the EA based on Agency comments (between 40 to 60 hours), for a total preparation time of 180 hours.

Based on a current review of the information collection, we have made no adjustments to the currently approved estimate.

Dated: June 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13434 Filed 6–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0482]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Associated With New Animal Drug Applications and Veterinary Master Files

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by July 25, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0032. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Reporting Associated With New Animal Drug Applications (NADA) and Veterinary Master Files—21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, 514.11, and 558.5

OMB Control Number 0910–0032—Extension

Under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(b)(1)), any person may file a new animal drug application (NADA) seeking our approval to legally market a new animal drug. Section 512(b)(1) of the FD&C Act sets forth the information required to be submitted in a NADA. Sections 514.1, 514.4, 514.6, 514.8, and 514.11 of our regulations (21 CFR 514.1, 514.4, 514.6, 514.8, and 514.11) further specify the information that the NADA must contain. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. FDA Guidance for Industry #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. We request that applicants utilize Form FDA 356V, as appropriate, to ensure efficient and accurate processing of information to support new animal drug approval.

Under section 512(b)(3) of the FD&C Act, any person intending to file a NADA or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with us prior to making a submission. Section 514.5 of our regulations (21 CFR 514.5) describes the procedures for requesting, conducting, and documenting presubmission conferences. We have found that these meetings have increased the efficiency of the drug development and drug review processes. We encourage sponsors to submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase of the new animal drug is the most appropriate and productive. This ''phased review'' of data submissions has created efficiencies for both us and the animal pharmaceutical industry.

Additionally, we have found that various uses of veterinary master files have increased the efficiency of the drug development and drug review processes for both us and the animal pharmaceutical industry. A veterinary master file is a repository for submission to FDA's Center for Veterinary Medicine of confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more veterinary drugs. The benefits of veterinary master files include confidential exchange of information with FDA, a process for reporting information outside of a NADA or an investigational new animal drug (INAD) file, as well as an opportunity for increased communication with FDA during early stages of product development. Respondents may choose to use veterinary master files to provide and organize confidential detailed information to the Agency. A holder of a veterinary master file may also authorize other parties to reference information in the veterinary master file without disclosing information in the file to those parties. Veterinary master files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden. Veterinary master files are already used by the animal pharmaceutical industry in support of information being submitted for NADAs, abbreviated new animal drug applications (ANADAs), INAD files, and generic investigational new animal drug (JINAD) files. In previous information collection requests, we have included the time necessary to compile and submit such information to veterinary master files within the burden estimates provided for applications and amended applications (for NADAs and INAD files) and abbreviated applications and amended abbreviated applications (for ANADAs and JINAD files), respectively. We are now combining the time necessary to compile and submit such information to veterinary master files within the burden estimates provided in this collection of information.

We are also developing new approaches to permit more complex uses of veterinary master files to facilitate the development of animal drug products. We expect respondents will want to use veterinary master files to submit information to us for review and consultation during all phases of animal drug product development (including product development that precedes the establishment of an INAD file or the submission of a NADA). This information could include information about processes, facilities, or articles used in the manufacturing, processing,

packaging, and storing of veterinary drugs and drug substances. Information submitted to FDA through a veterinary master file could also include drug characterization, methods, protocols, or other relevant information. In this request for OMB review, we seek approval of an increased use of veterinary master files by respondents to submit additional information to us for review and consultation during all phases of animal drug product development (including product development that precedes the establishment of an INAD file or the submission of a NADA). To account for an expected increase in reporting burden hours associated with the increased use of veterinary master files by respondents, we are separately estimating in table 1, row 10, the burden of the use of veterinary master files during all phases of product development (including product development that precedes the establishment of an INAD file or the submission of a NADA).

Finally, § 558.5(i) of our regulations (21 CFR 558.5(i)) describes the procedure for requesting a waiver of the labeling requirements of § 558.5(h) in the event that there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

The reporting associated with NADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(1) of the FD&C Act. We use the information collected to review the data, labeling, and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug.

Description of Respondents: Respondents include persons developing, manufacturing, and/or researching new animal drugs.

In the **Federal Register** of February 15, 2019 (84 FR 4479), 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]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.1 & 514.6; applications and amended applications	182	0.05	9	212	1,908
514.1(b)(8) and 514.8(c)(1) [2]; evidence to establish safety and effectiveness	182	0.10	18	90	1,620
514.5(b), (d), (f); requesting presubmission conferences	182	0.49	89	50	4,450
514.8(b); manufacturing changes to an approved application	182	1.40	255	35	8,925
514.8(c)(1); labeling and other changes to an approved application	182	0.05	9	71	639
514.8(c)(2) & (3); labeling and other changes to an approved application	182	0.43	78	20	1,560
514.11; submission of data, studies and other information	182	0.09	16	1	16
558.5(i); requirements for liquid medicated feed	182	0.01	2	5	10
Form FDA 356V	182	2.92	531	5	2,655
Use of veterinary master files during all phases of product development (including product development that precedes the establishment of an INAD file or the submission of an NADA)	15	1	15	20	300
Total			1,022		22,083

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

[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall pre-approval safety evaluation.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our previous estimates. However, as discussed, we have separately estimated the burden of the ''Use of veterinary master files during all phases of product development (including product development that precedes the establishment of an INAD file or the submission of an NADA)'' in table 1, line 10. We base our estimate of the total annual responses for the use of veterinary master files on such uses initiated during calendar year 2018. We base our estimate of the hours per response upon our experience with the respondents' use of veterinary master files. We estimate that the time it takes to compile information and submit it to a veterinary master file will vary from 1 to 50 hours depending on the complexity of the information; therefore, we are estimating on average the burden per response to be 20 hours. Accordingly, our estimated burden for the information collection reflects an overall increase of 124 hours and a corresponding increase of 14 responses.

Dated: June 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13430 Filed 6–24–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4534]

Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Reducing Microbial Food Safety Hazards in the Production of Seed for