwest ISO currently performs this function for the Eastern Interconnection. In the Western Interconnection, the Western Electricity Coordinating Council (WECC) uses automatic Time Error Correction, although periodic manual corrections still are required and are coordinated by WECC.¹⁰ The Electric Reliability

Council of Texas performs Time Error Correction functions for the Texas Interconnection.

8. NERC states that BAL-004-1 ensures that Time Error Corrections are conducted in a manner that does not adversely affect the reliability of the Interconnection.

3. Time Error Correction Reliability Standard Requirements

9. NERC's petition summarizes the proposed changes to the Time Error Correction Reliability Standard's compliance Requirements, as described below.¹¹

10. *Requirement R1:* Requirement R1 currently states that only a Reliability Coordinator is eligible to serve as an Interconnection Time Monitor, and that the NERC Operating Committee shall designate a single Reliability Coordinator in each Interconnection to serve as Interconnection Time Monitor. The proposed changes would remove the requirement that the NERC Operating Committee designate Interconnection Time Monitors. NERC indicates that the change would vest authority for designating Interconnection Time Monitors with the NERC Board of Trustees, based on NERC Operating Committee review and recommendation. NERC states that, once the proposed standard is approved, the NERC Board of Trustees will formally designate Interconnection Time Monitors.

11. *Requirement R2:* NERC proposes to remove the current Requirement R2 in its entirety; the current Requirement R2 states that the Interconnection Time Monitor will monitor Time Error and shall initiate or terminate corrective action orders in accordance with the North American Energy Standards Board (NAESB) Time Error Correction Procedure. NERC asserts that NERC Reliability Standards should not compel an entity to comply with NAESB business practices.

required to continuously automatically correct for their contribution to Time Error using automatic generation control systems. However, certain operational events may lead to suspension of automatic Time Error Correction, requiring manual Time Error Corrections to be completed at another time, under WECC's direction. See, *Western Electricity Coordinating Council Regional Reliability Standard Regarding Automatic Time Error Correction*, Order No. 723, 127 FERC ¶ 61,176 (2009) (approving WECC Automatic Time Error Correction regional Reliability Standard).

¹¹ Appendix A to this order, showing in redline the changes NERC proposed to the Time Error Correction Reliability Standard, is available for viewing at <http://www.ferc.gov> in the eLibrary version of this document.

12. *Requirement R3:*¹² Requirement R3 instructs Balancing Authorities to participate in a Time Error Correction when directed by the Reliability Coordinator serving as the Interconnection Time Monitor. The text of that Requirement would remain the same.

13. *Requirement R4:*¹³ Requirement R4 states that any Reliability Coordinator, either on its own accord or at the request of a Balancing Authority within its footprint, may request that the Interconnection Time Monitor terminate a Time Error Correction for reliability reasons. The text of that Requirement also would remain the same.

14. *Reference Document:* NERC states that its Operating Committee has approved a "Time Monitoring Reference Document," which details a process for identifying the Reliability Coordinator that will serve as the Interconnection Time Monitor for each Interconnection and outlines the responsibilities of Reliability Coordinators serving as Interconnection Time Monitors. NERC included the Reference Document in its filing; however, NERC indicates that the document is presented for informational purposes only, and that NERC is not requesting Commission approval of the Reference Document.

4. Time Error Correction Reliability Standard Development

15. The NERC Operating Committee submitted a Standard Authorization Request (SAR) to the NERC Standards Committee on July 11, 2007, proposing changes to BAL-004-0. The Operating Committee requested that the Standards Committee use the "Urgent Action" process in addressing the proposed revisions. At its September 11, 2007 meeting, the Standards Committee determined to post the SAR and proposed standard changes using the Urgent Action process, stating that the potential loss of a willing Reliability Coordinator to serve as the Interconnection Time Monitor justified use of the Urgent Access process.

16. NERC conducted an initial ballot in October 2007, the results of which included ten negative ballots, including seven with comments. All seven commenters were concerned that the proposed revisions left unclear what entity will assume the responsibility for serving as the Time Monitor for each Interconnection. Three commenters also indicated that the revisions did not state responsibility for directing

¹² With the elimination of current Requirement R2, the current Requirement R3 would become Requirement R2.

¹³ Similarly, the current Requirement R4 would become Requirement R3.

⁹ *Mandatory Reliability Standards for the Bulk Power System*, Order No. 693, FERC Stats. & Regs. ¶ 31,242, order on reh'g, Order No. 693-A, 120 FERC ¶ 61,053 (2007).

