Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–2479 for ''Gastroparesis: Clinical Evaluation of Drugs for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Juli Tomaino, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5373, Silver Spring, MD 20993–0002, 301–796–8812.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Gastroparesis: Clinical Evaluation of Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of diabetic and idiopathic gastroparesis. This draft guidance replaces the draft guidance for industry of the same name issued July 23, 2015 (80 FR 43781). This draft was updated to address public comments received in 2015 and to reflect FDA's current thinking on the development of clinical outcome assessment tools and statistical considerations for use of those tools as a measure of the primary and secondary efficacy endpoints.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the FDA's current thinking of FDA on ''Gastroparesis: Clinical Evaluation of Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: August 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17463 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2163]

Child-Resistant Packaging Statements in Drug Product Labeling; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Child-Resistant Packaging Statements in Drug Product Labeling.'' This guidance is intended to assist applicants,

manufacturers, packagers, and distributors who choose to include child-resistant packaging (CRP) statements in prescription and over-the-counter human drug product labeling. The guidance discusses what information should be included to support CRP statements and to help ensure that such labeling is clear, useful, informative, and, to the extent possible, consistent in content and format.

DATES: The announcement of the guidance is published in the **Federal Register** on August 14, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–2163 for ''Child-Resistant Packaging Statements in Drug Product Labeling.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4132, Silver Spring, MD 20993, 301–796–1697; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Child-Resistant Packaging Statements in Drug Product Labeling.'' In 1970, the Poison Prevention Packaging Act (PPPA) was enacted to protect children (under 5 years of age) from unintentional exposure to household substances including food, drugs, and cosmetics. Under the Federal Food, Drug, and Cosmetic Act, a drug that has packaging or labeling that is in violation of a regulation issued pursuant to section 3 or 4 of the PPPA is deemed to be misbranded. FDA was responsible for enforcing the PPPA until 1973, when jurisdiction was transferred to the U.S. Consumer Product Safety Commission (CPSC). Because of FDA's authority to regulate labeling for prescription and nonprescription drug products, if firms choose to make statements in their labeling for such products about child-resistant packaging, such statements must comply with FDA's statutory and regulatory requirements. The guidance explains that to ensure that CRP statements on labeling are not false or misleading, such statements should only be used when the drug product packaging has been shown to comply with CPSC regulatory standards and test procedures for CRP, as applicable. This guidance is intended to apply to FDA-regulated drug products that bear CRP statements, regardless of whether CRP is required for such products under 16 CFR 1700. For example, bulk packages of prescription drugs that are shipped to pharmacies for repackaging by a pharmacist are not required to utilize CRP, but a firm may nevertheless choose to use CRP (and a CRP statement) for such drugs.

CPSC's regulations list ''special packaging standards'' for a wide range of household products, including most oral prescription drugs and many nonprescription drug products (see 16 CFR 1700 for substances requiring special packaging and the relevant packaging standards and testing procedures). It should be noted that ''child-resistant'' should not be equated with ''child-proof,'' because CRP is not designed to completely eliminate the possibility of an accidental pediatric ingestion. It can only impede access to harmful products and is recognized by public health experts as only one component of preventing these events. There are different ways to make packaging child-resistant, with the most common forms being a child-resistant closure (*e.g.,* a ''safety cap'') and certain unit-dose blister packaging (*e.g.,* puncture-resistant and peel-push blisters). FDA advocates that all drugs, irrespective of the type of packaging, be stored safely out of reach and sight of children to further the overall public health efforts to address this safety issue.

Because health care professionals and consumers may not be able to determine on visual inspection whether the packaging is child-resistant, a labeling statement may help to identify this attribute. Therefore, in this guidance, we recommend text that may be appropriate to consider when including CRP statements in labeling. All of the stakeholder comments on the draft guidance were carefully reviewed and, where appropriate, clarifying edits were made in the final guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Child-Resistant Packaging Statements in Drug Product Labeling.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information for submitting labeling in original and supplemental new drug applications (NDAs), and abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) in 21 CFR 314.50(e) and (l), 314.94(a)(8), 314.70, and 314.97, and 21 CFR 601.2 and 601.12 has been approved under OMB control number 0910–0001 and 0910–0338, respectively. The collection of information for preparing prescription drug product labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collection of information for Drug Facts labeling under 21 CFR 201.66 has been approved under OMB control number 0910–0340. The collection of information for Medication Guides has been approved under OMB control number 0910–0393. The collection of information for submitting chemistry, manufacturing, and controls information in original and supplemental NDAs, ANDAs, and BLAs in 21 CFR 314.50(d)(1), 314.94(a)(9), 314.70, and 314.97, and 21 CFR 601.2 and 601.12 has been approved under OMB control number 0910–0001 and 0910–0338, respectively.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov*.

Dated: August 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17433 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Requests for NIH Certificates of Confidentiality

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), in the Office of the Director, the National Institutes of Health (NIH) is streamlining the electronic system for the submission and processing of requests for NIH to issue Certificates of Confidentiality (CoCs).

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Pamela Reed Kearney, Division of Human Subjects Research, OER, NIH, 6705 Rockledge Dr., Building Rockledge 1, Room 812–C, Bethesda, MD 20817, or call non-toll-free number (301) 402–2512, or email your request, including your address to: *NIH-CoC-Coordinator@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925–0689, exp., date 12/31/2019 REVISION. Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This request system provides one electronic form to be used by all research organizations that request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the agencies of Department of Health and Human Services (DHHS), including NIH, to authorize researchers to protect the privacy of human research subjects by prohibiting them from releasing names and identifying characteristics of