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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requirements for Submission of In Vivo Bioequivalence Data—21 CFR parts 314 and 320.

OMB Control Number 0910–0630—Extension

In the **Federal Register** of January 16, 2009 (74 FR 2849), the Agency published a final rule revising FDA regulations to require applicants to submit data on all bioequivalence (BE) studies, including studies that do not meet passing bioequivalence criteria, which are performed on a drug product formulation submitted for approval under an abbreviated new drug application (ANDA), or in an amendment or supplement to an ANDA that contains BE studies. In the final rule, FDA amended 314.94(a)(7)(i), 314.96(a)(1), 320.21(b)(1), and 314.97 (21 CFR 314.94(a)(7)(i), 314.96(a)(1), 320.21(b)(1), and 314.97) to require an ANDA applicant to submit information from all BE studies, both passing and nonpassing, conducted by the applicant on the same drug product formulation as that submitted for approval under an ANDA, amendment, or supplement.

In table 1, FDA has estimated the reporting burden associated with each section of this requirement. FDA believes that the majority of additional BE studies will be reported in ANDAs (submitted under 314.94), rather than supplements (reported in 314.97) because it is unlikely than an ANDA holder will conduct BE studies with a drug after the drug has been approved. With respect to the reporting of additional BE studies in amendments (submitted under 314.96), this should also account for a small number of reports because most BE studies will be conducted on a drug prior to the submission of the ANDA and will be reported in the ANDA itself.

FDA estimates applicants will require approximately 120 hours of staff time to prepare and submit each additional complete BE study report and approximately 60 hours of staff time for each additional BE summary report. The Agency believes that a complete report will be required approximately 20 percent of the time, while a summary will suffice approximately 80 percent of the time. Based on a weighted-average calculation using the information presented previously in this document, the submission of each additional BE study is expected to take 72 hours of staff time ($[120 \times 0.2] + [60 \times 0.8]$).

In the **Federal Register** of June 26, 2014 (79 FR 36320), 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]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
314.94(a)(7)	84	1	84	72	6,048
314.96(a)(1)	1	1	1	72	72
314.97	1	1	1	72	72
Total					6,192

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

Dated: December 10, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29425 Filed 12–15–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1409]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports

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 January 15, 2015.

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 0910–0284. 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, 8455 Colesville Road; 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.

Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports on Paper Forms FDA 1932, 1932a, and 2301—21 CFR 514.80; OMB Control Number 0910–0284—Extension

Section 512(*l*) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(*l*) and 514.80 (21 CFR 514.80) of FDA regulations require applicants of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects (see 514.80)(b)). Additionally, section 571(e)(3) of the FD&C Act (21 U.S.C. 360ccc(e)(3)) requires that

applicants for conditional approval of new animal drugs (CNADAs) maintain adequate reports and records of adverse drug experiences and product/manufacturing defects as applicable under section 512(*l*) of the FD&C Act.

The continuous monitoring of approved NADAs, ANADAs, and CNADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Post-approval marketing surveillance is important because data previously submitted to FDA may not be adequate as animal drug effects can change over time and less apparent effects may take years to manifest.

Under 514.80(d), an applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs,'' (see 514.80). Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,'' allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

In 2010, electronic versions of Forms FDA 1932 and 1932a were incorporated into the FDA Safety Reporting Portal. This electronic system is used for collecting, submitting, and processing adverse event reports and other safety information for all FDA regulated products. Burden for the electronic version of these forms is accounted for under OMB control number 0910–0645. This approval request accounts for the collection of information using existing paper Forms FDA 1932, 1932a, and 2301 and is currently approved under OMB control number 0910–0284. FDA estimates that, at this time, approximately 50 percent of the respondents utilize paper forms for submitting this information. We expect this number to decrease as more respondents avail themselves of the FDA Safety Reporting Portal.

In the **Federal Register** of September 29, 2014 (79 FR 58355), 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]

21 CFR section/section of the FD&C act	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.80(b)(1), 514.80(b)(2)(i) and (ii), 514.80(b)(3)	1932	22	81.05	1,783	1	1,783
Voluntary reporting FDA Form 1932a for the public	1932a	197	1	197	1	197
514.80(b)(4)	2301	200	8.11	1,622	16	25,952
514.80(b)(5)(i)	2301	200	0.57	114	2	228
514.80(b)(5)(ii)	2301	200	20.12	4,024	2	8,048
514.80(b)(5)(iii)	2301	190	0.1	20	2	40
Total Hours						36,248

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

TABLE 2—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
514.80(e)	646	7.20	4651	14	65,117

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

Dated: December 10, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29426 Filed 12–15–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1842]

Crabmeat—Fresh and Frozen—Adulteration With Filth, Involving the Presence of Escherichia coli; Compliance Policy Guide; Draft Guidance for Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for FDA staff entitled ''Compliance Policy Guide Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of *Escherichia coli*.'' The draft Compliance Policy Guide (CPG), when finalized, will update the previously issued ''CPG Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of the Organism *Escherichia coli*.'' This revised draft provides guidance for FDA staff on the level of *Escherichia coli* (*E. coli*) in crabmeat at which we may consider the crabmeat to be adulterated with filth.

DATES: Although you can comment on any guidance at any time (see 21 CFR