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

10.115(g)(5)), to ensure that FDA considers your comment on this draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by February 17, 2015.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

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

FOR FURTHER INFORMATION CONTACT: Mary E. Losikoff, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2300.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the draft CPG entitled ''Compliance Policy Guide Sec. 540.275 Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of *Escherichia coli.*'' The draft CPG, when finalized, will update the previously issued ''CPG Sec. 540.275 Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of the Organism *Escherichia coli,*'' which provides guidance for FDA staff on the level of *E. coli* in crabmeat (*i.e.,* 3.6 Most Probable Number per gram (MPN/g) of *E. coli*) at which FDA may consider the crabmeat to be adulterated with filth under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)). We revised the CPG for clarity and to update the format. Revisions generally include the addition of sections on Background and Policy, updates to the sections on Regulatory Action Guidance and Specimen Charges, and FDA office names. Specifically, in the section on Regulatory Action Guidance, we clarify that FDA's Districts have direct reference authority for both domestic seizure and import refusal based on the criteria described in the draft CPG. We also clarify the specific types of legal action to which the criteria for recommendations apply. In addition, we provide specimen charges relating to domestic seizure and import refusal. The draft CPG also contains information that may be useful to the regulated industry and to the public.

We are issuing the draft CPG consistent with our good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent our current thinking on the level of *E. coli* in fresh or frozen crabmeat at which we may consider the crabmeat to be adulterated with filth under section 402(a)(4) of the FD&C Act.

The draft CPG does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate 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 the draft CPG 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. Electronic Access

Persons with access to the Internet may obtain the document from FDA's Office of Regulatory Affairs CPG history page at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 10, 2014.

Melinda K. Plaisier,

Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2014–29314 Filed 12–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1697]

Privacy Act of 1974; Report of a New System of Records; Food and Drug Administration Commissioning of State and Local Officials; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of December 8, 2014. The document misstated the effective date of the new system of records. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Regulations Editorial Section, Regulations Policy and Management Staff, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9148.

SUPPLEMENTARY INFORMATION: The December 8, 2014 (79 FR 72687) notice published with an incorrect effective date of December 8, 2014, for the new system of records. This document corrects that error. For the convenience of the reader, the complete **DATES** language is set out below.

In 79 FR 72687, published on December 8, 2014, we are correcting the **DATES** section to read as follows:

DATES: *Effective Date:* The new system of records and related routine uses will be effective on January 22, 2015. Submit either electronic or written comments by January 22, 2015.

Dated: December 10, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29424 Filed 12–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day comment request; Generic Clearance for Satisfaction Surveys of Customers (CSR)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection