

(k) Material Incorporated by Reference

None.

Issued on June 2, 2023.

Michael Linegang,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

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DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****15 CFR Part 400**

[Docket No. 230131-0033]

RIN 0625-AB22

Foreign-Trade Zones Board Proceedings

AGENCY: Foreign-Trade Zones Board, International Trade Administration, Commerce.

ACTION: Proposed rule and request for comments.

SUMMARY: The Foreign-Trade Zones Board (the Board) proposes to amend its regulations and invites public comment on these proposed revisions. These modifications, if adopted, would allow for additional electronic fee payment options and make other minor clarifications and corrections to the regulatory language. Sections of the Board's 2012 regulations regarding application formats contained information collection requirements and could not be effective until the Office of Management and Budget (OMB) approved the information collection requests, which occurred on March 25, 2013.

DATES: To be assured of consideration, written comments must be received no later than July 10, 2023.

ADDRESSES: All comments must be submitted through the Federal eRulemaking Portal at <https://www.regulations.gov>, Docket No. ITA-230131-0033, unless the commenter does not have access to the internet. Commenters that do not have access to the internet may submit the original and one electronic copy of each set of comments by mail or hand delivery/courier. All comments should be addressed to: Executive Secretary, Foreign-Trade Zones Board, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 21013, Washington, DC 20230. Comments submitted to the Board will be uploaded to the eRulemaking Portal at www.Regulations.gov.

The Board will consider all comments received before the close of the comment period. All comments responding to this document will be a matter of public record and will be available on the Federal eRulemaking Portal at www.Regulations.gov. The Board will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason.

Any questions concerning the process for submitting comments should be submitted to Enforcement & Compliance (E&C) Communications office at (202) 482-0063 or ECCcommunications@trade.gov.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Whiteman at Elizabeth.Whiteman@trade.gov, (202) 482-0473, or Ashlande Gelin at Ashlande.Gelin@trade.gov, (240) 449-5911.

SUPPLEMENTARY INFORMATION:**Background**

Foreign-Trade Zones (FTZs or zones) are restricted-access sites in or near U.S. Customs and Border Protection (CBP) ports of entry. Zones are licensed by the Board and operated under the supervision of CBP (see 19 CFR part 146). Specifically, zones are physical areas into which foreign and domestic merchandise may be moved for operations involving storage, exhibition, assembly, manufacture or other processing not otherwise prohibited by law. Zone areas "activated" by CBP are considered outside of U.S. customs territory for purposes of CBP entry procedures. Therefore, the usual formal CBP entry procedure and payment of duties is not required on the foreign merchandise in FTZs unless and until it enters U.S. customs territory for U.S. domestic consumption. In fact, U.S. duties can be avoided on foreign merchandise re-exported from a FTZ, including after incorporation into a downstream product through activity in the FTZ. Zones have as their public policy objective the creation and maintenance of employment through the encouragement of operations in the United States which, for customs reasons, might otherwise have been carried on abroad.

Through this proposed action, the Board intends to update the rules for FTZs. The key revision in the proposed regulations pertains to providing flexibility on the method to submit application fees. The current regulations require that application fees be submitted by check. While the Board

has begun accepting "eChecks", the revisions proposed here would allow for the submission of additional forms of electronic payment.

This proposed action will move the existing requirement to admit merchandise subject to AD/CVD actions in "Privileged foreign" status to the "General conditions, prohibitions and restrictions applicable to authorized zones" section. This move of the existing language is intended to clarify that the provision applies to all merchandise that is admitted to FTZs.

Other revisions in this proposed rulemaking will update the language used to provide clarification and to reflect current practices.

On February 28, 2012, a final rule was published revising the regulations of the Foreign-Trade Zones Board (77 FR 12112). That rule was published with an effective date of April 30, 2012, except for §§ 400.21 through 400.23, 400.25 and 400.43(f). These sections contained information collection requirements and could not become effective until the Office of Management and Budget (OMB) approved these information collection requests pursuant to the Paperwork Reduction Act (44 U.S.C. Chapter 35). On March 25, 2013, OMB approved the information collections under control number 0625-0139, and the FTZ Board then began to use the new applications under §§ 400.21 through 400.23, 400.25 and 400.43(f).

Expected Impact of the Proposed Rule

The proposed edits will allow for additional flexibility on the submission of application fees and otherwise clarify existing language and practices. The proposed edits are not expected to impact the number of requests submitted to the FTZ Board or the operation and management of existing zones.

