(i) 2. Referenced Documents.

(ii) 2.1 ASTM Standards.[12] (A) F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;

(B) F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs;

(C) F2194 Consumer Safety Specification for Bassinets and Cradles;

(D) F2906 Standard Consumer Safety Specification for Bedside Sleepers.

(iii) 2.2 Federal Standards.[13]

(A) 16 CFR part 1218—Safety Standard for Bassinets and Cradles;

(B) 16 CFR part 1219—Safety Standard for Full-Size Baby Cribs;

(C) 16 CFR part 1220—Safety Standard for Non-Full-Size Baby Cribs;

(D) 16 CFR part 1221—Safety Standard for Play Yards; and

(E) 16 CFR part 1222—Safety Standard for Bedside Sleepers.

(7) Do not comply with sections 2.3 and 2.4 of ASTM F3118–17a, including Figures 1 and 2.

(8) In section 3.1.1 of ASTM F3118–17a, replace the following terms:

(i) Replace the term ''accessory inclined sleep product'' with ''accessory infant sleep product.''

(ii) Replace the term ''inclined sleep product'' with ''infant sleep product.''

(9) In section 3.1.2 of ASTM F3118–17a, replace the following terms:

(i) Replace the term ''compact inclined sleep product'' with ''compact infant sleep product.''

(ii) Replace the term ''newborn inclined sleep product'' with ''newborn infant sleep product.''

(10) Do not comply with sections 3.1.3 through 3.1.6 of ASTM F3118–17a.

(11) Instead of complying with section 3.1.7 of ASTM F3118–17a, comply with the following:

(i) 3.1.7 *infant sleep product, n*—a freestanding product, intended to provide a sleeping accommodation for an infant up to approximately 5 months of age, that is generally supported by a stationary or rocker base and that is not subject to any of the following standards:

(A) 16 CFR part 1218—Safety Standard for Bassinets and Cradles;

(B) 16 CFR part 1219—Safety Standard for Full-Size Baby Cribs;

(C) 16 CFR parts 1220 and 1221—Safety Standard for Non-Full-Size Baby Cribs and Play Yards; and

(D) 16 CFR part 1222—Safety Standard for Bedside Sleepers.

(ii) [Reserved].

(12) Do not comply with sections 3.1.7.1 through 3.1.9 of ASTM F3118–17a.

(13) Instead of complying with section 3.1.10 of ASTM F3118–17a, comply with the following:

(i) 3.1.10 *newborn sleep product, n*—a free standing product, intended to provide sleeping accommodations for a newborn up to approximately 3 months of age, that is supported by a stationary or rocker base and whose seat back length, measured from the bight, is not greater than 17 in. (432 mm) and that is not subject to any of the following standards:

(A) 16 CFR part 1218—Safety Standard for Bassinets and Cradles;

(B) 16 CFR part 1219—Safety Standard for Full-Size Baby Cribs;

(C) 16 CFR parts 1220 and 1221—Safety Standard for Non-Full-Size Baby Cribs and Play Yards; and

(D) 16 CFR part 1222—Safety Standard for Bedside Sleepers.

(ii) [Reserved].

(14) Do not comply with sections 3.1.11 through 3.1.13 of ASTM F3118–17a.

(15) Do not comply with section 5 of ASTM F3118–17a.

(16) Do not comply with sections 6.1 through 6.8 of ASTM F3118–17a.

(17) Instead of complying with section 6.9 of ASTM F3118–17a, comply with the following:

(i) *6.9 Maximum Seat Back Angle.*

(ii) *6.9.1 Accessory, Compact, and Infant Sleep Product*—The angle of the seat back surface intended for sleep along the occupant's head to toe axis relative to the horizontal shall not exceed 10° when tested in accordance with 7.11.2.

(iii) *6.9.2 Accessory, Compact, and Newborn Sleep Product*—The angle of the seat back surface intended for sleep along the occupant's head to toe axis relative to the horizontal shall not exceed 10° when tested in accordance with 7.11.3.

(iv) 6.9.3 *Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products*—shall meet requirements of 16 CFR part 1218 Safety Standard for Bassinets and Cradles.

(18) Do not comply with sections 6.10 through 7.10 of ASTM F3118–17a.

