TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Recommended activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities)	2	2	4	3	12
Repackaging Guidance					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.A of the Repackaging Guidance)	6	2	12	3	36
Total	8		16		48

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of our analysis, we characterize the burden associated with the time and effort expended on the information collection recommendations discussed in the respective guidance documents as either recordkeeping, reporting, or third-party disclosure activities. We reconfigured the original table by splitting it into three tables to better differentiate between the estimated annual recordkeeping burden, the estimated annual reporting burden, and the estimated annual third-party disclosure burden. At the same time, our findings show that compliance with recordkeeping requirements applicable to compounded and repackaged drug products is standard practice in the compounding and selling of these drug products under States' pharmacy laws and other State laws governing recordkeeping by healthcare professionals and healthcare facilities. Therefore, we excluded from our estimate recordkeeping practices discussed in the respective guidance documents we consider usual and customary. We invite comment on this assumption.

For the Repackaging Guidance, to correct a clerical error, we have adjusted the number of disclosures per respondent from 21 to 36 because each respondent is estimated to average 6 different products and average 6 different strengths, which requires 36 (6 × 6) unique labels per respondent. The initial narrative reflected that each product would come in 6 different strengths and thus require 6 unique labels, but due to a clerical error, this information was not correctly included in the table. We also adjusted the number of respondents to 6 to match the number of respondents designing, testing, and producing labels. In addition, we adjusted the total number of disclosures per respondent to 2 given the biannual reporting requirement.

For the Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance, a row for biannual product reporting was added to capture product reporting that was inadvertently omitted.

Our estimated burden for the information collection reflects constant respondent numbers. The original numbers were based on the information the program received from product reporting data. We do not have a mechanism in place to determine whether or not these numbers have fluctuated upward or downward; however, based on analogous observations of industry through program experience (some product reports), we believe these numbers are constant. Repackagers who are also registered as outsourcing facilities (OF) are not entity types that are individually regulated as repackagers. They are subsumed in the OF entity type and not easily distinguishable. They may or may not report their repackaging operations.

We are updating the information collection to include burden attendant to reporting and disclosure recommendations found in the Agency guidance documents that was inadvertently omitted in the original information collection due to clerical errors. The burden estimate is adjusted to reflect a resulting increase of 114 hours and 94 responses annually.

Dated: June 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12783 Filed 6–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4806]

Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under the Federal Food, Drug, and Cosmetic Act; Notice; Request for Information and Comments; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing this request for information to better understand the status of trading partners' interoperable systems and processes for enhanced drug distribution security as required by the Food, Drug and Cosmetic Act (FD&C Act). FDA is reopening the comment period for the notice, published in the **Federal Register** of November 20, 2023, establishing a public docket and requesting information and comments, to allow interested persons additional time to comment.

DATES: FDA is reopening the comment period on the notice published November 20, 2023 (88 FR 80726). Either electronic or written comments must be submitted by September 12, 2024.

ADDRESSES: You may submit information and comments 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–2023–N–4806 for ''Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act.'' 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, 240–402–7500.

• 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4258, Silver Spring, MD 20993, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 2023 (88 FR 80726), FDA established a public docket to solicit comments on ''Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act.'' The request for information highlights areas for consideration and policy development identified by the Center for Drug Evaluation and Research (CDER). The notice includes a series of questions to stimulate feedback from the public, including CDER and the Center for Biologics Evaluation and Research stakeholders.

Interested persons were originally given until February 20, 2024, to comment on the docket.

Following publication of the November 20, 2023, notice, and in consideration of the joint public meeting organized by FDA and Partnership for DSCSA Governance (PDG): ''PDG–FDA Joint Public Meeting: DSCSA Stabilization Period Midway Checkpoint'' scheduled for June 17–18, 2024 (*https://www.fda.gov/news-events/partnership-dscsa-governance-pdgfda-joint-public-meeting-dscsa-stabilization-period-midway*), FDA has decided to reopen the public docket to allow interested persons additional time to comment.

Dated: June 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12857 Filed 6–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Development of Public Health Vaccine and Prevention Educational Campaigns Involving Community Health Workers

AGENCY: Office of Minority Health, U.S. Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) seeks input on involving community health workers (CHWs) to increase ''cultural competency in educational campaigns on public health vaccines and prevention, including but not limited to influenza and COVID–19.''

DATES: Written comments must be received electronically at the email address provided below, no later than 11:59 p.m. on July 11, 2024.

ADDRESSES: OMH invites the submission of the requested information through one of the following methods:

• *Preferred method:* Submit information through the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submissions.

• *Email:* Send comments to *MinorityHealthInfo@hhs.gov* with the subject line ''OMH RFI: Development of Public Health Vaccine and Prevention Educational Campaigns Involving Community Health Workers.''

Submissions received after the deadline will not be reviewed. Respond concisely and in plain language. You may use any structure or layout that presents your information well. You may respond to some or all of our questions, and you can suggest other factors or relevant questions. You may also include links to online material or