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.


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

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

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

### Table 2—Estimated Annual Recordkeeping Burden ¹

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>514.80(e)</td>
<td>646</td>
<td>7.20</td>
<td>4651</td>
<td>14</td>
<td>65,117</td>
</tr>
</tbody>
</table>

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

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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:** 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 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
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.


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.


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