distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

# List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

# The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

# PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

# § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA– 2016–9116; Directorate Identifier 2016– NM–068–AD.

# (a) Comments Due Date

We must receive comments by November 14, 2016.

#### (b) Affected ADs

None.

# (c) Applicability

This AD applies to The Boeing Company Model 767–200, –300, and –400ER series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 767–53A0264, Revision 1, dated April 25, 2016.

#### (d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

## (e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the fuselage skin lap splices are subject to widespread fatigue damage (WFD). We are issuing this AD to detect and correct cracks at the fuselage skin lap splice, which can rapidly link up, possibly resulting in rapid

decompression and loss of structural integrity of the airplane.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

# (g) Repetitive Inspections and Corrective Actions

Except as specified by paragraph (h) of this AD, at the applicable times specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 767-53A0264, Revision 1, dated April 25, 2016: Do external surface high frequency eddy current (HFEC), internal surface HFEC, and external surface low frequency eddy current (LFEC) inspections, as applicable, to detect cracks in the fuselage skin lap splices, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767-53A0264, Revision 1, dated April 25, 2016. If any crack is found during any inspection required by this AD, before further flight, repair in accordance with Part 8 of the Accomplishment Instructions of Boeing Alert Service Bulletin 767-53A0264, Revision 1, dated April 25, 2016. Repeat the inspections thereafter at the times specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 767-53A0264, Revision 1, dated April 25, 2016, as applicable.

#### (h) Service Information Exception

Where Boeing Alert Service Bulletin 767–53A0264, Revision 1, dated April 25, 2016, specifies a compliance time "after the original issue date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

#### (i) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 767–53A0264, dated May 12, 2015.

# (j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has

been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(4)(i) and (j)(4)(ii) of this AD

apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

#### (k) Related Information

(1) For more information about this AD, contact Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6447; fax: 425–917–6590; email: wayne.lockett@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet: https://www.myboeingfleet.com. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on September 16, 2016.

#### Suzanne Masterson

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service. [FR Doc. 2016–23082 Filed 9–27–16; 8:45 am]

BILLING CODE 4910-13-P

### **DEPARTMENT OF ENERGY**

# Federal Energy Regulatory Commission

#### 18 CFR Part 40

[Docket No. RM16-13-000]

Balancing Authority Control, Inadvertent Interchange, and Facility Interconnection Reliability Standards

**AGENCY:** Federal Energy Regulatory Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Commission proposes to approve Reliability Standards BAL—005–1 (Balancing Authority Control)

and FAC-001-3 (Facility
Interconnection Requirements)
submitted by the North American
Electric Reliability Corporation.

**DATES:** Comments are due November 28, 2016.

**ADDRESSES:** Comments, identified by docket number, may be filed in the following ways:

• Electronic Filing through http:// www.ferc.gov. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.

• Mail/Hand Delivery: Those unable to file electronically may mail or handdeliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures Section of this document.

#### FOR FURTHER INFORMATION CONTACT:

Syed Ahmad (Technical Information), Office of Electric Reliability, Division of Reliability Standards, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (202) 502–8718, Syed.Ahmad@ferc.gov.

Julie Greenisen (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (202) 502–6362, Julie.Greenisen@ferc.gov.

# SUPPLEMENTARY INFORMATION:

1. Under section 215 of the Federal Power Act (FPA),1 the Commission proposes to approve Reliability Standards BAL-005-1 (Balancing Authority Control) and FAC-001-3 (Facility Interconnection Requirements), submitted by the North American Electric Reliability Corporation (NERC), and to retire Reliability Standards BAL-005-0.2b (Automatic Generation Control), FAC-001-2 (Facility Interconnection Requirements), and BAL-006-2 (Inadvertent Interchange). The Commission also proposes to approve the associated implementation plans, violation risk factors, and violation severity levels for Reliability Standards BAL-005-1 and FAC-001-3. Finally, the Commission proposes to approve three revised definitions for the glossary of terms used in NERC Reliability Standards (NERC Glossary).

2. Proposed Reliability Standards BAL–005–1 and FAC–001–3 will enhance the reliability of the Bulk-Power System, as compared to currently-effective Reliability Standards BAL–005–0.2b and FAC–001–2, by clarifying and consolidating existing requirements related to frequency control. The proposed Reliability Standards support more accurate and comprehensive calculation of Reporting Area Control Error (ACE) by requiring timely reporting of an inability to calculate Reporting ACE and by requiring balancing authorities to maintain minimum levels of annual availability of 99.5% for each balancing authority's system for calculating Reporting ACE.<sup>2</sup>

3. As discussed below, we have questions regarding the proposed retirement of Requirement R15 of Reliability Standard BAL-005-0.2b, which requires responsible entities to maintain and periodically test backup power supplies at primary control centers and other critical locations. Depending on the explanation received in comments, the Commission may issue a directive in the final rule to restore the substance of Requirement R15 in the Reliability Standards. Separately, we propose to approve NERC's request to retire Reliability Standard BAL-006-2 upon the latter of the effective date of proposed Reliability Standard BAL-005-1 and the NERC Operating Committee's approval of an Inadvertent Interchange Guideline

# document. I. Background

A. Mandatory Reliability Standards and Order No. 693 Directive

4. Section 215 of the FPA requires a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards that 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 NERC, subject to Commission oversight, or by the Commission independently.4

- 5. Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO,5 and subsequently certified NERC as the ERO.6 On March 16, 2007, the Commission issued Order No. 693. approving 83 of the 107 Reliability Standards filed by NERC, including Reliability Standards BAL-005-0 (Automatic Generation Control), FAC-001-0 (Facility Interconnection Requirements), and BAL-006-1 (Inadvertent Interchange).7 However, in approving Reliability Standards BAL-005-0 and BAL-006-1, the Commission directed NERC to develop modifications to those Reliability Standards through the standards development process.
- 6. With respect to Reliability Standard BAL-005-0, the Commission directed NERC to develop a modification that:
- (1) Develops a process to calculate the minimum regulating reserve a balancing authority must have at any given time taking into account expected load and generation variation and transactions being ramped into or out of the balancing authority; (2) changes the title of the Reliability Standard to be neutral as to the source of regulating reserves and to allow the inclusion of technically qualified DSM and direct control load management; (3) clarifies Requirement R5 of this Reliability Standard to specify the required type of transmission or backup plans when receiving regulation from outside the balancing authority when using non-firm service; and (4) includes Levels of Non-Compliance and a Measure that provides for a verification process over the minimum required automatic generation control or regulating reserves a balancing authority must maintain.8

Since then, the Commission has approved one interpretation of Reliability Standard BAL–005–0 and accepted two errata filings. The currently-effective version of the Reliability Standard is BAL–005–0.2b.

<sup>&</sup>lt;sup>2</sup> NERC states that Reporting ACE "represents a Balancing Authority Area's [] Area Control Error [] measured in megawatts [] as the difference between the [Balancing Authority Area's] Actual and Scheduled Net Interchange, plus its Frequency Bias Setting obligation and meter error corrections. Reporting ACE helps Responsible Entities provide reliable frequency control by indicating the current state of the entity's contribution to Reliability." NERC Petition at 3.

<sup>3 16</sup> U.S.C. 824o(d)(2).

<sup>4</sup> Id. 824o(e).

<sup>&</sup>lt;sup>5</sup> 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).

<sup>&</sup>lt;sup>6</sup> North American Electric Reliability Corp., 116 FERC ¶ 61,062, order on reh'g and compliance, 117 FERC ¶ 61,126 (2006), aff'd sub nom. Alcoa, Inc. v. FERC, 564 F.3d 1342 (D.C. Cir. 2009).

<sup>&</sup>lt;sup>7</sup> Mandatory Reliability Standards for the Bulk-Power System, Order No. 693, FERC Stats. & Regs. ¶ 31,242 at PP 420, 439, and 680, order on reh'g, Order No. 693–A, 120 FERC ¶ 61,053 (2007).

<sup>8</sup> Id. P 420.

<sup>&</sup>lt;sup>9</sup> See Modification of Interchange and Transmission Loading Relief Reliability Standards; and Electric Reliability Organization Interpretation of Specific Requirements of Four Reliability Standards, Order No. 713, 124 FERC ¶ 61,071 (2008); North American Electric Reliability Corp., Docket No. RD09–2–000 (May 13, 2009) (delegated letter order); North American Electric Reliability Corp., Docket No. RD12–4–000 (Sept. 13, 2012) (delegated letter order).

<sup>1 16</sup> U.S.C. 824(o).

7. With respect to Reliability Standard BAL-006-1, the Commission directed NERC to develop a modification "that adds Measures concerning the accumulation of large inadvertent imbalances and Levels of Non-Compliance." 10 The Commission explained the need for such a modification as follows:

While we agree that inadvertent imbalances do not normally affect the realtime operations of the Bulk-Power System and pose no immediate threat to reliability, we are concerned that large imbalances represent dependence by some balancing authorities on their neighbors and are an indication of less than desirable balancing of generation with load. The Commission also notes that the stated purpose of this Reliability Standard is to define a process for monitoring balancing authorities to ensure that, over the long term, balancing authorities do not excessively depend on other balancing authorities in the Interconnection for meeting their demand or interchange obligations.<sup>11</sup>

Since then, the Commission has approved one revision to Reliability Standard BAL-006-1 to remove the regional waiver of certain requirements for the Midwest ISO, following the Midwest ISO's transition to a single balancing authority model. 12 The currently-effective version of the Reliability Standard is BAL-006-2.

### B. NERC Petition

8. On April 20, 2016, NERC filed a petition seeking approval of proposed Reliability Standards BAL-005-1 (Balancing Authority Control) and FAC-001–3 (Facility Interconnection Requirements), nine new or revised definitions associated with the proposed Reliability Standards, and retirement of currently-effective Reliability Standards BAL–005–0.2b (Automatic Generation Control), FAC-001-2 (Facility Interconnection Requirements), and BAL-006-2 (Inadvertent Interchange).