Classifications*Executive Order 12866*

The Office of Management and Budget (OMB) has determined that this proposed rule is not significant for purposes of Executive Order 12866.

Paperwork Reduction Act

This proposed rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. chapter 35.

Executive Order 13132

This proposed rule does not contain policies with federalism implications as that term is defined in section 1(a) of Executive Order 13132, dated August 4, 1999 (64 FR 43255 (August 10, 1999)).

Regulatory Flexibility Act

The Chief Counsel for Regulation proposes to certify to the Chief Counsel for Advocacy of the Small Business Administration under the provisions of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), that the proposed rule would not have a significant economic impact on a substantial number of small business entities. A summary of the need for, objectives of and legal basis for this rule is provided in the preamble and is not repeated here.

The types of small entities using the FTZ program include miscellaneous manufacturing and ocean freight companies. Under the Small Business Administration Regulations implementing the RFA, these types of businesses are considered small entities when they have fewer than 500 employees. Using this criterion, of the approximately 1000 business entities operating in zones and impacted by this proposed rule, approximately 350 are likely considered small entities under the RFA. The edits proposed will not have a significant economic impact on any such entities.

The proposed action includes minor edits to existing regulations and does not create additional burden on any parties. Therefore, the proposed rule would not have a significant economic impact on a substantial number of small business entities. For this reason, an Initial Regulatory Flexibility Analysis is not required, and one has not been prepared.

List of Subjects in 15 CFR Part 400

Administrative practice and procedure, Confidential business information, Customs duties and inspection, Foreign-trade zones, Harbors, Imports, Reporting and recordkeeping requirements.

Dated: June 1, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

For the reasons stated, the Board proposes to amend 15 CFR part 400 as follows:

PART 400—REGULATIONS OF THE FOREIGN-TRADE ZONES BOARD

- 1. The authority citation for part 400 continues to read as follows:

Authority: Foreign-Trade Zones Act of June 18, 1934, as amended (Pub. L. 73-397, 48 Stat. 998-1003 (19 U.S.C. 81a-81u)).

- 2. In § 400.2:
a. Revise paragraphs (h) and (t);
b. Remove paragraph (u); and

- c. Redesignate paragraphs (v) through (aa) as paragraphs (u) through (z).

The revisions read as follows:

§ 400.2 Definitions.

(h) Foreign-trade zone (FTZ or zone) includes all sites/subzones designated under the sponsorship of a zone grantee, in or adjacent (as defined by § 400.11(b)(2)) to a CBP port of entry, operated as a public utility (within the meaning of § 400.42), with zone operations under the supervision of CBP.

(t) Usage-driven site means a site established for a single operator or user under the ASF.

- 3. In § 400.4, revise paragraphs (m) and (t) to read as follows:

§ 400.4 Authority and responsibilities of the Executive Secretary.

(m) Issue instructions, guidelines, forms and related documents specifying time, place, manner and formats for applications, notifications, application fees and zone schedules in various sections of this part, including §§ 400.21(b), 400.29, 400.43(f), and 400.44;

(t) Review zone schedules and determine their sufficiency under § 400.44(c);

- 4. In § 400.11, revise paragraph (b)(2)(i) to read as follows:

§ 400.11 Number and location of zones and subzones.

- (b) (2) * * *

(i) A zone site is located within 60 statute miles or 90 minutes' driving time (as determined or concurred upon by CBP) from the outer limits of a port of entry boundary as defined in 19 CFR 101.3.

- 5. In § 400.13:
a. Revise paragraph (a)(8);
b. Redesignate paragraph (c) as paragraph (d); and
c. Add a new paragraph (c).

The revision and addition read as follows:

§ 400.13 General conditions, prohibitions and restrictions applicable to authorized zones.

- (a) * * *
(8) Private ownership of zone land and facilities is permitted, provided the zone grantee retains the control

necessary to implement the approved zone. Such permission shall not constitute a vested right to zone designation, nor interfere with the Board's regulation of the grantee or the permittee, nor interfere with or complicate the revocation of the grant by the Board. Grantees shall retain a level of control which allows the grantee to carry out its responsibilities as grantee. The sale of zone-designated land/facility for more than its fair market value without zone designation could, depending on the circumstances, be subject to the prohibitions set forth in section 17 of the Act (19 U.S.C. 81q).

(c) Restrictions on items subject to antidumping and countervailing duty actions—(1) Board policy. Zone procedures shall not be used to circumvent antidumping duty (AD) and countervailing duty (CVD) actions under 19 CFR part 351.

