

**FOR FURTHER INFORMATION CONTACT:**

Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1639.

**SUPPLEMENTARY INFORMATION:****I. Background**

We are announcing the availability of a draft guidance entitled "Guidance for Industry: Acrylamide in Foods." We are issuing this draft guidance as a Level 1 draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on acrylamide in foods. 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 statutes and regulations.

The draft guidance is intended to provide information that may help growers, manufacturers, and food service operators reduce acrylamide in certain foods. Acrylamide is a chemical that can form in some foods during certain types of high-temperature cooking, and is a concern because it can cause cancer in laboratory animals at high doses, and is reasonably anticipated to be a human carcinogen. Reducing acrylamide in foods may mitigate potential human health risks from exposure to acrylamide. The draft guidance is intended to suggest a range of possible approaches to acrylamide reduction and not to identify specific recommended approaches.

In particular, the draft guidance is intended to give information to manufacturers on selecting and handling raw materials, modifying processing practices, and choosing ingredients, so as to reduce acrylamide in potato-based foods (such as fries, sliced potato chips, and fabricated potato chips) and cereal-based foods (such as cookies, crackers, and breads). The draft guidance also discusses acrylamide reduction in coffee. The draft guidance also is intended to give information to manufacturers for placing preparation and cooking instructions on frozen French fry packages. Lastly, the draft guidance is intended to give information for food service operations on preparation of potato-based and cereal-based foods.

**II. Paperwork Reduction Act of 1995**

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995

(the PRA) (44 U.S.C. 3501-3520). "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. Federal law at 44 U.S.C. 3506(c)(2)(A) requires Federal Agencies to publish a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice of the proposed collection of information in a future issue of the **Federal Register**.

**III. Comments**

Interested persons may submit either electronic comments regarding the draft guidance 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>.

**IV. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

Dated: November 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

**[Docket No. FDA-2013-N-1306]**

**International Medical Device Regulators Forum; Medical Device Single Audit Program International Coalition Pilot Program; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing participation in the Medical Device Single Audit Program International Coalition Pilot Program. The Medical

Device Single Audit Program (MDSAP) was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the diverse international regulatory requirements of medical devices quality management systems and other specific regulatory requirements of the regulatory authorities participating in the pilot program. FDA will be participating in the MDSAP and will accept the resulting audit reports as a substitute for routine Agency inspections.

**ADDRESSES:** Submit electronic comments on the MDSAP International Coalition Pilot Program 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:**

Kimberly A. Trautman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5400, Silver Spring, MD 20993-0002, 301-796-5515, [Kimberly.Trautman@fda.hhs.gov](mailto:Kimberly.Trautman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

The International Medical Device Regulators Forum (IMDRF) was conceived in 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world, which includes FDA, who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices. The purpose of the IMDRF is to accelerate international medical device regulatory harmonization and convergence. See <http://www.imdrf.org/>.

The IMDRF recognizes the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices. The IMDRF, at its inaugural meeting in Singapore in 2012, identified a Work Group (WG) to develop specific documents for advancing the concept of the MDSAP. See <http://www.imdrf.org/>.

This global approach opens possibilities and pathways to support the development of an international initiative of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an

international scale in a pilot program starting in January 2014. The international partners for the MDSAP pilot, Therapeutic Goods Administration of Australia, Brazil's Agência Nacional de Vigilância Sanitária, Health Canada, FDA, and Japan's Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency, are official observers and active participants in the pilot program's Regulatory Authority Council and subject matter expert groups.

The mission of the participants in the MDSAP International Coalition is to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers. The development of the MDSAP includes the use of third party auditors, much like some current regulatory audit programs, as well as regulatory inspectorates. Recognizing the increasingly global nature and number of medical device manufacturers, the use of third party auditors in addition to regulatory authority inspectorates, allows greater coverage in auditing manufacturers as opposed to relying solely on the government resources of individual countries. The government resources can then be focused on high risk or problematic medical devices, manufacturers that are not in compliance with the regulations, and oversight of the third party auditing organizations. The MDSAP Pilot is intended to allow MDSAP-recognized auditing organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot.

The regulatory authorities involved in the pilot will base their recognition and assessment process on the following final IMDRF MDSAP documents:

- IMDRF MDSAP WG N3—“Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition;”
- IMDRF MDSAP WG N4—“Competence and Training Requirements for Auditing Organizations;”
- IMDRF MDSAP WG N5—“Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations;” and
- IMDRF MDSAP WG N6—“Regulatory Authority Assessor Competency and Training Requirements.”

Each of these documents was proposed in draft by the IMDRF and comments were solicited. IMDRF is in the process of revising these documents based on comments received. The IMDRF MDSAP Working Group has submitted the four proposed final documents for the IMDRF Management Committee meeting in Brussels on November 12 to 14, 2013.

The proposed drafts for each document are not available during the revision process. When final, these documents will be available on the IMDRF Web site (see <http://www.imdrf.org/>).

In addition, the MDSAP International Coalition has also developed several documents in order to implement the pilot. As documents are finalized by the MDSAP International Coalition Regulatory Authority Council, the documents will be posted on FDA's Web site.

The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the requirements of medical devices. FDA will accept the MDSAP audit reports as a substitute for routine Agency inspections. Inspections conducted “For Cause” or “Compliance Followup” by FDA will not be affected by this program. Moreover, this MDSAP Pilot would not apply to any necessary preapproval or postapproval inspections for Premarket Approval (PMA) applications or to decisions under section 513(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

### III. Electronic Access

Additional information on the IMDRF MDSAP can be found at: <http://www.imdrf.org/> and at <http://www.fda.gov/MedicalDevices/>.

### V. Comments

Interested persons may submit either electronic comments regarding the MDSAP International Coalition Pilot Program 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>.

Dated: November 8, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–N–1038]

### Over-the-Counter Ophthalmic Drug Products—Emergency Use Eyewash Products; Rescheduling of Public Hearing

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

**ACTION:** Notice; rescheduling of public hearing.

**SUMMARY:** The Food and Drug Administration (FDA) is rescheduling a December 4, 2013, public hearing to obtain information on the formulation, manufacturing, and labeling of currently marketed over-the-counter (OTC) emergency use eyewash products, announced in the **Federal Register** of Wednesday, September 18, 2013. Based on a request received by the Agency, we are rescheduling the public hearing to March 7, 2014, and updating the related procedural dates that appeared in the September 18, 2013, notice.

**DATES:** The public hearing will be held on March 7, 2014, from 9 a.m. to 5 p.m. Submit electronic or written requests to make oral presentations and comments by February 14, 2014. If you wish to attend the hearing or make an oral presentation during the hearing, you must register by submitting an electronic request to [CDEREYEWASHMEETING@fda.hhs.gov](mailto:CDEREYEWASHMEETING@fda.hhs.gov) by close of business on February 14, 2014. For those unable to attend in person, FDA will provide a Webcast to the meeting; additional information about the Webcast location will be posted on the Web page at <http://www.fda.gov/Drugs/NewsEvents/ucm356526.htm> prior to March 7, 2014. Electronic or written comments will be accepted after the hearing until June 6, 2014.

**FOR FURTHER INFORMATION CONTACT:** Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–3519, FAX: 301–847–8753, [mary.gross@fda.hhs.gov](mailto:mary.gross@fda.hhs.gov); or Elaine Abraham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire