

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 September 26, 2013.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0339 and title "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed." 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, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 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 BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissue, and feeds made from such products.

Specifically, this regulation requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution to maintain written procedures specifying the cleanout procedures or other means, and

specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize their processes, and then to help inspection personnel confirm that the firm is operating in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being followed when they are conducting an inspection.

These written procedures must be maintained as long as the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process the record must be updated. Written procedures required by this section shall be made available for inspection and copying by FDA.

In the **Federal Register** of May 16, 2013 (78 FR 28852), 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 RECORDKEEPING BURDEN ¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintaining written procedures (§ 589.2000 (e)(1)(iv))	400	1	400	14	5,600

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

Dated: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-20821 Filed 8-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0938]

Draft Guidance for Industry on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products, Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDAs: Stability

Testing of Drug Substances and Products, Questions and Answers." This draft guidance clarifies stability testing recommendations for abbreviated new drug applications (ANDAs) by providing responses to public comments in a questions-and-answers format. This draft guidance addresses public comments regarding FDA's recommendation to generic drug manufacturers to follow International Conference on Harmonisation (ICH) stability guidances Q1A (R2) through Q1E.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 28, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for

Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Radhika Rajagopalan, Center for Drug Evaluation and Research (HFD-640), Food and Drug Administration, 7500 Standish Pl., MPN2, Rm. 243, Rockville, MD 20855, 240-276-8546.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers." Because of increases in the number and complexity of ANDAs and FDA's desire to standardize generic drug review, on September 25, 2012 (77 FR 58999), FDA published a draft and on June 20, 2013 (78 FR 37231), published a final guidance recommending the generic industry follow the approach in the ICH stability-related guidances: (1) "Q1A(R2) Stability Testing of New Drug Substances and Products," November 2003; (2) "Q1B Photostability Testing of New Drug Substances and Products," November 1996; (3) "Q1C Stability Testing for New Dosage Forms," November 1996; (4) "Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products," January 2003; and (5) "Q1E Evaluation of Stability Data," June 2004. These guidances can be found on the FDA Guidances (Drugs) Web site under International Conference on Harmonisation—Quality at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065005.htm>. FDA also recommended that industry follow the ICH outlined definitions, glossaries, references, and attachments.

While carefully considering the public comments on the September 2012 draft guidance, we decided to publish a draft guidance in a questions-and-answers format. This draft guidance discusses stability testing relating to general questions, drug master files, drug product manufacturing and packaging, amendments to pending ANDA applications, and stability studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It

is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20893 Filed 8–26–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0847]

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Institutional Review Board Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an Investigational New Drug/ Investigational Device Exemption is Needed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the

Determination of Whether an IND/IDE is Needed." The guidance announced in this notice is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in fulfilling responsibilities related to reviewing the qualifications of investigators and adequacy of research sites, and determining whether an investigational new drug (IND) application or investigational device exemption (IDE) is required, to protect the rights and welfare of human subjects involved in biomedical research.

DATES: Submit written or electronic comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, 1–888–463–6332 or 301–796–3400; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800; or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 4621, Silver Spring, MD 20993, 1–800–638–2041 or 301–796–7100. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Doreen Kezer, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5170, Silver Spring, MD 20993–0002, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the