(2) Admission of items subject to AD/CVD orders, or items which would be otherwise subject to suspension of liquidation under AD/CVD procedures if they entered U.S. customs territory, shall be placed in privileged foreign status (19 CFR 146.41) upon admission to a zone or subzone. Upon entry for consumption, such items shall be subject to duties under AD/CVD orders or to suspension of liquidation, as appropriate, under 19 CFR part 351.

- 6. In § 400.14:
a. Revise the section heading and paragraph (a); and
b. Remove paragraph (e).

The revisions read as follows:

§ 400.14 Production—requirement for prior authorization.

(a) In general. Production activity in zones shall not be conducted without prior authorization from the Board. To obtain authorization, the notification process provided for in §§ 400.22 and 400.37 shall be used. If Board review of a notification under § 400.37 results in a determination that further review is warranted for all or part of the notified activity, the application process pursuant to §§ 400.23, 400.31 through 400.32, 400.34, and 400.36 shall apply to the activity. Notifications and applications requesting production authority may be submitted by the zone's grantee or by the operator that proposes to undertake the activity (provided the operator at the same time furnishes a copy of the notification or application to the grantee and that submissions by the operator are

consistent with the grantee’s zone schedule).

* * * * *

■ 7. Revise § 400.16 to read as follows:

§ 400.16 Exemption from state and local ad valorem taxation of tangible personal property.

Tangible personal property imported from outside the United States and held in foreign status in the activated area of a zone for the purpose of storage, sale, exhibition, repackaging, assembly, distribution, sorting, grading, cleaning, mixing, display, manufacturing, or processing, and tangible personal property produced in the United States and held in the activated area of a zone for exportation, either in its original form or as altered by any of the processes set out in this section, shall be exempt from state and local ad valorem taxation.

■ 8. In § 400.21:

- a. Revise paragraphs (a) and (c)(1);
- b. In paragraph (c)(5), add the word “and” following the semicolon;
- c. Remove paragraph (c)(6);
- d. Redesignate paragraph (c)(7) as paragraph (c)(6);
- e. Remove paragraph (d)(2)(vi);
- f. Redesignate paragraphs (d)(2)(vii) and (ix) as paragraphs (d)(2)(vi) through (viii);
- g. Revise paragraphs (e)(3), (h), and (i); and
- h. Remove paragraph (j).

The revisions read as follows:

§ 400.21 Application to establish a zone.

(a) *In general.* An application for a grant of authority to establish a zone (including pursuant to the ASF procedures adopted by the Board (§ 400.2(c)) shall consist of an application letter and detailed contents to meet the requirements of this part.

* * * * *

(c) * * *

(1) The relationship of the proposal to the state enabling legislation and the applicant’s charter;

* * * * *

(e) * * *

(3) Appropriate information regarding usage-driven sites or ASF subzones.

* * * * *

(h) *Drafts.* Applicants are encouraged to submit a draft application to the Executive Secretary for review. A draft application must be complete with the possible exception of the application letter and/or resolution from the applicant.

(i) *Submission of completed application.* The applicant shall submit the complete application, including all attachments, via email or by the method

prescribed by the Executive Secretary pursuant to § 400.4(m).

■ 9. In § 400.24, revise paragraphs (a)(1), (c), and (d) to read as follows:

§ 400.24 Application for expansion or other modification to zone.

(a) * * *

(1) A grantee may apply to the Board for authority to expand or otherwise modify its zone (including pursuant to the ASF procedures adopted by the Board (§ 400.2(c)).

* * * * *

(c) *Minor modification to zone.* Other applications or requests under this subpart shall be submitted in letter form with information and documentation necessary for analysis, as determined by the Executive Secretary, who shall determine whether the proposed change is a minor one subject to this paragraph (c) instead of paragraph (b) of this section (see, § 400.38). Such applications or requests include those for minor revisions of zone or subzone boundaries based on immediate need, as well as for designation as a subzone of all or part of an existing zone site(s) (or site(s) that qualifies for usage-driven status), where warranted by the circumstances and so long as the subzone remains subject to the activation limit (see § 400.2(b)) for the zone in question.

