section 207 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), and consistent with the Medical Device User Fee Amendments 2017 (MDUFA IV) Commitment Letter and the FDA guidance document entitled ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' (*https://www.fda.gov/media/131064/download*), FDA has developed an ''electronic Submission Template and Resource'' (eSTAR) for Q-submissions to facilitate the preparation of submissions in electronic format (*https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program*). The use of eSTAR for Q-Submissions is currently voluntary. We assume approximately 40 percent of Q-Submissions will use eSTAR and that preparation using eSTAR will take approximately half the time of preparing a submission without using eSTAR.

We estimate a setup burden of 5 minutes for new eSTAR users. Respondents will only need to set up eSTAR the first time they use it. We note that because some respondents may have already undergone eSTAR set up for other types of submission, *e.g.,* premarket notification, fewer respondents may need to undergo eSTAR setup than estimated.

In the **Federal Register** of August 9, 2022 (87 FR 48488), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| **''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''** | | | | | |
| Q-Submissions: | | | | | |
| CDRH | 2,160 | 1 | 2,160 | 137 | 295,920 |
| CBER | 60 | 1 | 60 | 137 | 8,220 |
| **Q-Submissions using eSTAR (21 CFR part 814, subparts A through E; section 745A(b) of the FD&C Act)** | | | | | |
| CDRH | 1,440 | 1 | 1,440 | 69 | 99,360 |
| CBER | 40 | 1 | 40 | 69 | 2,760 |
| eSTAR setup | 1,480 | 1 | 1,480 | 0.08 (5 minutes) | 118 |
| Manufacturer request to participate in EPFP | 30 | 1 | 30 | 2 | 60 |
| Total | | | | | 406,438 |

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

Including the EPFP form represents a revision to this information collection request. Our estimated burden for the information collection reflects the availability of eSTAR to assist electronic preparation of Q-submissions and addition of the EPFP form, resulting in an overall decrease of 85,803 hours.

Dated: December 16, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–27815 Filed 12–21–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–3208]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on adverse event reporting by FDA on new animal drugs and product manufacturing defects.

**DATES:** Either electronic or written comments on the collection of information must be submitted by February 21, 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 February 21, 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–2022–N–3208 for ''Records and Reports Concerning Experiences with Approved New Animal Drugs: Adverse Event Reports.'' 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, including each proposed extension of an existing 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.

**Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports**

*OMB Control Number 0910–0284—Extension*

This information collection supports statutory and regulatory requirements governing reporting associated with certain animal drug products. With regard to adverse events and product/manufacturing defects associated with approved new animal drugs, section 512(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(l)) requires applicants with approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to establish and maintain records and reports of data relating to experience with uses of such drug, or with respect to animal feeds bearing or containing such drug, to facilitate a determination under section 512(e) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA under section 512(e) or 512(m)(4).

In 2020, FDA amended § 514.80 (21 CFR 514.80) to require electronic submission of certain postmarketing safety reports for approved new animal drugs and to provide a procedure for requesting a temporary waiver of the requirement. We, therefore, retain use of certain paper-based forms. Section 514.80 requires applicants and nonapplicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA. Following complaints from animal owners or veterinarians, or following their own detection of a problem, applicants or nonapplicants are required to submit adverse event reports and product/manufacturing defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) on Form FDA 1932.

The information collection includes electronic submission of adverse event reports and product/manufacturing defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) using Form FDA 1932.

The information collection also includes submissions under § 514.80(d)(2), by an applicant or nonapplicant requesting, in writing, a temporary waiver of the electronic submission requirements. The initial request may be by telephone or email to CVM's Division of Pharmacovigilance and Surveillance, with prompt written follow-up submitted as a letter to the application(s). FDA will grant waivers

on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

*Description of Respondents:* Respondents to this collection of information are applicants and nonapplicants as defined in 21 CFR 514.3. Respondents include individuals and the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section | FDA form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|---|
| Medicated feed reports, 510.301(a) and (b). | N/A | 8 | 1 | 8 | .25 (15 minutes) .. | 2 |
| Submission of postmarketing safety reports under § 514.80(b)(1), (2)(i) and (ii), (3), and (4)(iv)(A) and (C). | 1932 | 85 | 1249 | 98,639 | 1 ..... | 98,639 |
| Voluntary reporting FDA Form 1932a for the public. | 1932a | 106 | 1 | 106 | 1 ..... | 106 |
| 514.80(b)(4) Periodic Drug Experience Reports. | 2301 | 79 | 20 | 1,582 | 16 ..... | 25,312 |
| 514.80(b)(5)(i) Special Drug Experience Reports. | 2301 | 78 | 215 | 16,790 | 2 ..... | 33,580 |
| 514.80(b(5)(ii) Advertisement and Promotional labeling. | 2301 | 38 | 192 | 7,282 | 2 ..... | 14,564 |
| 514.80(b)(5)(iii) Distributor's Statements ... | 2301 | 22 | 2 | 36 | 2 ..... | 72 |
| 514.80(d)(2) ..... | N/A | 1 | 1 | 1 | 1 ..... | 1 |
| Total ..... | ..... | ..... | ..... | ..... | ..... | 172,276 |

[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 records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Recordkeeping, 510.301 [2] ..... | 8 | 1 | 8 | 4 | 32 |
| Recordkeeping, 21 U.S.C. 360b(1) and 514.80(e) [3] ..... | 79 | 1,575.14 | 124,436 | 14 | 1,742,104 |
| Total ..... | ..... | ..... | ..... | ..... | 1,742,136 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This estimate includes all recordkeeping by licensed medicated feed manufacturers under § 510.301.
[3] This estimate includes all recordkeeping by applicants of approved NADAs, ANADAs, and conditional NADAs under § 514.80(e).

Upon review of the information collection, we have adjusted our estimated burden to reflect an overall increase of 136,029.75 hours and 1,677,019 responses/records, annually.

Dated: December 16, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–27817 Filed 12–21–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–D–3054]**

### M11 Clinical Electronic Structured Harmonised Protocol; International Council for Harmonisation; Draft Guidance for Industry; Draft Template; and Technical Specification; 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 ''M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP),'' and two supplemental documents entitled ''M11 Template,'' and ''M11 Technical Specification.'' The draft guidance, template, and technical specification were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The draft guidance provides recommendations for a harmonized clinical trial protocol including the organization of standardized content and formatting. The draft template identifies headers, common text, and a set of data fields and terminologies that will be the basis for efficiencies in data exchange. The technical specification recommends the use of an open, non-proprietary standard to enable electronic exchange of clinical protocol information. The intent of the draft guidance and supporting documents is to create an international standard for the content and exchange of clinical trial protocol information facilitating review and assessment by regulators, sponsors,