(19) In section 7.11.2.1 of ASTM F3118–17a, replace ''*Infant Inclined Sleep Product and Infant Inclined Sleep Product Accessory*'' with ''*Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products.*''

(20) In section 7.11.2.1 of ASTM F3118–17a, replace ''If applicable, place the product in the manufacturer's recommended highest incline angle position.'' with ''If applicable, place the product in the manufacturer's recommended highest seat back angle position intended for sleep.''

(21) In section 7.11.3 of ASTM F3118–17a, replace ''*Newborn Inclined Sleep Product and Newborn Inclined Sleep Product Accessory*'' with ''*Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products.*''

(22) Do not comply with sections 7.12 through 9, or the Appendix, of ASTM F3118–17a.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2019–23724 Filed 11–8–19; 8:45 am]

BILLING CODE 6355–01–P

[12] For referenced ASTM standard, visit the ASTM website, *www.astm.org,* or contact ASTM Customer Service at *service@astm.org.* For Annual Book of ASTM Standards volume information, refer to the standard's Document Summary page on the ASTM website.

[13] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St. NW, Mail Stop: SDE, Washington, DC 20401, *http://www.access.gpo.gov.*

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 160

RIN 3038–AE91

Privacy of Consumer Financial Information

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is proposing to make a correction to one of the Commission's regulations to restore text that was inadvertently deleted in a 2011 amendment to that regulation.

DATES: Comments must be received on or before December 12, 2019.

ADDRESSES: You may submit comments, identified by RIN 3038–AE91, by any of the following methods:

- *CFTC Comments Portal: https://comments.cftc.gov.* Select the ''Submit Comments'' link for this rulemaking and follow the instructions on the Public Comment Form.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Follow the same instructions as for Mail, above.

Please submit your comments using only one of these methods. Submissions through the CFTC Comments Portal are encouraged.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be

posted as received to *https://comments.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act (''FOIA''), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://comments.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Joshua Sterling, Director, (202) 418–6056, *jsterling@cftc.gov;* Frank Fisanich, Chief Counsel, (202) 418–5949, *ffisanich@cftc.gov;* or Jacob Chachkin, Special Counsel, (202) 418–5496, *jchachkin@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

Section 501 of Title V of the Gramm-Leach-Bliley Act (''Title V'') mandates that certain agencies covered by Title V establish appropriate safeguards for the financial institutions subject to their jurisdiction relating to administrative, technical and physical safeguards—(1) to insure the security and confidentiality of customer records and information; (2) to protect against any anticipated threats or hazards to the security or integrity of such records; and (3) to protect against unauthorized access to or use of such records or information which could result in substantial harm or inconvenience to any customer.[2] The Commission and entities subject to its jurisdiction were originally excluded from Title V's coverage.[3] However, section 124 of the Commodity Futures Modernization Act of 2000[4] amended the Commodity Exchange Act (''CEA'') to add section 5g,[5] providing that futures commission merchants (''FCMs''), commodity trading advisors (''CTAs''), commodity pool operators (''CPOs''), and introducing brokers (''IBs'')[6] fall under the requirements of Title V and requiring the Commission to prescribe regulations in furtherance of Title V. Thus, in 2001, the Commission promulgated part 160 of its regulations to establish standards relating to Title V, and, specifically, § 160.30 in relation to section 501's mandate.[7]

Commission regulation 160.30 implements this mandate by requiring every FCM, RFED, CTA, CPO, IB, MSP, or SD that is subject to the jurisdiction of the Commission (''Covered Persons'')[8] to adopt policies and procedures to address administrative, technical and physical safeguards for the protection of customer records and information (the ''General Requirement'').[9] In addition, mirroring section 501 of the GLB Act, the 2001 Rulemaking further required (the ''Detailed Requirements'') that the policies and procedures be reasonably designed to: (i) Insure the security and confidentiality of customer records and information; (ii) protect against any anticipated threats or hazards to the security or integrity of customer records and information; and (iii) protect against unauthorized access to or use of customer records or information that could result in substantial harm or inconvenience to any customer.[10] However, when the 2011 Amendment revised § 160.30 to add SDs and MSPs to the list of entities in § 160.30's introductory sentence (and, thus, subject to it), the Detailed Requirements were inadvertently deleted.[11]

II. Proposal

The Commission is now proposing (the ''Proposal'') to restore the inadvertently deleted Detailed Requirements in § 160.30 as shown in the proposed amended rule text in this release. As discussed above, the Detailed Requirements mirror the requirements of section 501 of the GLB Act, pursuant to which part 160 of the Commission's regulations was adopted.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act[12] (''RFA'') requires federal agencies to consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, to provide a regulatory flexibility analysis regarding the economic impact on those entities. The Proposal would restore the inadvertently deleted Detailed Requirements in § 160.30. To the extent that the Proposal would impact Covered Persons that may be small entities for purposes of the RFA,[13] the Commission considered whether the Proposal would have a significant economic impact on such Covered Persons.

