

Recommendations.” In January 2011, CDRH published the “Plan of Action for Implementation of 510(k) and Science Recommendations,” denoting as one of the action items to update the 1998 510(k) Paradigm Guidance.

FDA recognizes and supports efforts for global convergence of regulatory systems, and in particular, through its participation in the Global Harmonization Task Force which published the “Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)” on February 21, 2008. The Agency has specifically considered the STED principles in the FDA Guidance titled “Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s” and has also incorporated those principles in this guidance as appropriate. FDA is specifically interested in seeking comment with respect to how these principles may be further applied in this guidance document and to 510(k) submissions and review generally.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on the 510(k) decision-making process and policies with respect to the 510(k) program. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from CBER at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

To receive “Draft Guidance for Industry and Food and Drug Administration Staff; The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],” you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to (301) 847-8149 to receive a hard copy. Please

use the document number 1766 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently 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 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 56.115 have been approved under OMB control number 0910-0130; the collections of information found in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 21, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0893]

### Draft Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Center for Devices and Radiological Health (CDRH) Appeals Processes.” This document describes the processes available to outside stakeholders to request additional review of decisions and actions by CDRH employees. The document also provides general information about each process as well as guidance on how to submit related requests to CDRH and FDA. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 26, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled “Center for Devices and Radiological Health (CDRH) Appeals Processes” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to (301) 847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** David S. Buckles, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, rm. G414, Silver Spring, MD 20993-0002, (301) 796-5447.

### SUPPLEMENTARY INFORMATION:

#### I. Background

The draft guidance for industry and FDA staff entitled “Center for Devices and Radiological Health (CDRH) Appeals Processes” revises, updates, and combines two previous guidance documents: “Medical Device Appeals and Complaints: Guidance for Dispute

Resolution,” dated February 1998, and “Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA,” dated July 2001. When finalized, “Center for Devices and Radiological Health (CDRH) Appeals Processes” is intended to supersede the previously listed two guidance documents.

The draft document is intended to provide clarity to internal and external audiences regarding CDRH’s appeal processes. Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including requests for supervisory review of an action, petitions, and hearings. In most cases, it is up to the party seeking resolution of an adverse action or resolution of a difference of opinion to determine the appropriate process for a given circumstance or issue. The guidance describes these mechanisms and includes the following topics: (1) Appealable actions (i.e., warning letters, post-approval study requirements, premarket decisions, deficiency letters, or requests for additional information); (2) paths and options available at different stages of appeals; (3) use of expedited or “paper” appeals versus appeal meetings or teleconferences; (4) recommended format for appeals; (5) appeal authorities; (6) appeal conflicts; and (7) issues that are appropriate for dispute resolution.

**II. Significance of Guidance**

This 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 Agency’s current thinking on CDRH’s appeals processes. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Center for Devices and Radiological Health (CDRH) Appeals Processes” you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to (301) 847–8149 to receive a hard copy. Please use the document number 1742 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

Under the Paperwork Reduction Act of 1995 (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 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.

*Draft Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health (CDRH) Appeals Processes*

This draft guidance is intended to describe the processes available to outside stakeholders to request additional review of decisions and actions by CDRH employees. There are several processes for resolution, including a request for supervisory review of an action, petitions, and hearings. The proposed information collection seeks approval for the reporting burden associated with requests for additional review of decisions and actions by CDRH employees under this guidance. The draft guidance also refers to currently approved information collections found in FDA regulations.

The collections of information in 21 CFR 10.30 are approved under OMB control number 0910–0437; the collections of information in 21 CFR 10.33 are approved under OMB control number 0910–0485; the collections of information in 21 CFR 10.35 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 12 are approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 900 are approved under OMB control number 0910–0309.

*Description of Respondents:* The respondents to this collection of information are manufacturers, applicants, sponsors, or any other interested persons requesting additional review of decisions and actions taken by CDRH employees. The Agency estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Guidance title	No. of respondents	No. of responses per respondents	Total annual responses	Average burden per responses	Total hours
Center for Devices and Radiological Health (CDRH) Appeals Processes .....	50	1	50	8	400

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

FDA estimates it will receive 50 requests annually from outside stakeholders requesting additional review of decisions and actions by CDRH employees. The Agency reached this estimate based on data collected about requests received over the last 2 years. FDA estimates it will take outside stakeholders approximately 8 hours to prepare a request based on the Agency's experience with past requests.

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 21, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0313]

#### Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation." The document provides guidance to egg producers on how to comply with certain provisions

contained in FDA's final rule "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (the final rule), including how to implement *Salmonella* Enteritidis (SE) prevention measures, how to sample for SE., and how to maintain records documenting compliance with the final rule.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Nancy Bufano, Center for Food Safety and Applied Nutrition (HFS-316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, (240) 402-1493.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of July 9, 2009 (74 FR 33030), FDA issued a final rule requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, to maintain records concerning their compliance with the final rule, and to register with FDA. This final rule became effective September 8, 2009. In the **Federal Register** of August 12, 2010 (75 FR 48973), FDA made available a draft guidance entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" and gave interested parties an opportunity to submit comments by October 12, 2010. The Agency reviewed and evaluated these comments and has modified the guidance where appropriate.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on how to comply with

certain SE prevention measures, how to sample for SE., and how to maintain records documenting compliance with the final rule. It 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. Paperwork Reduction Act of 1995

This 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 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910-0660.

#### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the guidance. 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.

#### IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: December 22, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming teleconference meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one