9. NERC requests that the two revised Reliability Standards and the revised definitions of Automatic Generation Control, Pseudo-Tie, and Balancing Authority become effective on the first day of the first calendar quarter twelve months from the effective date of the applicable governmental authority's approval of NERC's petition. NERC also requests that the retirement of Reliability Standard BAL-006-2 become effective upon the latter of the effective date of proposed Reliability Standard BAL-005-1 and the NERC Operating Committee's approval of the Inadvertent

Interchange Guideline document. For the six remaining definitions (Reporting ACE and its component definitions-Actual Frequency, Actual Net Interchange, Scheduled Net Interchange, Interchange Meter Error, and Automatic Time Error Correction), NERC requests an effective date of July 1, 2016, to coincide with the effective date for BAL-001-2.

10. NERC subsequently withdrew its request for approval of the six Reporting ACE-related definitions from the instant docket, and filed for expedited approval of the six definitions in a separate docket. The six definitions were approved by delegated letter order on June 23, 2016, and are no longer at issue in the instant proceeding.13

11. NERC explains in its petition that proposed Reliability Standards BAL-005-1 and FAC-001-3 and the proposed retirement of Reliability Standard BAL-006-2 came about as part of the second phase of NERC's project to "clarify, consolidate, streamline, and enhance the Reliability Standards addressing frequency control." 14 NERC indicates in its petition that the standard drafting team developed the proposed revisions after reviewing applicable Commission directives, "Paragraph 81" criteria, and the recommendations of the periodic review team that examined Reliability Standards BAL-005-0.2b and BAL-006 - 2.15

12. NERC describes the revisions to Reliability Standard BAL-005-0.2b as clarifying and refining the current requirements "for accurate, consistent, and complete" Reporting ACE, which is a key frequency control and reliability indicator. 16 These revisions include relocating some of the current requirements of Reliability Standard BAL-005-0.2b, which relate to confirming that facilities are within a balancing authority's metered boundary, into the proposed Facility Interconnection Requirements Reliability Standard, FAC-001-3. In addition, NERC proposes to relocate

Requirement R3 of currently-effective Reliability Standard BAL-006-2 into proposed Reliability Standard BAL-005–1, explaining that the requirement relates to ensuring that balancing authorities use consistent data sources to calculate Reporting ACE, and therefore more properly belongs in Reliability Standard BAL-005.

13. NEŘC explains that the proposed Reliability Standards "represent substantial improvements over existing Reliability Standards by helping to support more accurate and comprehensive calculation of Reporting ACE and satisfying all remaining Commission directives for Reliability Standards BAL-005 and BAL-006." 17 Further, NERC maintains that proposed Reliability Standard BAL-005-1 is an improvement over the currentlyeffective version, BAL-005-0.2b. because it "consolidates unnecessary or repetitive Requirements and moves certain metrics for calculating Reporting ACE to the revised, proposed definition of Reporting ACE." <sup>18</sup> Among other things, NERC proposes to move requirements applicable to generator operators and transmission operators in currently-effective Reliability Standard BAL-005-0.2b, into a more appropriate standard, explaining that "[a]s the purpose of FAC-001-3 is more commensurate with interconnection responsibilities, interconnection procedures contained in currently effective BAL-005-0.2b should be included in proposed Reliability Standard FAC-001-3." 19

14. In addition, NERC asserts that proposed Reliability Standard BAL-005-1 improves on the currentlyeffective version of the Reliability Standard because proposed Requirement R2 clarifies the performance expectations for notification to reliability coordinators when a balancing authority is unable to calculate Reporting ACE for 30 minutes or more,20 and Requirement R5 "introduces a new obligation . . . to assure the availability of a BA's system used to calculate Reporting ACE, requiring a minimum availability of 99.5% in each calendar year.21

15. NERC states that the proposed package of revisions reflected in its petition address the outstanding directives related to Reliability Standards BAL-005 and BAL-006 from Order No. 693. Specifically, NERC states that the title of Reliability Standard

<sup>10</sup> Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P 428.

<sup>11</sup> Id.

<sup>&</sup>lt;sup>12</sup> See North American Electric Reliability Corp., 134 FERC ¶ 61,007 (2011).

<sup>13</sup> North American Electric Reliability Corp.. Docket No. RD16-7-000 (June 23, 2016) (delegated letter order).

<sup>&</sup>lt;sup>14</sup> NERC Petition at 2 (referencing Project 2010-14.2.1 Phase 2 of Balancing Authority Reliability-

<sup>&</sup>lt;sup>15</sup> Id. at 3 (citing North American Elec. Reliability Corp., 138 FERC ¶ 61,193 at P 81, order on reh'g and clarification, 139 FERC ¶ 61,168 (2012); Petition of the North American Electric Reliability Corporation for Approval of Retirement of Requirements in Reliability Standards, Docket No. RM13-8-000, at Exhibit A ("Paragraph 81 Criteria") (filed Feb. 28, 2013); Electric Reliability Organization Proposed to Retire Requirements in Reliability Standards, Order No. 788, 145 FERC ¶ 61,147 (2013)).

<sup>&</sup>lt;sup>16</sup> Id.

<sup>17</sup> Id. at 12.

<sup>18</sup> Id. at 13.

<sup>19</sup> Id. at 23.

<sup>20</sup> Id. at 16.

<sup>21</sup> Id. at 19.