In restoring the inadvertently deleted Detailed Requirements the Proposal would simply set forth, consistent with

[1] 17 CFR 145.9. Commission regulations referred to herein are found at 17 CFR chapter I.

[2] Section 501, Subtitle A, Title V, Public Law 106–102, 113 Stat. 1338 (1999), as codified at 15 U.S.C. 6801.

[3] 15 U.S.C. 6809(3)(B).

[4] Section 124, Appendix E of Public Law 106–554, 114 Stat. 2763 (2000).

[5] 7 U.S.C. 7b–2.

[6] For the definitions of these intermediary categories, *see* section 1a of the CEA and § 1.3 of the Commission's regulations. 7 U.S.C. 1a and 17 CFR 1.3.

[7] Privacy of Customer Information, 66 FR 21235 (April 27, 2001) (''2001 Rulemaking''). The Commission later modified its part 160 regulations to apply them to retail foreign exchange dealers (''RFEDs''), swap dealers (''SDs''), and major swap participants (''MSPs''). Regulation of Off-Exchange Retail Foreign Exchange Transactions and Intermediaries, 75 FR 55409 (Sept. 10, 2010) for RFEDs, and Privacy of Consumer Financial Information; Conforming Amendments Under Dodd-Frank Act, 76 FR 43874 (July 22, 2011) for SDs and MSPs (''2011 Amendment''). For the definition of RFED, *see* § 5.1(h). 17 CFR 5.1(h). For the definitions of SD and MSP, *see* section 1a of the CEA and § 1.3 of the Commission's regulations. 7 U.S.C. 1a and 17 CFR 1.3.

[8] 17 CFR 160.30. Part 160 does not apply to foreign (non-resident) FCMs, RFEDs, CTAs, CPOs, IBs, MSPs, and SDs that are not registered with the Commission. 17 CFR 160.1. Therefore, they are not ''Covered Persons'' as defined in this release.

[9] 17 CFR 160.30.

[10] *See* 2001 Rulemaking at 21250.

[11] *See* 2011 Amendment at 43879. With respect to § 160.30, the preamble to the 2011 Amendment only discusses amending the introductory sentence of § 160.30 to add SDs and MSPs to the list of CFTC registrants that must comply with that regulation. *See id.* at 43876. Further, the Commission notes that the Detailed Requirements continued to be included in Commission staff guidance on compliance with § 160.30 after the 2011 Amendment. *See* CFTC Staff Advisory No. 14–21 (Feb. 26, 2014) (''§ 160.30 Guidance''). In addition, the Commission notes that restoring the Detailed Requirements will make § 160.30 more consistent with similar rules adopted by the Securities and Exchange Commission (''SEC'') and the Federal Trade Commission (''FTC'') under the GLB Act. *See* 17 CFR 248.30 and 16 CFR 314.3, respectively.

[12] 5 U.S.C. 601 *et seq.*

[13] The Commission has previously determined that certain entities are not ''small entities'' for purposes of the RFA. *See, e.g.,* 47 FR 18618, 18619 (Apr. 30, 1982) (registered FCMs); 75 FR 55410, 55416 (Sept. 10, 2010) (RFEDs); 77 FR 2613, 2620 (Jan. 19, 2012) (SDs and MSPs). However, the Commission has determined that CPOs exempt pursuant to 17 CFR 4.13(a) are small entities. *See* 46 FR 26004 (May 8, 1981); 47 FR at 18619. The definitions of IB and CTA are also broad enough to potentially encompass ''small entities.'' *See* 48 FR 35248, 35276 (Aug. 3, 1983) (recognizing that the IB definition ''undoubtedly encompasses many business enterprises of variable size''); 47 FR at 18620 (the category of CTAs is ''too broad'' for a general determination regarding their small entity status).

the § 160.30 Guidance and the GLB Act, what is necessary to satisfy the General Requirement that already applies to Covered Persons. Therefore, the Commission believes that the Proposal will not have a significant economic impact on a substantial number of small entities, as defined in the RFA.

Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the Proposal will not have a significant economic impact on a substantial number of small entities. The Commission invites comment on the impact of the Proposal on small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'') [14] imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA. The Commission may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (''OMB'') control number.

The Commission has previously received a control number from OMB that includes the collection of information associated with the General Requirement. The title for this collection of information is ''Privacy of Consumer Financial Information, OMB control number 3038–0055''.[15] Collection 3038–0055 is currently in force with its control number having been provided by OMB. Because in restoring the inadvertently deleted Detailed Requirements, the Proposal would simply set forth what is necessary to satisfy the General Requirement that already applies to Covered Persons, the Commission believes that the Proposal would not impose any new recordkeeping or information collection requirements, or other collections of information that require approval of OMB under the PRA.

The Commission invites the public and other Federal agencies to comment on any aspect of the proposed information collection requirements discussed above. Refer to the **ADDRESSES** section of this notice for comment submission instructions to the Commission. A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *www.RegInfo.gov.*

C. Cost-Benefit Considerations

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) considerations.

As discussed above, the Commission is proposing to restore the inadvertently deleted Detailed Requirements in § 160.30. Below, the Commission discusses the costs and benefits of the Proposal.[16] The baseline against which the costs and benefits are considered is the current status quo for Covered Persons with respect to their obligation to satisfy the General Requirement under § 160.30.[17] The Commission recognizes that there are inherent costs and benefits to Covered Persons in providing requirements for specific customer privacy policies and procedures, which Congress took into account in codifying the GLB Act.

The inadvertent deletion of the Detailed Requirements in § 160.30 affected entities that were required to comply with the Detailed Requirements prior to the 2011 Amendment as well as the two types of entities (SDs and MSPs) the rule was being revised to include. Due to the inadvertent nature of the deletion of the Detailed Requirements, and that they applied prior to the 2011 Amendment, the Commission expects the number of entities affected by the Proposal to be negligible, if any. Consequently, to the extent the Proposal restores the Detailed Requirements in § 160.30, consistent with the § 160.30 Guidance and the GLB Act, the Proposal would not alter existing benefits and costs. The Commission, however, recognizes that the Proposal may benefit certain Covered Persons by, consistent with the GLB Act, specifying what types of policies and procedures are necessary to satisfy the General Requirement. In doing so, the Proposal may reduce any potential confusion and allow Covered Persons to design and maintain their policies and procedures to focus on the specified areas mandated by the GLB Act. In this regard, the Proposal may allow Covered Persons to more efficiently utilize their resources in developing policies and procedures in compliance with § 160.30. The Proposal also will, consistent with the GLB Act,[18] result in § 160.30 being more similar to regulations adopted by the SEC and FTC pursuant to the GLB Act and to which certain Covered Persons may be subject.[19]

The Commission recognizes that, as a result of the Proposal, certain Covered Persons may become subject to more specific requirements under § 160.30 than they are currently. However, given that the General Requirement currently applies to Covered Persons, and the § 160.30 Guidance that remains in effect takes into account the substance of the Detailed Requirements, the Commission believes that the burden of the Proposal on Covered Persons will not be significant.

1. Section 15(a) Considerations

In light of the foregoing, the CFTC has evaluated the costs and benefits of the Proposal pursuant to the five considerations identified in section 15(a) of the CEA as follows:

(1) Protection of Market Participants and the Public

The Proposal's restoration of the Detailed Requirements may protect market participants and the public by ensuring that the policies and procedures required under § 160.30 are reasonably designed to address the

[14] 44 U.S.C. 3501 *et seq.*

[15] *See* OMB Control No. 3038–0055, *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=3038-0055#* (last visited Nov. 5, 2019).

[16] The Commission endeavors to assess the expected costs and benefits of its proposed rules in quantitative terms where possible. Where estimation or quantification is not feasible, the Commission provides its discussion in qualitative terms. Given a general lack of relevant data, the Commission's assessment is generally provided in qualitative terms.

[17] The Commission notes that the consideration of costs and benefits below is based on the understanding that the markets function internationally, with many transactions involving United States firms taking place across international boundaries; with some Commission registrants being organized outside of the United States; with some leading industry members typically conducting operations both within and outside the United States; and with industry members commonly following substantially similar business practices wherever located. Where the Commission does not specifically refer to matters of location, the discussion of costs and benefits below refers to the effects of this proposal on all activity subject to the proposed and amended regulations, whether by virtue of the activity's physical location in the United States or by virtue of the activity's connection with or effect on United States commerce under CEA section 2(i). In particular, the Commission notes that some Covered Persons are located outside of the United States.

