TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Voluntary national retail program standards (August 2022)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Program self-assessments for element Nos. 1 through 8 ..	500	1	500	92.3	46,150
Program element No. 9; risk factor study and intervention strategy.	500	1	500	333	166,500
Program Verification audit	500	1	500	46.15	23,075
Program records; associated documentation/maintenance of worksheets, assessments, associated program tools.	500	1	500	94.29	47,145
FDA Form 3958; VNRFP National Registry Report	500	1	500	0.1 (6 minutes)	50
Requests for program documentation (dedicated email)	500	3	1,500	0.1 (6 minutes)	150
Proposed Form FDA 5017; Waiver of Annual Maintenance Requirement.	10	1	10	0.35 (21 minutes).	3.5
Proposed Form FDA 5018; Food Safety Inspection Officer Annual Maintenance.	130	1	130	0.35 (21 minutes).	43
Proposed Form FDA 5019; Food Safety Inspection Officer Nomination.	14	1	14	0.35 (21 minutes).	5
Total	.....	.....	4,154	.....	283,121.5

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

Our estimate of burden for the associated program activities as identified in table 1 is based on our experience with the information collection, along with other regulatory standards programs we administer. Upon reorganizing the collection to reflect the cumulative activities, we have accounted for burden that may be attributable recordkeeping for risk-factor studies and verification tasks that may have been previously overlooked. The burden we attribute to completing and submitting FDA Form 3958, ''Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report,'' is exclusive of other program records, which we account for in row 4. We have also accounted for burden we assume will be attendant to the completion and submission of newly developed Agency forms. As a result of these changes and adjustments, the information collection reflects an increase of 235,776.5 hours and 1,654 responses annually.

Dated: September 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20226 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–N–3743]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection applicable to the electronic record signature provisions found in Agency regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by November 20, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 20, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–3743 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Requirements for Nonclinical Laboratory Studies.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Electronic Records; Electronic Signatures—21 CFR Part 11

OMB Control Number 0910–0303—Revision

This information collection supports implementation of statutory and regulatory authorities that govern criteria for the acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Agency regulations in part 11 (21 CFR part 11), provide for the submission of records and reports and establish that information may be submitted to FDA electronically provided that we have stated our ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met. The regulations apply to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in Agency regulations and to electronic records submitted under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations.

Regulations in part 11, subpart B (§§ 11.10 through 11.70) and) require the establishment of standard operating procedures to ensure appropriate use of and precautions for systems using electronic records and signatures, including the following: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; and (3) § 11.50 specifies procedures and controls for persons who use electronic signatures.

Regulations in subpart C (§§ 11.100 through 11.300) require specific controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords.

On March 3, 2023 (88 FR 13018), we revised the regulations. Before using an electronic signature in an electronic record required by FDA, a person must submit a letter of nonrepudiation to FDA (§ 11.100(c)). Letters of nonrepudiation are required under § 11.100(c)(1) to certify that a person's electronic signatures are intended to be the legally binding equivalent of traditional handwritten signatures. The regulations were amended to update the address for submission of a certification in paper form and to provide an option for electronic submission. The regulations were also amended to communicate that information on where to submit the certification may be found on FDA's website, currently available at: *https://www.fda.gov/industry/about-esg/appendix-g-letters-non-repudiation-agreement.*

We estimate the burden of the information collection as follows:

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