and preserving the identity, strength, quality, and purity of the new animal drug and, in the case of a generic drug, to ensure that it is equivalent to the reference listed new animal drug (RLNAD).

In order to improve the process for submission and review of CMC information for animal drugs, CVM has developed draft GFI #234 entitled ''Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications.'' This guidance contains 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 QbR, these questions provide a general framework for original CMC submissions to INAD and JINAD files, NADAs, ANADAs, CNADAs, and VMFs.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of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This draft guidance refers to previously approved collections of information found in FDA regulations.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; 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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: March 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06119 Filed 3–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0663]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.

DATES: Submit either electronic or written comments on the collection of information by May 17, 2016.

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–2013–N–0663 for ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.'' 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 redacted/blacked out, will be available for public viewing and posted on *http://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 *http://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.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans, OMB Control Number 0910–0672—Extension

In the **Federal Register** of October 31, 2013 (78 FR 65338), FDA published a document entitled ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.'' The document clarified the Agency's expectations for timely review, evaluation, and submission of relevant and useful safety information and implemented internationally harmonized definitions and reporting standards for IND safety reports. The document also required safety reporting for bioavailability and bioequivalence studies. The document was intended to improve the utility of Investigational New Drug (IND) safety reports, expedite FDA's review of critical safety information, better protect human subjects enrolled in clinical trials, and harmonize safety reporting requirements internationally.

The rulemaking included the following information collection under the PRA that was not already included in 21 CFR 312.32 and approved under OMB control number 0910–0014.

Section 312.32(c)(1)(ii) and (c)(1)(iii) requires reporting to FDA, in an IND safety report, of potential serious risks from clinical trials within 15 calendar days for findings from epidemiological studies, pooled analyses of multiple studies, or other clinical studies that suggest a significant risk in humans exposed to the drug.

Section 312.32(c)(1)(iii) specifies the requirements for reporting to FDA in an IND safety report potential serious risks from clinical trials within 15 calendar days for findings from in vitro testing that suggest a significant risk to humans.

Section 312.32(c)(1)(iv) requires reporting to FDA in an IND safety report within 15 calendar days of any clinically important increase in the rate of occurrence of serious suspected adverse reactions over that listed in the protocol or investigator brochure.

The rulemaking also included new information collection under the PRA by requiring safety reporting for bioavailability and bioequivalence studies (21 CFR 320.31(d)).

In tables 1 and 2 of this document, the estimates for ''No. of Respondents,'' ''No. of Responses per Respondent,'' and ''Total Annual Responses'' were obtained from the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) reports and data management systems for submissions received in 2013, 2014, and 2015, and from other sources familiar with the number of submissions received under the noted 21 CFR section. The estimates for ''Hours per Response'' are unchanged based on information from CDER and CBER individuals familiar with the burden associated with these reports and from prior estimates received from the pharmaceutical industry. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—(CDER) [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	13	15	195	14	2,730
312.32(c)(1)(ii) and (c)(1)(iii) IND Safety Reports	100	6	600	12	7,200
312.32(c)(1)(iv) IND Safety Reports	10	1	10	12	120
Total (CDER)					10,050

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—(CBER) [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	1	1	1	14	14
312.32(c)(1)(ii) and (c)(1)(iii) IND Safety Reports	137	4	548	12	6,576
312.32(c)(1)(iv) IND Safety Reports	5	1.4	7	12	84
Total (CBER)					6,674

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

Dated: March 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06128 Filed 3–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3225]

Wesley A. McQuerry: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Wesley A. McQuerry from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. McQuerry was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product and otherwise relating to the regulation of a drug product under the FD&C Act. Mr. McQuerry was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. McQuerry failed to respond. Mr. McQuerry's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective March 18, 2016.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, (ELEM–4144), Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the FD&C Act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the FD&C Act. On February 10, 2015, the U.S. District Court for the Northern District of Illinois entered judgment against Mr. McQuerry for one count of falsifying a material fact, in violation of 18 U.S.C. 1001(a)(1).

The factual basis for this conviction is as follows: Mr. McQuerry was the study coordinator for a drug clinical trial at an institution in the Northern District of Illinois. The clinical trial occurred under the authority of FDA, and clinical trial data was required to be submitted to FDA before the drug could be approved for sale in the United States.

As study coordinator, Mr. McQuerry's responsibilities for administering the clinical trial included, among other things, coordinating patient visits, maintaining patient files, ensuring that administrative procedures were followed regarding the collection of patient data, disbursing American Express gift checks to trial participants, and transmitting clinical trial data from the institution to the administrator, which was administering the clinical trial on behalf of the pharmaceutical company. Mr. McQuerry knew that the results of the clinical trial would be reported to FDA, and he knew it was unlawful to provide false information to the pharmaceutical company.

Beginning no later than January 2008, and continuing through at least October 2008, in the Northern District of Illinois, Mr. McQuerry knowingly and willfully falsified, concealed, and covered up by trick, scheme, and device material facts in a matter within the jurisdiction of FDA, namely that at least four patients and others were participating in the drug clinical trial, when in fact these patients did not participate in that clinical trial. Specifically, between January and October 2008, Mr. McQuerry created fifteen to twenty fictional patients, whom he claimed were participants in the clinical trial. Mr. McQuerry falsified signatures of those patients on consent forms and falsified doctors' signatures on medical evaluations for those patients. He provided his own blood, stool, and EKG results, which he claimed were provided by the fictional patients. He also transmitted false data and information to the administrator regarding these fictional patients and made and caused to be made false statements regarding their participation in the study and attendance at office visits, all of which he knew would be provided to the pharmaceutical company and to FDA.

Mr. McQuerry made false statements to the administrator about the whereabouts of the fictitious trial participants. In particular, on August 28, 2008, he provided false and fraudulent statements to the administrator regarding the attendance of two patients at study visits, knowing that the two patients were not in fact enrolled in the study and did not attend a single study visit.

As study coordinator, Mr. McQuerry was responsible for disbursing gift checks, which were provided by the pharmaceutical company to patients at various points during the patients' participation in the clinical trial. Mr. McQuerry falsely and fraudulently claimed to have disbursed gift checks when, in fact, no checks were disbursed