[18] *See* Section 6804(a)(2) of the GLB Act. 15 U.S.C. 6804(a)(2).

[19] *See* n.11, *supra.*

specific areas mandated by Congress in the GLB Act.

(2) Efficiency, Competitiveness, and Financial Integrity of Markets

The Proposal may reduce confusion and allow Covered Persons to design and maintain their policies and procedures to focus on the specified areas mandated by the GLB Act. This may allow Covered Persons to more efficiently utilize their resources in developing policies and procedures in compliance with § 160.30. In addition, consistent with the GLB Act, the Proposal will further align the consumer privacy regulations of the Commission, FTC, and SEC, which may lower costs for certain Covered Persons.

(3) Price Discovery

The Commission has not identified an impact on price discovery as a result of the Proposal.

(4) Sound Risk Management

The Commission has not identified an impact on sound risk management as a result of the Proposal.

(5) Other Public Interest Considerations

Consistent with the GLB Act, the Proposal will further align the consumer privacy regulations of the Commission, FTC, and SEC.

2. Request for Comments on Cost-Benefit Considerations

The Commission invites public comment on its cost-benefit considerations, including the section 15(a) factors described above. Commenters are also invited to submit any data or other information that they may have quantifying or qualifying the costs and benefits of the Proposal with their comment letters.

D. Antitrust Considerations

Section 15(b) of the CEA [20] requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the objectives of the CEA, as well as the policies and purposes of the CEA, in issuing any order or adopting any Commission rule or regulation (including any exemption under section 4(c) or 4c(b)), or in requiring or approving any bylaw, rule, or regulation of a contract market or registered futures association established pursuant to section 17 of the CEA.

The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition. The Commission requests comment on whether the Proposal implicates any other specific public interest to be protected by the antitrust laws.

The Commission has considered the Proposal to determine whether it is anticompetitive and has preliminarily identified no anticompetitive effects. The Commission requests comment on whether the Proposal is anticompetitive and, if it is, what the anticompetitive effects are.

Because the Commission has preliminarily determined that the Proposal is not anticompetitive and has no anticompetitive effects, the Commission has not identified any less anticompetitive means of achieving the purposes of the CEA. The Commission requests comment on whether there are less anticompetitive means of achieving the relevant purposes of the CEA that would otherwise be served by adopting the Proposal.

List of Subjects in 17 CFR Part 160

Brokers, Consumer protection, Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 160 as set forth below:

PART 160—PRIVACY OF CONSUMER FINANCIAL INFORMATION UNDER TITLE V OF THE GRAMM-LEACH-BLILEY ACT

■ 1. The authority citation for part 160 continues to read as follows:

Authority: 7 U.S.C. 7b–2 and 12a(5); 15 U.S.C 6801, *et seq.,* and sec. 1093, Pub. L. 111–203, 124 Stat. 1376.

■ 2. Revise § 160.30 to read as follows:

§ 160.30 Procedures to safeguard customer records and information.

Every futures commission merchant, retail foreign exchange dealer, commodity trading advisor, commodity pool operator, introducing broker, major swap participant, and swap dealer subject to the jurisdiction of the Commission must adopt policies and procedures that address administrative, technical and physical safeguards for the protection of customer records and information. These policies and procedures must be reasonably designed to:

(a) Insure the security and confidentiality of customer records and information;

(b) Protect against any anticipated threats or hazards to the security or integrity of customer records and information; and

(c) Protect against unauthorized access to or use of customer records or information that could result in substantial harm or inconvenience to any customer.

Issued in Washington, DC, on November 6, 2019, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Privacy of Consumer Financial Information—Commission Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2019–24581 Filed 11–8–19; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2019–N–3065]

RIN 0910–AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; additional materials; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the proposed rule that appeared in the **Federal Register** of August 16, 2019. The Agency is providing additional information in the docket and reopening the public comment period for 15 days to afford the public an opportunity to comment on this additional information.

DATES: FDA is reopening the comment period on the proposed rule published August 16, 2019 (84 FR 42754). Submit either electronic or written comments by November 27, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 27, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until

[20] 7 U.S.C. 19(b).