BAL-005-1 has been modified from Automatic Generation Control to Balancing Authority Control "to reflect the connection to Reporting ACE and resource-neutral requirements." <sup>22</sup> In addition, NERC indicates that it has revised the definition of Automatic Generation Control to ensure a resourceneutral process for controlling demand and resources.<sup>23</sup>

16. NERC states that the requirements of proposed Reliability Standard BAL-005-1 all have a "medium" violation risk factor, thereby addressing the Commission's directive to revise the violation risk factor for Reliability Standard BAL-005-0, Requirement R17 to "medium." 24 Similarly, NERC asserts that it has met the directive to consider Xcel and FirstEnergy's comments about the scope of Requirement R17, which set minimum accuracy requirements for time error and frequency devices, by retiring part of the currently-effective requirement and moving the minimum accuracy requirements into Requirement R3 of Reliability Standard BAL-005-1. NERC maintains that this has "streamlined obligations to use specific frequency metering equipment that is necessary for operation of [automatic generation control (AGC)] and accurate calculation of Reporting ACE, as this ensures that costs associated with implementation are commensurate with reliability benefit." 25

17. NERC proposes to move Requirement R3 from currently-effective Reliability BAL–006–2 into proposed Reliability Standard BAL–005–1, but proposes to retire the rest of the requirements of Reliability Standard BAL–006–2 (Requirements R1, R2, R4, and R5). NERC states that the standard drafting team determined that, aside from Requirement R3, each of the requirements in Reliability Standard BAL–006–2 are "energy accounting standards" and/or are "administrative" in nature, and should accordingly be retired.<sup>26</sup>

18. While NERC acknowledges that the Commission previously directed it to develop measures concerning the accumulation of large inadvertent imbalances, based on the Commission's concern that large imbalances may indicate an underlying problem, NERC

explains that the requirements of Reliability Standard BAL–001–2, which require balancing authorities to maintain clock-minute ACE within the Balancing Authority ACE Limit, as well as the requirements of Reliability Standard BAL–003–1 and proposed Reliability Standard BAL–002–2, which require entities to restore Reporting ACE within predefined bounds, prevent any excessive dependency on other entities. As NERC explains in its petition:

Because entities are supporting frequency through this coordinated suite of reliability standards, entities will not excessively depend on other entities in the Interconnection such that the purely economic issue that was addressed by BAL–006–2 becomes a reliability issue for a NERC Reliability Standard.<sup>27</sup>

19. In order to address "any remaining or potential concerns with retirement of BAL-006-2," NERC proposes that the retirement become effective only upon the Operating Committee's approval of an Inadvertent Interchange Guideline document.28 NERC states that the Inadvertent Interchange Guideline document was based on a white paper developed by the standard drafting team for Reliability Standards BAL-005 and BAL-006, and maintains that it provides an in-depth justification for why a NERC Reliability Standard is not necessary for inadvertent interchange.

20. With respect to the three proposed definitions that remain at issue in this proceeding, NERC explains that (1) "Automatic Generation Control" has been revised to set forth a resource-neutral process for controlling demand and resources; (2) "Pseudo-Tie" has been updated to reflect the use of the term "Reporting ACE"; and (3) "Balancing Authority" has been revised to more accurately describe a balancing authority's resource demand function.

# C. NERC Supplemental Filing

21. On June 14, 2016, NERC submitted supplemental information in support of its April 20, 2016 petition (Supplemental Filing), to provide additional explanation and support for the retirement of Requirement R15 in currently-effective Reliability Standard BAL–005–0.2b.<sup>29</sup> In its Supplemental

Filing, NERC maintains that Requirement R15 should be retired because the objectives of that requirement (i.e., to ensure the continued operation of AGC and certain data recording equipment during the loss of normal power supply) are being addressed through other Reliability Standards and requirements. Specifically, NERC maintains that Reliability Standard EOP-008-1 requires a balancing authority to have a backup control center facility and an operating plan that allows it to meet its functional obligations with regard to the reliable operation of the bulk electric system in the event that its primary control center functionality is lost.30

22. In addition, NERC maintains that the proposed performance requirements of Requirement R3 of Reliability BAL–005–1, which would require balancing authorities to "use frequency metering equipment for the calculation of Reporting ACE that is available a minimum of 99.95% of each calendar year," will help to ensure that balancing authorities can continuously operate the equipment necessary for the calculation of Reporting ACE, effectively eliminating the need for Requirement R15.31

# II. Discussion

23. Pursuant to FPA section 215(d)(2), we propose to approve Reliability Standards BAL-005-1 and FAC-001-3 as just, reasonable, not unduly discriminatory or preferential, and in the public interest. Proposed Reliability Standard BAL-005-1 and FAC-001-3 will enhance reliability as compared to currently-effective Reliability Standards BAL-005-0.2b and FAC-001-2, because the proposed Reliability Standards clarify and consolidate existing requirements related to frequency control. In addition, proposed Reliability Standard BAL-005-1 supports more accurate and comprehensive calculation of Reporting ACE by requiring timely reporting of an inability to calculate Reporting ACE (Requirement R2) and by requiring minimum levels of availability and accuracy for each balancing authority's system for calculating Reporting ACE (Requirement R5).