(d) *Applications for other revisions to authority.* Applications or requests for other revisions to authority, such as for Board action to establish or modify an activation limit for a zone, modification of a restriction, reissuance of a grant of authority or request for a voluntary termination shall be submitted in letter form with information and documentation necessary for analysis, as determined by the Executive Secretary. If the change involves the removal or significant modification of a restriction included by the Board in its approval of authority or the reissuance of a grant of authority, the review procedures of §§ 400.31 through 400.34 and 400.36 shall be followed, where relevant. If not, the procedure set forth in § 400.38 shall generally apply (although the Executive Secretary may elect to follow the procedures of §§ 400.31 through 400.34 and 400.36 when warranted).

■ 10. In § 400.26:

- a. Revise the section heading;
- b. In paragraph (d), add the word “and” following the semicolon;
- c. In paragraph (e), remove “; and” and add a period in its place; and
- d. Remove paragraph (f).

The revision reads as follows:

§ 400.26 Criteria for evaluation of proposals, including for zones, expansions, subzones, or other modifications of zones.

* * * * *

■ 11. In § 400.27, revise the introductory text to read as follows:

§ 400.27 Criteria applicable to evaluation of applications for production authority.

The Board shall apply the criteria set forth in this section in determining whether to approve an application for authority to conduct production activity pursuant to § 400.23. The Board’s evaluation shall take into account information such as pertains to market conditions, price sensitivity, degree and nature of foreign competition, intra-industry and intra-firm trade, effect on exports and imports, ability to conduct the proposed activity outside the United States with the same U.S. tariff impact, analyses conducted in connection with prior Board actions, and net effect on U.S. employment and the U.S. economy:

* * * * *

■ 12. In § 400.29:

- a. Revise paragraphs (b) and (c); and
- b. Remove paragraph (d).

The revisions read as follows:

§ 400.29 Application fees.

* * * * *

(b) *Uniform system of user fee charges.* The following fee schedule establishes fees for certain types of applications and requests for authority on the basis of their estimated average processing time.

(1) Additional zones (§ 400.21; § 400.11(a)(2))—\$3,200.

(2) Subzones (§ 400.25):

(i) Not involving production activity or involving production activity with fewer than three products—\$4,000.

(ii) Production activity with three or more products—\$6,500.

(3) Expansions (§ 400.24(b))—\$1,600.

(c) *Timing and manner of payment.*

Application fees shall be paid prior to the FTZ Board docketing an application and in a manner specified by the Executive Secretary.

■ 13. In § 400.31, revise paragraph (b) to read as follows:

§ 400.31 General application provisions and pre-docketing review.

* * * * *

(b) *Pre-docketing review.* The applicant shall submit a complete copy of an application for pre-docketing review. The Executive Secretary shall determine whether the application satisfies the requirements of §§ 400.12, 400.21, and 400.23 through 400.25 and other applicable provisions of this part such that the application is sufficient for docketing. The applicant shall be

notified within 30 days whether the pre-docketing copy of the application is sufficient. If the application is not sufficient, the applicant will be notified of the specific deficiencies. An affected zone participant may also be contacted regarding relevant application elements requiring additional information or clarification. If the applicant does not correct the deficiencies and submit a corrected pre-docketing application copy within 30 days of notification, the pre-docketing application shall be discarded. For applications subject to § 400.29, the fees shall be paid in accordance with § 400.29 once the application is determined to be sufficient.

■ 14. Revise § 400.32 to read as follows:

§ 400.32 Procedures for docketing applications and commencement of case review.

(a) Once the pre-docketing copy of the application is determined to be sufficient and any fees under § 400.29 have been paid, the Executive Secretary shall within 15 days:

- (1) Formally docket the application, thereby initiating the proceeding or review;
- (2) Assign a case-docket number; and
- (3) Notify the applicant of the formal docketing action.

(b) After initiating a proceeding based on an application under §§ 400.21 and 400.23 through 400.25, the Executive Secretary shall:

(1) Designate an examiner to conduct a review and prepare a report or memorandum with recommendations for the Board;

(2) Publish in the **Federal Register** a notice of the formal docketing of the application and initiation of the review. The notice shall include the name of the applicant, a description of the proposal, and an invitation for public comment. If the application requests authority for production activity and indicates that a component to be used in the activity is subject to a trade-related measure or proceeding (e.g., AD/CVD order or proceeding, suspension of liquidation under AD/CVD procedures), the notice shall include that information. For applications to establish or expand a zone or for production authority, the comment period shall normally close 60 days after the date the notice appears. For applications for subzone designation, the comment period shall normally close 40 days after the date the notice appears. However, if a hearing is held (see § 400.52), the comment period shall not close prior to 15 days after the date of the hearing. The closing date for general comments shall ordinarily be followed by an additional 15-day period

for rebuttal comments. Requests for extensions of a comment period will be considered, subject to the standards of § 400.28(c). Submissions must meet the requirements of § 400.28(b). With the exception of submissions by the applicant, any new evidence or new factual information and any written arguments submitted after the deadlines for comments shall not be considered by the examiner or the Board. Submission by the applicant of new evidence or new factual information may result in the (re)opening of a comment period. A comment period may otherwise be opened or reopened for cause;

