DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0620]

Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications; Guidance for Industry; 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 guidance for industry #234 entitled ''Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications.'' To improve the process for submission and review of chemistry, manufacturing, and controls (CMC) information for animal drugs, the Center for Veterinary Medicine has developed a series of questions that focus on the critical scientific and regulatory issues and pharmaceutical attributes essential for ensuring the quality of new animal drug substances and products. Termed Question-based Review, these questions provide a general framework for original CMC submissions to investigational new animal drug files, generic investigational new animal drug files, new animal drug applications, abbreviated new animal drug applications, conditional approval of applications for conditional approval, and veterinary master files.

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

ADDRESSES: You may submit comments as follows:

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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–0620 for ''Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *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 Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julie Bailey, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0700, *julie.bailey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 18, 2016 (81 FR 14859), FDA published the notice of availability for a draft guidance entitled ''Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications'' giving interested persons until May 17, 2016, to comment on the draft guidance. FDA received no comments on the draft guidance. The guidance announced in this notice finalizes the draft guidance dated March 2016.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements

of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This 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 part 514 have been approved under OMB control number 0910–0032; the collections of information in section 512(n)(1) of the FD&C Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: December 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30613 Filed 12–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0139]

Agency Information Collection Activities: Electronic Visa Update System

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Electronic Visa Update System (EVUS). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before February 21, 2017 to be assured of consideration.

ADDRESSES: All submissions received must include the OMB Control Number 1651–0139 in the subject line and the agency name. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Email.* Submit comments to: (*CBP_PRA@cbp.dhs.gov*). The email should include the OMB Control number in the subject line.

(2) *Mail.* Submit written comments to CBP PRA Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 10th Floor, 90 K St NE., Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, or via email (*CBP_PRA@cbp.dhs.gov*). Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP Web site at *https://www.cbp.gov/*. For additional help: *https://help.cbp.gov/app/home/search/1*.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following Information collection:

Title: Electronic Visa Update System.

OMB Number: 1651–0139.

Form Number: N/A.

Abstract: The Electronic Visa Update System (EVUS) provides a mechanism through which visa information updates can be obtained from certain nonimmigrant aliens in advance of their travel to the United States. This provides CBP access to updated information without requiring aliens to apply for a visa more frequently. The EVUS requirements apply to nonimmigrant aliens who hold a passport issued by an identified country containing a U.S. nonimmigrant visa of a designated category. EVUS enrollment is currently limited to nonimmigrant aliens who hold unrestricted, maximum validity B–1 (business visitor), B–2 (visitor for pleasure), or combination B–1/B–2 visas, which are generally valid for 10 years, contained in a passport issued by the People's Republic of China.

EVUS provides for greater efficiencies in the screening of international travelers by allowing DHS to identify nonimmigrant aliens who may be inadmissible before they depart for the United States, thereby increasing security and reducing traveler delays upon arrival at U.S. ports of entry. EVUS aids DHS in facilitating legitimate travel while also enhancing public safety and national security.

Current Actions: This submission is being made to extend the expiration date. There are no changes to the information collected.

Type of Review: Extension without change to the burden hours.

Affected Public: Individuals.

Estimated Number of Respondents: 3,595,904.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 3,595,904.

Estimated Time per Response: 25 minutes.

Estimated Total Annual Burden Hours: 1,499,492.

Dated: December 14, 2016.

Seth Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2016–30527 Filed 12–19–16; 8:45 am]

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