FOR FURTHER INFORMATION CONTACT: Julia Oriani, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0788, *julia.oriani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revised guidance for industry #3 entitled ''General Principles for Evaluating the Human Food Safety of New Animal Drugs used in Food-Producing Animals.'' This draft revised guidance is intended to inform sponsors of the scientific data and/or information that may provide an acceptable basis to determine that the residue of a new animal drug in or on food, when consumed, presents a reasonable certainty of no harm to humans. This guidance describes a recommended approach for providing human food safety scientific data and/or information. CVM acknowledges that alternate approaches also may be appropriate and encourages sponsors to discuss with CVM whether an alternate approach may be appropriate for specific new animal drugs.

II. Significance of Guidance

This level 1 draft revised guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft revised guidance, when finalized, will represent the current thinking of FDA on the type of information sponsors provide to address the human food safety of new animal drugs used in food-producing animals. 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This draft guidance refers to previously approved collections of information found in FDA regulations.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 part 514 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: July 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17188 Filed 7–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2013–N–0093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts

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 (the PRA).

DATES: Fax written comments on the collection of information by August 22, 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 0910–0746. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications (NME NDAs) and Original Biologics License Applications (BLAs) in Prescription Drug User Fee Acts (OMB Control Number 0910–0746)—Extension

As part of its commitments in the Prescription Drug User Fee Act (PDUFA) V, FDA established a new review Program to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applies to all NME NDAs and original BLAs that are received from October 1, 2012, through September 30, 2017. The Program is described in detail in section II.B of the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (the Commitment Letter) (available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the Program is an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The PDUFA V Commitment Letter specifies that the assessments be conducted by an independent contractor and that they include interviews of pharmaceutical manufacturers who submit NME NDAs and original BLAs to the Program in PDUFA V. The contractor for the assessments of the Program is Eastern Research Group, Inc. (ERG), and the statement of work for the assessments is available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM304793.pdf.*

In accordance with the PDUFA V Commitment Letter, FDA contracted with ERG to conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing review transparency and communication during the review process. ERG will anonymize and aggregate sponsor responses prior to inclusion in the assessments and any

presentation materials at public meetings. FDA will publish ERG's assessments, with interview results and findings, in the **Federal Register** for public comment.

Description of Respondents: The respondents to this collection of information are sponsor representatives for NME NDAs and original BLAs.

In the **Federal Register** of December 10, 2015 (80 FR 76699), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-test	5	1	5	1.5	7.50
Interviews	135	1	135	1.5	202.50
Total					210

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

FDA typically reviews approximately 40 to 45 NME NDAs and original BLAs per year. ERG interviews 1 to 3 sponsor representatives at a time for each application that receives a first-cycle action from FDA, up to 135 sponsor representatives per year. ERG conducts a pretest of the interview protocol with five respondents. FDA estimates that it will take 1.0 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. We estimate that up to 135 respondents will take part in the post-action interviews each year, with each interview lasting 1.0 to 1.5 hours, for a total of a maximum of 202.5 hours. Thus, the total estimated annual burden is 210 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: July 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17185 Filed 7–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0406]

Determination of Regulatory Review Period for Purposes of Patent Extension; QUTENZA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for QUTENZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by September 19, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 17, 2017. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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–2010–E–0406 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; QUTENZA.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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