(3) Transmit or otherwise make available copies of the docketing notice and the application to CBP;

(4) Arrange for hearings, as appropriate;

(5) Transmit the report and recommendations of the examiner and any comments by CBP to the Board for appropriate action; and

(6) Notify the applicant in writing (via electronic means, where appropriate) and publish notice in the **Federal Register** of the Board's determination.

(c) Any comments by CBP pertaining to the application shall be submitted to the Executive Secretary by the conclusion of the public comment period described in paragraph (b)(2) of this section.

■ 15. In § 400.33, revise paragraph (e)(3) to read as follows:

§ 400.33 Examiner's review—application to establish or modify a zone.

* * * * *

(e) * * *

(3) If the factors considered for an examiner's recommendation(s) change as a result of new evidence, the applicable procedures of paragraphs (e)(1) and (2) of this section shall be followed.

* * * * *

■ 16. In § 400.34, revise paragraph (a)(5)(iv)(C) to read as follows:

§ 400.34 Examiner's review—application for production authority.

(a) * * *

(5) * * *

(iv) * * *

(C) If the factors considered for an examiner's recommendation(s) change as a result of new evidence, the applicable procedures of paragraphs (a)(5)(iv)(A) and (B) of this section shall be followed.

* * * * *

■ 17. In § 400.35, revise paragraph (c) to read as follows:

§ 400.35 Examiner's review—application for subzone designation.

* * * * *

(c) If the factors considered for an examiner's recommendation(s) change as a result of new evidence, the applicable procedures of paragraphs (a) and (b) of this section shall be followed.

* * * * *

■ 18. In § 400.36:

■ a. Revise paragraphs (b) and (e); and

■ b. Remove the paragraph heading from paragraph (f).

The revisions read as follows:

§ 400.36 Completion of case review.

* * * * *

(b) In its advisory role to the Board, CBP headquarters staff shall provide any comments within 15 days for applications under § 400.25 and within 30 days for all other applications.

* * * * *

(e) If the Board is unable to reach a unanimous decision, the applicant shall be notified and provided an opportunity to meet with the Board members or their delegates.

* * * * *

■ 19. In § 400.37, revise paragraph (a) to read as follows:

§ 400.37 Procedure for notification of proposed production activity.

(a) *Submission of notification.* A notification for production authority pursuant to §§ 400.14(a) and 400.22 shall be submitted simultaneously to the Board's Executive Secretary and to CBP.

* * * * *

■ 20. Revise § 400.38 to read as follows:

§ 400.38 Procedure for request for minor modification of zone.

(a) The Executive Secretary shall make a determination in cases under § 400.24(c) involving minor modifications of zones that do not require Board action, such as boundary modifications, including certain relocations, and shall notify the requestor in writing of the decision on the request within 30 days of the Executive Secretary's receipt of the complete request and the CBP comments under paragraph (b) of this section. Depending on the specific request, the decision could be that the request cannot be processed under § 400.24(c). The requestor shall submit a copy of its request to CBP no later than the time of the requestor's submission of the request to the Executive Secretary.

(b) If not previously provided to the requestor for inclusion with the requestor's submission of the request to the Executive Secretary, any CBP comments on the request shall be provided to the Executive Secretary within 20 days of the requestor's submission of the request to the Executive Secretary.

§ 400.42 [Amended]

■ 21. In § 400.42, remove and reserve paragraph (b).

§ 400.43 [Amended]

■ 22. In § 400.43, remove paragraph (i).

■ 23. In § 400.44:

■ a. Revise paragraphs (a), (b)(5), and (e); and

■ b. Remove paragraph (f).

The revisions read as follows:

§ 400.44 Zone schedule.

(a) The zone grantee shall submit to the Executive Secretary (electronic copy or as specified by the Executive Secretary) a zone schedule which sets forth the elements required in this section. No element of a zone schedule (including any amendment to the zone schedule) may be considered to be in effect until such submission has occurred. If warranted, the Board may subsequently amend the requirements of this section by Board Order.