¹⁰ Under Regional Reliability Standard BAL-004-WECC-01 (Automatic Time Error Correction), Balancing Authorities within WECC generally are

implementation of a Time Error Correction. Two commenters suggested that the Reliability Standards should include a requirement to comply with NAESB business practices because those practices also are FERC-approved. One commenter suggested revising Requirement R2 to omit the reference to the NAESB business practice, and one commenter objected to use of the Urgent Action process.

17. In response to these comments, the NERC Operating Committee indicated that it was working on a documented process for identifying the entity that would serve as the Interconnection Time Monitor for each Interconnection and for reviewing the Interconnection Time Monitors' performance on a forward-going basis, as it has done for many years.

18. NERC posted its response to the comments on November 8, 2007, and subsequently conducted a recirculation ballot, as required under NERC's Rules of Procedure. The revised standard passed with 97.45 percent of the 157 ballot pool participants voting, resulting in a weighted segment approval of 94.10 percent.

19. The NERC Board of Trustees approved the revised Reliability Standard on March 26, 2008, and NERC filed its petition on March 11, 2009. NERC requests that BAL-004-1 become effective on the first day of the first quarter after applicable regulatory approval or, in those jurisdictions where regulatory approval is not required, upon Board of Trustees approval.

II. Discussion

20. The Commission proposes to remand the proposed Reliability Standard, BAL-004-1, in order for NERC to develop several modifications, as discussed below.

A. Requirement R1

21. NERC proposes to revise Requirement R1 to remove from the Reliability Standard the requirement that the NERC Operating Committee designate one Reliability Coordinator as the Interconnection Time Monitor in each Interconnection, arguing that the NERC Operating Committee is not a user, owner or operator of the Bulk-Power System and it is not appropriate for that Committee alone to assign requirements to users, owners or operators of the Bulk-Power System without NERC Board of Trustees' approval. NERC further argues that it is not appropriate for a stakeholder-based committee to designate a particular entity for a position that will be accountable for complying with a Reliability Standard Requirement.

Commission Analysis:

22. With regard to Requirement R1, the Commission is concerned that the Time Monitor selection process is contained in a guidance document that is not subject to Commission review and may be changed without notice. Commission review of proposed changes, and appropriate notice of such proposed changes, is necessary to ensure that the changes are just, reasonable, not unduly discriminatory or preferential, and in the public interest. Thus, the Commission proposes, on remand, to direct NERC to describe the Interconnection Time Monitor designation process within a Commission-approved document, such as NERC's Rules of Procedure or within the Reliability Standard itself.

B. Requirement R2

23. The revised Reliability Standard also proposes to delete Requirement R2 in its entirety. Requirement R2 includes the requirement that Interconnection Time Monitors monitor Time Error and initiate or terminate corrective action in accordance with the NAESB Time Error Correction Procedure. NERC states that now that the "Version 0 Reliability Standards" are mandatory and enforceable, much of the process to implement Time Error Corrections has become a NAESB procedure, because Time Error Correction itself is not a reliability issue. NERC explains that the fact that an Interconnection Time Monitor chooses to act and initiate a Time Error Correction based on the NAESB procedure has no reliability relevance and that NERC Reliability Standards should not compel an entity to comply with NAESB business practices, and that eliminating Requirement R2 accomplishes this. NERC adds that there are no current concerns with the performance of the volunteer Interconnection Time Monitors, and that the NERC Operating Committee will continue to address Interconnection Time Monitor performance in the future should the Commission approve the proposed Reliability Standard. NERC concludes that approving the proposed Reliability Standard would maintain the *status quo* and serve the best interests of reliability.

Commission Analysis:

24. In Order No. 672, the Commission identified a number of criteria it will use in determining whether a proposed Reliability Standard or a proposed revision to a Reliability Standard is just, reasonable, not unduly discriminatory or preferential, and in the public

interest.¹⁴ One of these criteria is that a proposed Reliability Standard must be clear and unambiguous as to what is required and who is required to comply.¹⁵ The Commission believes the proposal to remove Requirement R2 in its entirety does not satisfy this criterion, and therefore proposes to remand the proposed Reliability Standard. Removing Requirement R2 makes the Reliability Standard incomplete and ambiguous, since it would not explain the circumstances under which a Time Error Correction needs to be initiated or ended, indicate that Time Error Correction must be performed, or identify the entity that has the obligation and authority to initiate a Time Error Correction.