24. We also propose to approve the violation risk factors and violation severity levels associated with Reliability Standards BAL–005–1 and FAC–001–3; the proposed revisions to the definitions of Automatic Generation Control, Pseudo-Tie, and Balancing Authority; the proposed retirement of

<sup>&</sup>lt;sup>22</sup> Id. at 13 (referencing Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P 404, and noting that the Commission's directive related to resource-neutrality for regulating reserves is now moot, as Requirement R2 of Reliability Standard BAL–005–0.2b, which required entities to maintain regulating reserves, has been retired).

<sup>&</sup>lt;sup>23</sup> *Id.* at n.39.

<sup>&</sup>lt;sup>24</sup> Id. at 17; see also North American Elec. Reliability Corp., 121 FERC P 61,179 at P 58 (2007).

<sup>25</sup> Id. at 18.

<sup>&</sup>lt;sup>26</sup> *Id.* at 25–26.

<sup>&</sup>lt;sup>27</sup> Id. at 27.

<sup>&</sup>lt;sup>28</sup> The Inadvertent Interchange Guideline document is expected to be presented to the NERC Operating Committee in mid-September 2016, and will be posted for a 45-day comment period.

<sup>&</sup>lt;sup>29</sup> As NERC notes in its Supplemental Filing, NERC stated in its initial petition that "Requirements R2, R7 and R15... are redundant, ineffective, and should be retired based on Commission-approved Paragraph 81 Criteria." NERC Supplemental Filing at 1 (quoting April 20 Petition at 15).

<sup>&</sup>lt;sup>30</sup> NERC Supplemental Filing at 2.

<sup>31</sup> Id. at 4.

Reliability Standards BAL–005–0.2b, FAC–001–2, and BAL–006–2 in accordance with NERC's implementation plan; and NERC's implementation plans for proposed Reliability Standards BAL–005–1 and FAC–001–3.

25. As discussed below, the Commission seeks comment from NERC and other interested entities regarding the retirement of Requirement R15 of Reliability Standard BAL–005–0.2b, which requires responsible entities to maintain and periodically test backup power supplies at primary control centers and other critical locations. Depending on the explanation received in the comments, the Commission may issue a directive in the final rule requiring NERC to restore this requirement through the standards development process.

A. Retirement of Reliability Standard BAL–005–0.2b, Requirement R15

26. Proposed Reliability Standard BAL–005–1 would eliminate currently-effective Requirement R15 from the standard, which states as follows:

The Balancing Authority shall provide adequate and reliable backup power supplies and shall periodically test these supplies at the Balancing Authority's control center and other critical locations to ensure continuous operation of AGC and vital data recording equipment during loss of the normal power supply.

27. NERC contends that Requirement R15 should be retired because it is "redundant" and "ineffective," and points to a number of other Reliability Standards and requirements that, NERC maintains, achieve the same objective as Requirement R15. Specifically, NERC explains that requirements in Reliability Standard EOP-008-1 (Loss of Control Center Functionality) and the performance requirements of Requirement R3 in proposed Reliability Standard BAL-005-1 address the same objectives as existing Requirement R15 (i.e., to ensure the continued operations of AGC and certain data recording equipment during the loss of normal power supply).<sup>32</sup>
28. NERC contends that Reliability

28. NERC contends that Rehability Standard EOP–008–1 requires a balancing authority to have a backup control center facility and an operating plan that allows it to meet its functional obligations with regard to the reliable operation of the bulk electric system in the event that its primary control center functionality is lost. NERC asserts that these requirements effectively address the same reliability objective as Reliability Standard BAL–005–0.2b

Requirement R15 because a balancing authority's "functional obligations regarding reliable operations" <sup>33</sup> include the continuous operation of AGC and the data recording equipment necessary to balance generation and load. Further, NERC contends that Requirement R7 of Reliability Standard EOP–008–1 requires balancing authorities to test their operating plans annually to demonstrate the viability of their backup functionality.

29. NERC maintains that the proposed performance requirements in Requirement R3 of Reliability Standard BAL-005-1, which require balancing authorities to "use frequency metering equipment for the calculation of Reporting ACE that is available a minimum of 99.95% of each calendar year," will help ensure that balancing authorities can continuously operate the equipment necessary for the calculation of Reporting ACE. NERC notes that if a balancing authority "fails[s] to have adequate and reliable backup power supplies at its control center to ensure continuous operation of its AGC and vital data recording equipment, the Balancing Authority risks violation of the performance obligation in proposed Reliability Standard BAL-005-1, Requirement R3 if its normal power supply is lost."34

**Commission Request for Comments** 

30. We recognize that the approach taken in revised Reliability Standard BAL-005-1, combined with the requirements of Reliability Standard EOP-008-1, represents a more performance-based approach to maintaining functionality for reliable operation of the interconnected bulk electric system, including ensuring the continued operation of AGC and certain data recording equipment during the loss of normal power supply, compared to the more specific approach of Requirement R15 in Reliability Standard BAL-005-0.2b. Moreover, balancing authorities currently appear to be the only type of functional entity explicitly required to have and to test adequate and reliable backup supply at critical locations. For example, there is no provision parallel to Requirement R15 that reliability coordinators or transmission operators provide "adequate and reliable backup power supplies" at their primary control centers and "other critical locations."

