V. Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); supplemental NADAs and ANADAs (21 CFR 514.8(a)(1)); investigational new animal drug applications (INADs) and generic investigational new animal drug applications (JINADs) (21 CFR 511.1(b)(10)); and food additive petitions (21 CFR 571.1(c)) must contain a claim for categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA's Center for Veterinary Medicine has received approximately 1,140 claims for categorical exclusion as required under § 25.15(a) and (d) and 9 EAs as required under § 25.40(a) and (c). Assuming an average of 10 claims per respondent, FDA estimates that approximately 114 respondents will submit an average of 10 claims for categorical exclusion. FDA further estimates that nine respondents will submit an average of one EA. FDA estimates that it takes sponsors/applicants approximately 3 hours to prepare a claim of categorical exclusion and an average of 2,160 hours to prepare an EA. Based on recent numbers, we now estimate a total of 22,860 hours for animal drugs (a decrease of 27,090 hours).

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	114	10	1,140	3	3,420
25.40(a) and (c)	9	1	9	2,160	19,440
Total					22,860

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

VI. Estimated Annual Reporting Burden for Tobacco Products

Under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements, premarket tobacco applications (PMTAs), substantial equivalence (SE), exemption from SE, and modified risk tobacco product applications (MRTPAs) must contain a claim for categorical exclusion or an EA. The majority of the EA burden for tobacco products is covered under already existing information collections. The burden for SEs is currently approved under OMB control number 0910–0673; the burden for PMTAs are currently approved under OMB control number 0910–0768; the burden for SE exemptions are currently approved under OMB control number 0910–0684.

FDA's estimates are based on actual report data from fiscal year (FY) 2018 to FY 2020. On average, FDA estimated it received approximately 14 MRTPAs from 14 respondents. Based on updated data for this collection, FDA estimates 14 EAs from 14 respondents. A total of 14 respondents will submit an average of one application for environmental assessment. Based on FDA's experience, previous information provided by potential sponsors, and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA. Based on recent MRTPA numbers, we now estimate a total of 14 annual responses and 1,120 hours for tobacco products (a decrease of 13 responses and 1,040 hours).

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	14	1	14	80	1,120

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

FDA estimates the burden for this information collection to be 30,315 annual responses, and 314,736 hours. These estimates reflect an overall increase of 13,463 responses and 94,078 hours. These adjustments are attributed to an increase in the number of responses the various centers in FDA have received over the last few years.

Dated: August 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18239 Filed 8–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1216]

Electronic Common Technical Document; Data Standards; Specifications for the Electronic Common Technical Document Validation Criteria

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are announcing the date that FDA will begin rejecting submissions which fail Electronic Common Technical Document (eCTD) validations 1306 or 1323 that have been raised to high validation errors as described in the ''Specifications for eCTD Validation Criteria.''

FOR FURTHER INFORMATION CONTACT: Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993–0002, 301–796–7997, *Jonathan.Resnick@fda.hhs.gov:* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is issuing this **Federal Register** notice to announce that eCTD validations 1306 and 1323, described in ''Specifications for eCTD Validation Criteria,'' have been raised to high validation errors. Beginning March 1, 2022, FDA will reject submissions that fail either of these validations.

According to the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications,'' submissions subject to section 745A(a) of the Federal Food, Drug, and Cosmetic Act must be submitted in eCTD format using the version of eCTD currently supported by FDA (unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver). The version of eCTD currently supported by FDA is specified in the Data Standards Catalog. eCTD submissions must follow FDA eCTD technical specification entitled ''The Comprehensive Table of Contents Headings and Hierarchy.'' Documents which are not properly referenced in the eCTD backbone as described in the ''M2 eCTD: Electronic Common Technical Document Specification'' and ''The eCTD Backbone Files Specification for Module 1,'' result in content that is not accessible within FDA eCTD technical specification ''The Comprehensive Table of Contents Headings and Hierarchy.'' eCTD validations 1306 (''No leaf element for file'') and 1323 (''No file for leaf element''), within the ''Specifications for eCTD Validation Criteria,'' describe parts of the eCTD specifications which were not followed correctly. Rejection for failing to pass either eCTD validations 1306 or 1323 will begin on March 1, 2022.

Dated: August 18, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18303 Filed 8–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0356]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment and Operation of Clinical Trial Data Monitoring Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 24, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0581. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishment and Operation of Clinical Trial Data Monitoring Committees

OMB Control Number 0910–0581—Extension

This collection of information supports Agency regulations and associated Agency guidance. Sponsors are required to monitor studies evaluating new drugs, biologics, and devices (21 CFR 312.50 and 312.56 for drugs and biologics, and 21 CFR 812.40 and 812.46 for devices). Various individuals and groups play different roles in clinical trial monitoring. One such group is a data monitoring committee (DMC), appointed by a sponsor to evaluate the accumulating outcome data in some trials. A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DMC advises the sponsor regarding the continuing safety of current trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The guidance document entitled ''Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees'' (March 2006) is intended to assist sponsors of clinical trials in determining when a DMC is needed for monitoring a study and how such committees should operate and is available from our website at: *https://www.fda.gov/media/75398/download.* The guidance addresses the roles, responsibilities, and operating procedures of DMCs and describes certain reporting and recordkeeping responsibilities, including the following: (1) Sponsor reporting to FDA on DMC recommendations related to safety; (2) standard operating procedures (SOPs) for DMCs; (3) DMC meeting records; (4) sponsor notification to the DMC regarding waivers; and (5) DMC reports based on meeting minutes to the sponsor.

1. Sponsor Reporting to FDA on DMC Recommendations Related to Safety

The requirement of the sponsor to report DMC recommendations related to serious adverse events in an expedited manner in clinical trials of new drugs (§ 312.32(c)) (21 CFR 312.32(c)) would not apply when the DMC recommendation is related to an excess of events not classifiable as serious. Nevertheless, the Agency recommends in the guidance that sponsors inform FDA about all recommendations related to the safety of the investigational product whether or not the adverse event in question meets the definition of ''serious.''

2. SOPs for DMCs

In the guidance, FDA recommends that sponsors establish procedures to do the following things:

- Assess potential conflicts of interest of proposed DMC members;
- ensure that those with serious conflicts of interest are not included in the DMC;