25. The Commission therefore proposes to remand the proposed Reliability Standard and, further proposes that, on remand, NERC should modify its proposed changes to Requirement R2 to (1) indicate that the Time Monitor, designated according to a process described in a Commission-approved document as discussed above, is responsible for initiating or terminating a Time Error Correction in a reliable manner; and (2) explain the circumstances under which the Time Monitor should start or end a Time Error Correction. The Commission is not persuaded by NERC's argument that much of the process to implement Time Error Corrections is now just a voluntary NAESB procedure, because Time Error Correction itself is not a reliability issue. In Order No. 693, we disagreed with arguments that Time Error Correction is really more a NAESB business practice. Rather, we stated that the Time Error Correction Reliability Standard is intended to ensure that Time Error Corrections are performed in a manner that does not adversely affect reliability, and the technical details, including the means to carry out the procedure, are a reliability issue.¹⁶

26. We also are not persuaded by NERC's argument that, because the Interconnection Time Monitors are performing well, we should approve removal of technical details from the Reliability Standard. The Reliability Standard should include technical details regarding what is required from all participants involved with Time Error Corrections to avoid confusion

¹⁴ Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards, Order No. 672, FERC Stats. & Regs. ¶ 31,204, order on reh'g, Order No. 672-A, FERC Stats. & Regs. ¶ 31,212 (2006).

¹⁵ *Id.* P. 325.

¹⁶ Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P. 383.

regarding each participant's expectations and obligations. While the Commission does not oppose NERC's proposal to remove the clause in Requirement R2 directing the Time Monitor to proceed in accordance with the NAESB Time Error Correction Procedure, as noted above, the proposed Reliability Standard is incomplete and ambiguous as it does not include pertinent technical details regarding the Time Error Correction process. Additionally, when an issue has both reliability and business aspects, the Commission has directed NERC and NAESB to work together to coordinate their efforts in order to provide a workable Reliability Standard that addresses the reliability issue.¹⁷ The Commission expects that to occur here.

27. NERC has stated that in its view Time Error itself is not a reliability risk, and the purpose of the Time Error Correction Reliability Standard is not to account for Time Error, but to ensure Time Error Corrections are implemented in a reliable manner. Any time the Balancing Authorities within an Interconnection undertake an actual modification to their generation dispatch to correct for Time Error, it must be coordinated and monitored by a Reliability Coordinator to ensure that each Balancing Authority schedules the same frequency and preclude negative impacts on reliable operation, allowing the Reliability Coordinator to maintain a wide area view of other activities, planned or unplanned, occurring on the system at the time. Any Reliability Coordinator can qualify to perform the Interconnection Time Monitor function, and each Interconnection requires one Time Monitor, which is responsible for determining when to implement Time Error Corrections, and for coordinating

their execution. The requirement to appoint a single Time Monitor for each Interconnection ensures that a Time Error Correction is well coordinated and communication runs smoothly. If more than one Time Monitor were assigned to each Interconnection, there would be a risk of uncoordinated Time Error Corrections, resulting in inefficient Time Error Corrections and inadvertent power flows (which could lead to congestion issues on the Bulk-Power System (potentially reaching or exceeding System Operating Limits or Interconnection reliability Operating Limits)) or failure to terminate a Time Error Correction quickly (due to unclear lines of authority, communication issues, or confusion when requested by a Reliability Coordinator or Balancing Authority) if necessary to preserve system reliability.

28. The current, previously-approved Reliability Standard ensures that Time Error Corrections are implemented in a reliable manner by requiring one designated Reliability Coordinator to serve as Time Monitor for each Interconnection and to perform the function of calling for Time Error Corrections, taking into account system conditions, and to halt Time Error Corrections if system conditions warrant, as well as requiring Balancing Authorities to participate and follow the specified procedures. The current Reliability Standard also allows any Reliability Coordinator or Balancing Authority to call for termination of a Time Error Correction for reliability considerations.

29. The greater reliability risk associated with Time Error Correction appears to lie in executing a Time Error Correction rather than in monitoring for Time Error. Accordingly, any penalties arising from the Time Error Correction Reliability Standard should appropriately consider and differentiate between the differing levels of reliability risk arising from differing actions required from Interconnection Time Monitors and should shield the Interconnection Time Monitors from liability beyond their control such as when a Balancing Authority fails to respond appropriately to directives from the Interconnection Time Monitors.

30. Thus, NERC should consider developing compliance evaluation measures that assess the reliability risk associated with each action, and tie any penalty to each action. Requirement R2 might be divided into sub-requirements in order to facilitate development of such compliance evaluation measures.