31. Nonetheless, after considering NERC's Petition and Supplemental Filing addressing the matter, we continue to have questions as to

whether the objectives of Requirement R15 are met, as NERC contends, by other requirements in Reliability Standard EOP-008-1 and proposed Reliability Standard BAL-005-1. In particular, Requirement R15 of currently-effective Reliability Standard BAL-005-0.2b helps to ensure continued operability of balancing authorities' primary control centers, despite the loss of normal power supply, without evacuation to or activation of backup control centers. Thus, this provision appears to provide additional robustness in the primary control center and mitigates the risk of problems occurring in the transition to a secondary control center. We also note that NERC's Independent Expert Review Project (IERP) report did not include Requirement R15 among the requirements recommended for retirement when it reviewed Reliability Standard BAL-005-0.2b in 2013.35 While the IERP report explicitly recommended retiring other provisions of Reliability Standard BAL–005–0.2b, it recommended retaining Requirement R15 as part of the Future Enforceable Set of requirements.<sup>36</sup>

32. Accordingly, we are not persuaded based on the current record that it is appropriate to eliminate balancing authorities' existing obligation to have and periodically test backup power supply at a primary control center. We, therefore, seek additional justification for the retirement of Requirement R15 of Reliability Standard BAL-005-0.2b. Specifically, the Commission seeks comment on the benefits and potential burden of retaining Requirement R15. We also seek an explanation as to why, historically, there is no parallel to Requirement R15 for reliability coordinators and transmission operators, and whether any reason exists to distinguish between balancing authorities and other entities, such as reliability coordinators and transmission operators, that may operate a control center or critical facility with respect to the need for backup power supply and testing at such locations.

33. The Commission further seeks comment on the following questions:

1. If Requirement R15 of Reliability Standard BAL-005-0.2b is retired, can balancing authorities comply with Reliability Standard EOP-008-1 by having a primary control center and "backup functionality" without a backup power supply at the primary control center or without a backup

<sup>&</sup>lt;sup>33</sup> *Id.* at 3.

<sup>&</sup>lt;sup>34</sup> *Id.* at 4–5.

<sup>&</sup>lt;sup>35</sup> Standards Independent Experts Review Project at 26, http://www.nerc.com/pa/Stand/Resources/Documents/Standards\_Independent\_Experts\_Review Project\_Report.pdf.

<sup>36</sup> Id. at 1.

power supply at the location providing backup functionality? Are reliability coordinators and transmission operators compliant with Reliability Standard EOP–008–1 by having a primary control center and "backup functionality" without a backup power supply at the primary control center or without a backup power supply at the location providing backup functionality?

2. Explain the benefits and potential burdens for the reliable operation of the bulk electric system in having a backup power supply at the primary control center. Is it more appropriate to have backup power supply sited at a location providing backup functionality? Does the potential impact to reliability change if the entity is a reliability coordinator or transmission operator?

3. Describe current practices with respect to the availability of backup power supplies at primary control centers and other critical locations. In particular, do any reliability coordinators, transmission operators, or balancing authorities currently have a primary control center without a backup power supply?

4. What does the reference in Reliability Standard BAL–005–0.2b Requirement R15 to "other critical locations" include? Does it include facilities beyond primary control centers and locations providing backup

functionality?

5. Does the use of frequency metering equipment to calculate Reporting ACE that is available a minimum of 99.95% of each calendar year, as proposed in Reliability Standard BAL–005–1, Requirement R3, ensure "continuous operation of AGC and vital data recording equipment during loss of the normal power supply," per Reliability Standard BAL–005–0.2b, Requirement R15? What other functions would be included as part of the metering equipment and data collection of Reliability Standard BAL–005–1, Requirement R3? What functions currently part of Reliability Standard BAL–005–0.2b,

6. Do the requirements in Reliability Standard EOP-008-1 for backup functionality ensure the "continuous operation of AGC and vital data recording equipment," and the ability to collect data to calculate Reporting ACE, in the case of the unavailability of such equipment for a period within the bounds of proposed Reliability Standard BAL-005-1, Requirement R3?

Requirement R15 would be omitted?

# **III. Information Collection Statement**

34. The Paperwork Reduction Act (PRA) <sup>37</sup> requires each federal agency to seek and obtain Office of Management and Budget (OMB) approval before undertaking a collection of information directed to ten or more persons, or contained in a rule of general applicability. The OMB regulations require that OMB approve certain reporting and recordkeeping (collections of information) imposed by an agency.<sup>38</sup> Upon approval of a collection(s) of information, OMB will assign an OMB control number and expiration date.

Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

35. The Commission is submitting these reporting and recordkeeping requirements to OMB for its review and approval under section 3507(d) of the PRA. Comments are solicited on the Commission's need for this information, whether the information will have practical utility, the accuracy of the provided burden estimate, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing the respondent's burden, including the use of automated information techniques.

36. This Notice of Proposed Rulemaking (NOPR) proposes to approve revisions to Reliability Standards BAL-005, associated with FERC-725R and FAC-001, associated with FERC-725D. These proposed revisions streamline and clarify the current requirements related to the calculation of Reporting ACE—a key frequency control and reliability indicator factor-including consolidating the seventeen requirements of currently-effective BAL-005-0.2b, associated with FERC-725R, into seven requirements in BAL-005–1, relocation of certain requirements related to interconnection requirements for transmission owners and generation owners into FAC-001-3, relocation of Requirement R3 in currently-effective BAL-006-2 into proposed BAL-005-1, and relocation of certain metrics and calculations required for calculating Reporting ACE into the NERC definition of Reporting ACE and its component definitions.

