TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 11.100; submission of nonrepudiation letters	5,000	1	5,000	1	5,000

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of record per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
§ 11.10; controls for closed systems	2,500	1	2,500	20	50,000
§ 11.30; controls for open systems	2,500	1	2,500	20	50,000
§ 11.50; signature manifestations	5,000	1	5,000	20	100,000
§ 11.300; controls for identifications and passwords	5,000	1	5,000	20	100,000
Total					300,000

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

Based on a review of the information collection since our last request for OMB approval, we have increased our estimated burden. We assume 5,000 nonrepudiation letters will be submitted annually. We arrived at this figure by looking at the average number of nonrepudiation letters received through March 2023. We further assume that half of the estimated respondents will establish controls for open systems and half will establish controls for closed systems. Finally, we assume all respondents will establish controls for the remaining technical specifications required by the regulations.

Dated: September 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20233 Filed 9–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA–2023–D–2482]

Regulatory Considerations for Prescription Drug Use-Related Software; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Regulatory Considerations for Prescription Drug Use-Related Software.'' This draft guidance describes FDA's application of its drug labeling authorities to certain software outputs that are disseminated by or on behalf of a drug sponsor for use with a prescription drug or a prescription drug-led, drug-device combination product, which is assigned to the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research as the lead center.

DATES: Submit either electronic or written comments on the draft guidance by December 18, 2023 to ensure that the Agency considers your comments 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 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–D–2482 for ''Regulatory Considerations for Prescription Drug Use-Related Software.'' 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.

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, 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, or to the Office of Policy, 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: Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993, 301–796–2500, *CDEROMP@fda.hhs.gov;* Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7256, Silver Spring, MD 20993, 240–402–5683; or Sonja Fulmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5536, Silver Spring, MD 20993–0002, 240–402–5979, *digitalhealth@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Regulatory Considerations for Prescription Drug Use-Related Software.'' This draft guidance expands on and was developed in response to comments submitted in response to the **Federal Register** notice ''Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments'' (November 20, 2018; 83 FR 58574). As explained in this draft guidance, prescription drug use-related software generally includes software that: (1) is disseminated by or on behalf of a drug sponsor and (2) produces an end-user output that supplements, explains, or is otherwise textually related to one or more of the sponsor's drug products. A software function is any distinct purpose of the software, and end-user output is any material (content) that the prescription drug use-related software presents to the end user (a patient, caregiver, or health care practitioner). As discussed in this draft guidance, FDA considers end-user output a type of prescription drug labeling.

This draft guidance, when finalized, will clarify how FDA intends to apply its drug labeling authorities to end-user output of prescription drug use-related software, how FDA intends to treat certain prescription drug use-related software as FDA-required labeling, and when and how sponsors should submit end-user output to FDA. Generally, the recommendations provided in this draft guidance are intended to align with ongoing Agency initiatives across all product centers, including digital health initiatives at the Center for Devices and Radiological Health. This draft guidance considers existing Agency policies for the regulation of software to ensure efficient, coordinated review in instances when prescription drug use-related software is reviewed by the Agency as a device.

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 ''Regulatory Considerations for Prescription Drug Use-Related Software.'' 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. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 for new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 601.2 and 601.12 for biologics license applications and supplemental applications have been approved under OMB control number 0910–0338. The collections of information in Form FDA 2253 have been approved under OMB control number 0910–0001. The collections of information for prescription drug product labeling requirements in 21 CFR 201.56 have been approved under OMB control number 0910–0572. The collections of information in 21 CFR 202.1 for prescription drug advertisements have been approved under OMB control number 0910–0686.

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, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20241 Filed 9–18–23; 8:45 am]

BILLING CODE 4164–01–P