Respondents: ORR Grantee Staff.

Annual Burden Estimates: The following burden estimates were previously approved by OMB for data collection under OMB #0970–0466. The addition of these data elements does not increase reporting or record keeping burden.

ESTIMATED OPPORTUNITY BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form)	150	297	0.22	9,801

Total: 9,801.

ESTIMATED RECORDKEEPING BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form)	150	297	0.08	3,564

Total: 3,564.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno, Attorney General of the United States, et al.,* Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–05624 Filed 3–17–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0567]

Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.'' This guidance provides recommendations regarding the use of restricted delivery systems to limit unintentional ingestion of oral liquid drug products (*e.g.,* oral solution, oral suspension) by children. The recommendations in this guidance apply broadly to oral liquid drug and biological products. FDA's recommendations are intended to minimize the potential for harm due to unintentional ingestions.

DATES: Submit either electronic or written comments on the draft guidance by May 18, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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 Division of Dockets Management, 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–2020–D–0567 for ''Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.'' 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.govinfo.gov/content/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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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: Rhiannon Leutner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993–0002, 240–402–5998, 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.'' This guidance provides recommendations regarding the use of restricted delivery systems to limit unintentional ingestion of oral liquid drug products (*e.g.,* oral solution, oral suspension) by children. The recommendations in this guidance apply broadly to oral liquid drug and biological products.

A restricted delivery system, according to USP General Chapter <659> Packaging and Storage Requirements, is a packaging system that is designed or constructed to restrict (control) the amount of drug product that is delivered. Manufacturers should consider a restricted delivery system, such as a flow restrictor, as an additional measure to further reduce the risk that unintended ingestions of oral liquid drug products pose to public health. FDA is issuing this guidance to describe the elements that should be considered in developing restricted delivery systems for oral liquid drug 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 ''Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.'' 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.

II. The 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 part 314, including the submission of new drug and abbreviated new drug applications and supplements, have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601, including the submission of biologics license applications and supplements, have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 201.66 for format and content requirements for over-the-counter drug product labeling have been approved under OMB control number 0910–0340; and the collections of information in 21 CFR 201.56 and 201.57 for format and content requirements for human prescription drug and biological product labeling have been approved under OMB control number 0910–0572.

III. Electronic Access

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

Dated: March 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05617 Filed 3–17–20; 8:45 am]

BILLING CODE 4164–01–P