31. The Commission further reminds NERC that, in Order No. 693, we directed the Electric Reliability

Organization to develop additional Measures and add Levels of Non-Compliance to assure that the requirements in the current Requirement R3 are achieved.¹⁸

32. The Commission seeks comments on the proposals discussed above.

III. Information Collection Statement

33. The Office of Management and Budget (OMB) regulations require that OMB approve certain reporting and recordkeeping (collections of information) imposed by an agency.¹⁹ The information contained here is also subject to review under section 3507(d) of the Paperwork Reduction Act of 1995.²⁰ As stated above, the Commission previously approved, in Order No. 693, the Reliability Standard that is the subject of the current rulemaking. In the first instance, the Commission is proposing to remand the proposed revisions to BAL-004-1, thus the reporting burden would not change. In the event that the Commission, after receiving comments, determines to adopt the proposed revisions to the Reliability Standard, they are minor; therefore, they would not add to or increase entities' current reporting burden. Thus, the current proposal would not materially affect the burden estimates relating to the currently effective version of the Reliability Standard presented in Order No. 693.²¹

34. For example, the proposed modifications to BAL-004-1 do not modify or otherwise affect the collection of information already in place. Moreover, the proposed removal of business practice-related requirements from Reliability Standard BAL-004-1 likely will decrease, not increase, the reporting burden associated with the current, Commission-approved version of the Reliability Standard.

35. Thus, the proposed modifications to the current Reliability Standard effected by this proposed rule will not increase the reporting burden nor impose any additional information collection requirements.

36. The Commission does not foresee any additional impact on the reporting burden for small businesses, because the proposed modifications are minor and do not increase the existing burden. However, we will submit this proposed rule to OMB for informational purposes.

Title: Modification of Time Error Correction Reliability Standard.

Action: Proposed Collection.

¹⁸ Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P 384.

¹⁹ 5 CFR 1320.11.

²⁰ 44 U.S.C. 3507(d).

²¹ See Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P 1905-07.

¹⁷ See, e.g., *Modification of Interchange and Transmission Loading Relief Reliability Standards and Electric Reliability Organization Interpretation of Specific Requirements of Four Reliability Standards*, 123 FERC ¶ 61,064, at P 49 (2008) ("The Commission has long supported the coordination of business practices and Reliability Standards. As early as May 2002, the Commission urged the industry expeditiously to establish the procedures for ensuring coordination between NAESB and NERC."); *Preventing Undue Discrimination and Preference in Transmission Service*, Order No. 890-A, FERC Stats. & Regs. ¶ 31,261, at P 56 (2007), *order on reh'g*, Order No. 890-B, 123 FERC ¶ 61,299 (2008) ("The Commission affirms the decision in Order No. 890 to rely on the NERC reliability standards development process, and the NAESB business practices development process, to achieve a more coherent and uniform determination of ATC. We disagree that this conflicts with the Commission's obligations under section 215 of the FPA."); *Electricity Market Design and Structure*, 99 FERC ¶ 61,171, at P 22 (2002), *order on reh'g*, 101 FERC ¶ 61,297 (2002) ("We also consider coordination between business practice standards and reliability standards to be critical to the efficient operation of the market.")

OMB Control No.: 1902–0244.

Respondents: Businesses or other for-profit institutions; not-for-profit institutions.

Frequency of Responses: On Occasion.

Necessity of the Information: This proposed rule proposes to remand modifications to a Reliability Standard pertaining to Time Error Corrections.

Internal Review: The Commission has reviewed the proposed Reliability Standard and made a determination that its action is necessary to implement section 215 of the FPA. These requirements, if modified as discussed above should conform to the Commission's expectation for Time Error Correction as well as procedures within the energy industry.

37. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426 [Attention: Michael Miller, Office of the Executive Director, Phone: (202) 502–8415, fax: (202) 273–0873, e-mail: michael.miller@ferc.gov].

38. For submitting comments concerning the collection(s) of information and the associated burden estimate(s), please send your comments to the contact listed above and to the Office of Information and Regulatory Affairs, Office of Information and Regulatory Affairs, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone (202) 395–4650, fax: (202) 395–7285, e-mail: oir_submission@omb.eop.gov].

IV. Environmental Analysis

39. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.²² The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.²³ The actions proposed herein fall within this categorical exclusion in the Commission's regulations.

²² *Regulations Implementing the National Environmental Policy Act of 1969*, Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987).

²³ 18 CFR 380.4(a)(2)(ii).

