

I. Background

We are announcing the availability of revised CPG Sec. 540.275 Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of *Escherichia coli*. The CPG updates the previously issued CPG Sec. 540.275 Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of *Escherichia coli*. We are issuing this CPG consistent with our good guidance practices regulation (21 CFR 10.115). The CPG represents the current thinking of FDA on this topic. 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.

The CPG provides guidance for FDA staff on the level of *E. coli* in fresh or frozen 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 (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. The CPG provides criteria that the FDA District Offices may use to determine whether to recommend an enforcement action. Consistent with our standard business process, the CPG provides guidance to the FDA field offices for submitting an enforcement action recommendation to FDA's Center for Food Safety and Applied Nutrition (CFSAN) for case review. The CPG also provides direct reference authority to the FDA field offices in certain situations. Rather than submitting the recommendation to CFSAN, direct reference authority allows the FDA field offices to submit the recommendation directly to the appropriate office in FDA's Office of Regulatory Affairs, thus streamlining the Agency's internal case review process. Specifically, in the section on Regulatory Action Guidance, we clarify that FDA's District Offices have direct reference authority for both domestic seizure and import refusal based on the criteria described in the 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 CPG also contains information that may be useful to the regulated industry and to the public.

In the **Federal Register** of December 16, 2014 (79 FR 74729), we made available draft CPG Sec. 540.275 “Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of *Escherichia coli*.” We gave interested parties an opportunity to submit comments on the draft CPG by February 17, 2015, for us to consider before beginning work on the final version of the CPG. We received no comments on the draft CPG. We are issuing the CPG with no changes other than for clarity and to update the format. The CPG announced in this notice finalizes the draft CPG dated December 2014.

II. Electronic Access

Persons with access to the Internet may obtain the CPG at either <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 CPG.

Dated: April 25, 2016.

Katherine Bent,

Assistant Commissioner for Compliance Policy.

[FR Doc. 2016-09951 Filed 4-27-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0557]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarket Surveillance

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 information collection requirements for postmarket surveillance of medical devices.

DATES: Submit either electronic or written comments on the collection of information by June 27, 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-0557 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarket Surveillance.” 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.

Postmarket Surveillance—21 CFR Part 822—OMB Control Number 0910-0449—Extension

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with part 822 (21 CFR part 822) in §§ 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with § 822.38. Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Activity/21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|---------------|
| Postmarket surveillance submission (§§ 822.9 and 822.10) | 131 | 1 | 131 | 120 | 15,720 |
| Changes to PS plan after approval (§ 822.21) | 15 | 1 | 15 | 40 | 600 |
| Changes to PS plan for a device that is no longer marketed (§ 822.28) | 80 | 1 | 80 | 8 | 640 |
| Waiver (§ 822.29) | 1 | 1 | 1 | 40 | 40 |
| Exemption request (§ 822.30) | 16 | 1 | 16 | 40 | 640 |
| Periodic reports (§ 822.38) | 131 | 3 | 393 | 40 | 15,720 |
| Total | | | | | 33,360 |

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

Explanation of Reporting Burden Estimate. The burden captured in table 1 of this document is based on the data from FDA's internal tracking system.

Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because it entails no burden other than

that necessary to identify the respondent, the date, the respondents address, and the nature of the instrument (See 5 CFR 1320.3(h)(1)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| Activity/21 CFR section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---------------------------------------|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| Manufacturer records (§ 822.31) | 131 | 1 | 131 | 20 | 2,620 |
| Investigator records (§ 822.32) | 393 | 1 | 393 | 5 | 1,965 |
| Total | | | | | 4,585 |

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

Explanation of Recordkeeping Burden Estimate. FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with postmarket surveillance.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-09940 Filed 4-27-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

American Indians Into Nursing Program; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on March 28, 2016, for the FY 2016 American Indians into Nursing. The notice contained incorrect project period lengths.

FOR FURTHER INFORMATION CONTACT: Naomi Aspaas, BSN, RN, Program Official, Office of Human Resource, Division of Health Professions Support, 5600 Fishers Lane, Mail Stop: OHR 11E53A, Rockville, MD 20857, Telephone (301) 443-5710. (This is not a toll-free number.)

Correction

In the **Federal Register** of March 28, 2016, in FR Doc. 2016-06969, on page 17182, in the third column, under the heading "III. Eligibility Information, 1. Eligibility, (b) Priorities", the correct paragraphs should read as follows:

1. *Priority I:* At least two awards to public or private college or university, school of nursing which provides DNP, MSN, BSN, ADN (registered nurse,

nurse practitioner, nurse midwife) degrees, not to exceed \$400,000 per year up to a project period of three years.

2. *Priority II:* At least three awards to a Tribally-controlled community college, school of nursing which provides BSN and ADN (registered nurse) degrees, not to exceed \$400,000 per year up to a project period of three years.

Dated: April 18, 2016.

Elizabeth A. Fowler,

Deputy Director for Management Operations, Indian Health Service.

[FR Doc. 2016-09939 Filed 4-27-16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

Agency Information Collection Activities: Extension, With Changes, of an Existing Information Collection

AGENCY: U.S. Immigration and Customs Enforcement, DHS.

ACTION: 30-Day Notice of information collection for review; form no. I-352SA/I-352RA; electronic bonds online (eBonds) access; OMB control no. 1653-0046.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** on January 26, 2016, Vol. 81 No. 4332 allowing for a 60 day comment period. No comments were received on this information collection. The purpose of this notice is to allow an additional 30 days for public comments.

Written comments and suggestions regarding items contained in this notice and especially with regard to the

estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to oira_submission@omb.eop.gov or faxed to (202) 395-5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, with changes, of a currently approved information collection.

(2) *Title of the Form/Collection:* Electronic Bonds Online (eBonds) Access.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-352SA (Surety eBonds Access Application and Agreement); Form I-352RA (eBonds Rules of Behavior Agreement); U.S Immigration and Customs Enforcement.