37. NERC's proposed revisions to Reliability Standards BAL-005 and FAC-001will not result in an increase in the record-keeping and reporting requirements imposed on balancing authorities, other than the one-time cost of administering the change to the revised standard. All other recordkeeping and reporting obligations imposed on balancing authorities under the revised requirements essentially track those that already exist under currently-effective Reliability Standards BAL-005-0.2b and FAC-001-2. The proposed revisions to FAC-001-3 will result in a limited increase in the record-keeping and reporting requirements imposed on those transmission owners and generator owners that are not also transmission operators and generator operators (about 198 entities in the United States), as

shown in the chart below.<sup>39</sup> Many of the revisions to the Reliability Standards reflected in this NOPR were developed to help clarify and streamline existing requirements related to calculation of Reporting ACE, and are expected to simplify these entities' overall burden with respect to recordkeeping, reporting, and compliance. Moreover, the NOPR proposes to allow the retirement of the bulk of the requirements in Reliability Standard BAL-006-2, further reducing the overall record-keeping and reporting requirements for balancing authorities. Accordingly, the Commission estimates that the overall change in the recordkeeping and reporting requirements as a result of this rulemaking will be de minimis on a per-entity basis.

38. Public Reporting Burden: The changes reflected in proposed Reliability Standard BAL-005-1 are not expected to result in an increase in the annual record-keeping and reporting requirements on applicable entities (balancing authorities). However, balancing authorities will have to perform a one-time review of the new standard to ensure that their compliance practices (including record-keeping) are consistent with the revised requirements. The relocation of Requirement R1 of Reliability Standard BAL-005-0.2b into Reliability Standard FAC-003-1 will result in an increase in the number of entities subject to the requirement, as the requirement will be applicable to transmission owners and generator owners rather than transmission operators and generator operators. This limited increase in annual record-keeping and reporting burden, along with the one-time burden of administering the change from BAL-005-0.2b to BAL-005-1, is however expected to be offset to some extent by the decrease in record-keeping and reporting burden associated with the retirement of Reliability Standard BAL-006-2 (in considering the overall record-keeping and reporting requirements associated with the revised Reliability Standards).

<sup>&</sup>lt;sup>37</sup> 44 U.S.C. 3501–3520.

<sup>&</sup>lt;sup>38</sup> 5 CFR 1320.11.

<sup>&</sup>lt;sup>39</sup>Proposed Reliability Standard FAC-001-3 replaces and strengthens currently effective Reliability Standard FAC-001-2 by moving currently effective Requirement R1 of Reliability Standard BAL-005-0.2b to proposed Reliability Standard FAC-001-3, requiring that transmission owner and generator owner interconnection requirements include procedures for confirming that new or materially modified facilities connecting to the bulk electric system are within a balancing authority's metered boundaries. NERC explains that these interconnection requirements should be relocated to Reliability Standard FAC-001-3, as FAC-001-3 establishes facility interconnection requirements.

Data collection FERC 725D & 725R (modifications in RM16–13–000)	Number of respondents <sup>40</sup>	Number of responses per respondent	Total number of responses	Average burden hours & cost per response 41	Annual burden hours & total annual cost 42
	(1)	(2)	$(1) \times (2) = (3)$	(4)	$(3) \times (4) = (5)$
BAL-005-1 (FERC-725R) FAC-001-3 R3 (FERC-725D)		1 (one-time)	105 198	1 \$95.35	105 \$10,325
Retirement of current standard BAL-006-02 currently in (FERC-725R).		-1 (annual)	- 105	44 \$63.25 - 1 - \$31.15	\$12,523.50 105 - \$3,270.75
Total					\$19,577.75

Title: FERC–725D, Mandatory Reliability Standards: FAC Reliability Standards; FERC–725R, Mandatory Reliability Standards: BAL Reliability Standards

Action: Proposed Revisions. OMB Control No: 1902–0247 (FERC–725D); 1902–0268 (FERC–725R). Respondents: Business or other for-

profit and not-for-profit institutions. Frequency of Responses: On-going. Necessity of the Information: The Commission has reviewed the requirements of Reliability Standards BAL-005-1 and FAC-001-3 and has made a determination that the requirements of these Reliability Standards are necessary to implement section 215 of the FPA.

Internal Review: The Commission reviewed the proposed Reliability Standards and made a determination that its action is necessary to implement section 215 of the FPA. The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

39. 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: Ellen Brown, Office of the Executive Director, email: DataClearance@ferc.gov, phone: (202) 502–8663, fax: (202) 273–0873].

40. For submitting comments concerning the collection(s) of information and the associated burden estimate(s), please send your comments to the Commission and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–4638, fax: (202) 395–7285]. For security reasons, comments to OMB should be submitted by email to: *oira* submission@omb.eop.gov. Comments submitted to OMB should include FERC-725R and Docket Number RM16-13-000.

#### IV. Environmental Analysis

41. 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.<sup>45</sup> 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.46 The actions proposed here fall within this categorical exclusion in the Commission's regulations.