V. Regulatory Flexibility Act Analysis

40. The Regulatory Flexibility Act of 1980 (RFA)²⁴ generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. Agencies are not required to provide such an analysis if a rule would not have such an effect. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a proposed rule and that minimize any significant economic impact on a substantial number of small entities. The Small Business Administration's Office of Size Standards develops the numerical definition of a small business. (See 13 CFR 121.201.) For electric utilities, a firm is small if, including its affiliates, it is primarily engaged in the transmission, generation and/or distribution of electric energy for sale and its total electric output for the preceding twelve months did not exceed four million megawatt hours.

41. NERC and the entities that act as Interconnection Time Monitors, and thus would be affected by the proposed Reliability Standard, do not fall within the RFA's definition of small entity. NERC is the Commission-certified Electric Reliability Organization for the continental United States, and is responsible for developing and enforcing mandatory Reliability Standards for the United States. NERC enforces compliance with NERC Reliability Standards through a rigorous program of monitoring, audits and investigations, and the imposition of financial penalties and other enforcement actions for non-compliance.

42. The Midwest Independent Transmission System Operator, Inc. (Midwest ISO) is a non-profit organization with over 131,000 megawatts of installed generation. Midwest ISO has 93,600 miles of transmission lines and serves 15 states and one Canadian province.

43. The Electric Reliability Council of Texas (ERCOT) manages the flow of electric power to 22 million Texas customers. As the independent system operator for the region, ERCOT schedules power on an electric grid that connects 40,000 miles of transmission lines and more than 550 generation units.

44. The Western Electricity Coordinating Council (WECC) is responsible for coordinating and promoting bulk electric system reliability in the Western

Interconnection. WECC's service territory extends from Canada to Mexico. It includes the provinces of Alberta and British Columbia, the northern portion of Baja California, Mexico, and all or portions of the 14 Western states between.

45. In any event, the RFA is not implicated by this proposed rule because by remanding the proposed Reliability Standard the Commission is maintaining the status quo until future revisions to the Reliability Standard are filed with and approved by the Commission.

VI. Comment Procedures

46. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be remanded, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due April 28, 2010. Comments must refer to Docket No. RM09–13–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

47. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at <http://www.ferc.gov>. The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

48. Commenters that are not able to file comments electronically must send an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

49. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

VII. Document Availability

50. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (<http://www.ferc.gov>) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m.

²⁴ 5 U.S.C. 601–12.

Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

51. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

52. User assistance is available for eLibrary and the Commission's web site during normal business hours from FERC Online Support at (202) 502-6652 (toll free at (866) 208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. E-mail the Public Reference Room at public.referenceroom@ferc.gov.

By direction of the Commission.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2010-6481 Filed 3-26-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 202

[Docket No. FDA-2009-N-0582]

RIN 0910-AG27

Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Specifically, the proposed rule would implement a new requirement of the Federal Food, Drug, and Cosmetic Act (the act), added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), that the major statement in DTC television or radio advertisements (or ads) relating to the side effects and contraindications of an advertised prescription drug intended for use by humans be presented in a clear, conspicuous, and neutral manner. FDA is also proposing, as directed by FDAAA, standards that the agency would consider in

determining whether the major statement in these advertisements is presented in the manner required by FDAAA.

DATES: Submit written or electronic comments on the proposed rule by June 28, 2010. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by April 28, 2010, (see section "VI. Paperwork Reduction Act of 1995" of this document). See section II.D of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2009-N-0582 and/or RIN 0910-AG27, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

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.

Instructions: All submissions received must include the agency name, docket number, and Regulatory Information Number (RIN) 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 "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(s), 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.

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments

regarding information collection by April 28, 2010, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Marissa Chaet Brykman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3238, Silver Spring, MD, 20993-0002, 301-796-1200; or *For information concerning human biological products:* Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD, 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 502(n) of the act (21 U.S.C. 352(n)) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, section 502(n) of the act requires advertisements to contain "a true statement" of certain information including "information in brief summary relating to side effects, contraindications, and effectiveness" as required by regulations issued by FDA.

FDA's current prescription drug advertising regulations in § 202.1 (21 CFR 202.1) describe requirements for print and broadcast advertisements. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements that are broadcast through media such as television, radio, or telephone communications systems must disclose the major side effects and contraindications of the advertised product in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the "major statement" (Ref. 1).¹

¹ If a broadcast advertisement omits the major statement, or if the major statement minimizes the major side effects and contraindications associated with the use of the drug, the advertisement could render the drug misbranded in violation of the act, 21 U.S.C. 352(n) and section 201(n) of the act (21