of a Zika Domestic Readiness Initiative communication and education effort.

The total estimated annualized burden hours are 560. There are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
U.S. Domestic Adults	Zika Readiness Initiative Questionnaire	1,800	1	14/60
Puerto Rico Adults	Zika Readiness Initiative Questionnaire	600	1	14/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–16332 Filed 8–2–17; 8:45 am]

BILLING CODE 4163–18–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Child-Resistant Packaging Statements in Drug Product Labeling; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Child-Resistant Packaging Statements in Drug Product Labeling.''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: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 2, 2017.

ADDRESSES: You may submit comments 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 Division of Dockets Management. 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.

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; or to 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 draft 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 draft 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 (the FD&C 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 CRP, such statements must comply with FDA's statutory and regulatory requirements. The draft 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 the applicable CPSC regulatory standards and test procedures for CRP. 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'' (also referred to herein as child-resistant packaging, or CRP) 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). 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).

Child-resistant packaging is regarded as an important public health safety tool for avoiding harmful outcomes related to unsupervised pediatric ingestions. 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 on the containers and packaging of products.

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 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. Because FDA's guidance documents do not bind the public or FDA to any requirements, this guidance is not considered to be subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft 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), 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 draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: July 31, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–16379 Filed 8–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2489]

Receipt of Notice That a Patent Infringement Complaint Was Filed Against a Biosimilar Applicant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.