#### V. Regulatory Flexibility Act Certification

42. The Regulatory Flexibility Act of 1980 (RFA) 47 generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The RFA does not mandate any particular outcome in a rulemaking. It only requires consideration of alternatives that are less burdensome to small entities and an agency explanation of why alternatives were rejected. The Small Business Administration (SBA) revised its size standard effective January 22, 2014 for electric utilities from a standard based on megawatt hours to a standard based on the number of employees, including affiliates. Under SBA's size standards, some balancing authorities, generation owners, and transmission owners will fall under the following category and associated size threshold: Electric bulk power transmission and control, at 500 employees.48

43. Ås noted above, the Commission estimates a very limited, one-time increase in record-keeping and reporting burden on balancing authorities due to the changes in the revised Reliability Standards, with no other increase in the cost of compliance. Approximately 24 of the 105 balancing authorities are expected to meet the SBA's definition for a small entity. In addition, approximately 198 entities will be subject to new record-keeping and reporting requirements under revised Reliability Standard FAC-001-3, with no other increase in the cost of compliance. Approximately 177 of these entities are expected to meet the SBA's definition of a small entity.

44. Even assuming that the one-time cost of compliance for administering the change from Reliability Standard BAL–005–0.2b to BAL–005–1 is an annual

<sup>&</sup>lt;sup>40</sup> The estimated number of respondents is based on the NERC compliance registry as of August 12, 2016. According to the NERC compliance registry, there are 70 U.S. balancing authorities (BA) in the Eastern Interconnection, 34 balancing authorities in the Western Interconnection and one balancing authority in the Electric Reliability Council of Texas (ERCOT).

<sup>&</sup>lt;sup>41</sup> The burden hours and cost are based on the hourly cost for an engineer for BAL–005–1, the average of the hourly cost for an engineer and clerical staff for FAC–001–3, and the hourly cost for clerical staff for changes associated with the retirement of BAL–006–2.

<sup>&</sup>lt;sup>42</sup>For purposes of determining the overall annual cost of the record-keeping and reporting changes reflected in this NOPR, the one-time cost associated with administering the change to BAL–005–1 is being treated as an annual cost.

<sup>&</sup>lt;sup>43</sup> Per the NERC compliance registry, there are 56 generator owners (GO) that are not also generator operators and 142 transmission owners (TO) that are not also transmission operators, for a total of 198 new entities in the United States subject to FAC–001–3 Requirement R3.

<sup>&</sup>lt;sup>44</sup>The project cost per response for recordkeeping and reporting associated with the revisions in FAC–001–3 reflect an average of the hourly cost for an engineer and for clerical staff.

<sup>&</sup>lt;sup>45</sup> Regulations Implementing National Environmental Policy Act of 1969, Order No. 486, FERC Stats. & Regs., ¶ 30,783 (1987).

<sup>46 18</sup> CFR 380.4(a)(2)(ii).

<sup>&</sup>lt;sup>47</sup> 5 U.S.C. 601–612.

<sup>&</sup>lt;sup>48</sup> 13 CFR 121.201, Sector 22 (Utilities), NAICS code 221121 (Electric Bulk Power Transmission and Control)

cost, and assuming that all of the affected entities qualify as small entities, the total annual cost to the industry as a whole is minimal (\$19,577.75), and the average cost per affected entity is \$63.23.

45. According to SBA guidance, the determination of significance of impact "should be seen as relative to the size of the business, the size of the competitor's business, and the impact the regulation has on larger competitors." <sup>49</sup> The Commission does not consider the estimated burden to be a significant economic impact. As a result, the Commission certifies that the reforms proposed in this NOPR would not have a significant economic impact on a substantial number of small entities.

#### VI. Comment Procedures

46. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due November 28, 2016. Comments must refer to Docket No. RM16–13–000, 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 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 5:00 p.m. 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 the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

By direction of the Commission. Issued: September 22, 2016.

#### Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016-23442 Filed 9-27-16; 8:45 am]

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# DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

# 21 CFR Part 101

[Docket No. FDA-2016-D-2335]

Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive information and comments on the use of the term "healthy" in the labeling of human food products. This action is consistent with our recently released 2016–2025 Foods and Veterinary Medicine (FVM) Program's strategic plan with specific goals for nutrition and other planned and recent activity including the issuance of final rules updating certain of our nutrition labeling regulations. In addition, we received a citizen petition asking that we update, among other things, our nutrient content claim regulations to be consistent with current federal dietary guidance. In particular, the petitioners request that FDA amend the regulation defining the nutrient content claim "healthy" with respect to total fat intake and amend the regulation to emphasize whole foods and dietary patterns rather than specific nutrients. We invite public comment on the term "healthy", generally, and as a nutrient content claim in the context of food labeling and on specific questions contained in this document.

**DATES:** Submit either electronic or written comments by January 26, 2017. **ADDRESSES:** You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http:// www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

# Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted,

<sup>&</sup>lt;sup>49</sup>U.S. Small Business Administration, A Guide for Government Agencies: How to comply with the Regulatory Flexibility Act, at 18 (May 2012), https:// www.sba.gov/sites/default/files/advocacy/rfaguide\_ 0512\_0.pdf.