(b) * * *

(5) Information identifying any operator which offers services to the public and which has requested that its information be included in the zone schedule; and

* * * * *

(e) A complete copy of the zone schedule shall be freely available for public inspection at the offices of the zone grantee. The Board shall make copies of zone schedules available on its website.

■ 24. In § 400.45, revise paragraph (b) to read as follows:

§ 400.45 Complaints related to public utility and uniform treatment.

* * * * *

(b) *Objections to rates and charges.* A zone participant showing good cause may object to any rate or charge related to the zone on the basis that it is not fair and reasonable by submitting to the Executive Secretary a complaint in writing with supporting information. If necessary, such a complaint may be made on a confidential basis pursuant to paragraph (a) of this section. The Executive Secretary shall review the complaint and issue a report and decision, which shall be final unless appealed to the Board within 30 days. The Board or the Executive Secretary may otherwise initiate a review for cause. The primary factor considered in reviewing fairness and reasonableness is the cost of the specific services rendered. Where those costs incorporate charges to the grantee by one or more parties undertaking functions on behalf of the grantee, the Board may consider the costs incurred by those parties or evidence regarding market rates for the

undertaking of those functions. The Board may rely on best estimates, as necessary. The Board will also give consideration to any extra costs incurred relative to non-zone operations, including return on investment and reasonable out-of-pocket expenses.

■ 25. In § 400.52, revise paragraph (b)(2) to read as follows:

§ 400.52 Notices and hearings.

* * * * *

(b) * * *

(2) The request must be made within 30 days of the beginning of the initial period for public comment (see § 400.32) and must be accompanied by information establishing the need for the hearing and the basis for the requesting party's interest in the matter.

* * * * *

■ 26. In § 400.61, revise paragraphs (a) and (c) to read as follows:

§ 400.61 Revocation of authority.

(a) *In general.* As provided in this section, the Board can revoke in whole or in part authority for a zone (see § 400.2(h)) whenever it determines that the zone grantee has violated, repeatedly and willfully, the provisions of the Act.

* * * * *

(c) *Appeals.* As provided in section 18 of the Act (19 U.S.C. 81r(c)), the grantee of the zone in question may appeal an order of the Board revoking authority.

[FR Doc. 2023-12123 Filed 6-8-23; 8:45 am]

BILLING CODE 3510-DS-P

FEDERAL TRADE COMMISSION**16 CFR Part 318****Health Breach Notification Rule**

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: The Federal Trade Commission (“FTC” or “Commission”) proposes to amend the Commission’s Health Breach Notification Rule (the “HBN Rule” or the “Rule”) and requests public comment on the proposed changes. The HBN Rule requires vendors of personal health records (“PHRs”) and related entities that are not covered by the Health Insurance Portability and Accountability Act (“HIPAA”) to notify individuals, the FTC, and, in some cases, the media of a breach of unsecured personally identifiable health data.

DATES: Written comments must be received on or before August 8, 2023.

ADDRESSES: Interested parties may file a comment online or on paper by following the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Health Breach Notification Rule, Project No. P205405” on your comment and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex H), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT:

Ryan Mehm (202) 326-2918, Elisa Jillson, (202) 326-3001, Ronnie Solomon, (202) 326-2098, Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The amendments would: (1) clarify the Rule’s scope, including its coverage of developers of many health applications (“apps”); (2) amend the definition of breach of security to clarify that a breach of security includes data security breaches and unauthorized disclosures; (3) revise the definition of PHR related entity; (4) clarify what it means for a vendor of personal health records to draw PHR identifiable health information from multiple sources; (5) modernize the method of notice; (6) expand the content of the notice; and (7) improve the Rule’s readability by clarifying cross-references and adding statutory citations, consolidating notice and timing requirements, and articulating the penalties for non-compliance.

I. Background

Congress enacted the American Recovery and Reinvestment Act of 2009 (“Recovery Act” or “the Act”),¹ in part, to advance the use of health information technology and, at the same time, strengthen privacy and security protections for health information. Recognizing that certain entities that hold or interact with consumers’ personal health records were not subject to the privacy and security requirements of HIPAA,² Congress created requirements for such entities to notify individuals, the Commission, and, in some cases, the media of the breach of

¹ American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115 (2009).

² Health Insurance Portability and Accountability Act, Public Law 104-191, 110 Stat. 1936 (1996).