other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 3, 2016.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Examination and Treatment for Emergency Medical Conditions and Women in Labor; *Use:* Pursuant to regulation sections 488.18, 489.20 and 489.24, during Medicare surveys of hospitals and State agencies CMS will review hospital records for lists of on-call physicians, and will review and obtain the information which must be recorded on hospital medical records for individuals with emergency medical conditions and women in labor, and the emergency department reporting information Medicare participating hospitals and Medicare State survey agencies must pass on to CMS. Additionally, CMS will use the QIO Report assessing whether an individual had an emergency condition and whether the individual was stabilized to determine whether to impose a CMP or physician exclusion sanctions. Without such information, CMS will be unable to make the hospital emergency services compliance determinations that Congress expects CMS to make under sections 1154, 1866 and 1867 of the Act. *Form Number:* CMS–R–142 (OMB control number: 0938–0667); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 6,149; *Total Annual Responses:* 6,149; *Total Annual Hours:* 1. (For policy questions regarding this collection contact Renate Dombrowski at 410–786–4645.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* HIPAA Administrative Simplification Complaint Form; *Use:* The Health Insurance Portability and Accountability Act (HIPAA) became law in 1996 (Pub. L. 104–191). Subtitle F of Title II of HIPAA, titled ''Administrative Simplification,'' (A.S.) requires the Secretary of HHS to adopt national standards for certain information-related activities of the health care industry. The HIPAA provisions, by statute, apply only to ''covered entities'' referred to in section 1320d–2(a)(1) of this title. Responsibility for administering and enforcing the HIPAA A.S. Transactions, Code Sets, Identifiers has been delegated to the Centers for Medicare & Medicaid Services (CMS). This updated information collection will be used to initiate enforcement actions.

This reinstatement request clarifies the removal of the HIPAA Security complaint category. Specifically, the information collection revisions clarify the ''Identify the HIPAA Non-Privacy/Security complaint category'' section of the complaint form. In this section, complainants are given an opportunity to check the ''Unique Identifiers'' and ''Operating Rules'' option to additionally categorize the type of HIPAA complaint being filed. The revised form now includes an option for identifying Unique Identifier and Operating Rules complaints. It also requests email information about filed against entities, if available. *Form Number:* CMS–10148 (OMB control number: 0938–0948); *Frequency:* Occasionally; *Affected Public:* Individuals; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Cecily Austin at 410–786–0895.)

Dated: August 30, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–21201 Filed 9–1–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0450]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Abbreviated New Animal Drug Applications

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 October 3, 2016.

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 0910–0669. Also

include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Abbreviated New Animal Drug Applications—Sections (b)(2) and (n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2) and (n)(1))—OMB Control Number 0910–0669—Extension

Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an ANADA is described in section 512(n)(1) of the FD&C Act. Among other things, an ANADA is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved new animal drug. We use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug. We allow applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review. Applicants may submit Form FDA 356v with a complete ANADA or a phased review submission to ensure efficient and accurate processing of information.

In the **Federal Register** of May 11, 2016 (81 FR 29273), 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]

FD&C Act sections 512(b)(2) and (n)(1)	FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA	356v	18	1	18	159	2,862
Phased Review with Administrative ANADA	356v	3	5	15	31.8	477
Total						3,339

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

We base our estimates on our experience with ANADA submissions and requests for phased review. We estimate that we will receive 21 ANADA submissions per year over the next three years and that three of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately five phased reviews per application. We estimate that an applicant will take approximately 159 hours to prepare either an ANADA or the estimated 5 ANADA phased review submissions and the administrative ANADA.

Dated: August 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21128 Filed 9–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0520]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

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 October 3, 2016.

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 0910–0339. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, 20852, *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.

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR 589.2000(e)(1)(iv) OMB Control Number 0910–0339—Extension

This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with