

Dated: March 12, 2014.

**Peter Lurie,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0373]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On December 30, 2013, the Agency submitted a proposed collection of information entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910-0541. The approval expires on February 28, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

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**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0223]

#### Humanitarian Device Exemption: Questions and Answers; Draft Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff; Availability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 "Humanitarian Device Exemption (HDE): Questions and Answers." This draft guidance answers commonly asked questions about humanitarian use devices (HUDs) and HDE applications. This guidance document reflects changes to the HDE program as a result of the Food and Drug Administration Safety and Innovation Act (FDASIA). 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 June 16, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Humanitarian Device Exemption (HDE): Questions and Answers" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. 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:

Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION

##### I. Background

This draft guidance answers commonly asked questions about HUDs and HDE applications authorized under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)). Section 613 of FDASIA (Pub. L. 112-144), signed into law on July 9, 2012, amended section 520(m) of the FD&C Act. This draft guidance document reflects the changes in the HDE program as a result of FDASIA. Upon issuance as a final guidance document, this guidance will replace the existing HDE guidance entitled "Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff—Humanitarian Device Exemption Regulation: Questions and Answers," issued on July 8, 2010, which was developed and issued prior to the enactment of FDASIA.

HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit), except in certain circumstances. FDASIA expands the types of HDE-approved HUDs that are eligible to be sold for profit, subject to restrictions in section 520(m)(6) of the FD&C Act.

FDASIA also amends the definition of the annual distribution number (ADN). Under section 520(m)(6) of the FD&C Act, if FDA makes a determination that a HUD meets certain conditions, the HUD is permitted to be sold for profit after receiving HDE approval as long as the number of devices distributed in any

calendar year does not exceed the ADN that FDA determines for the device.

## 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 commonly asked questions about HUDs and HDE applications. 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 "Humanitarian Device Exemption (HDE): Questions and Answers," 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 1816 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft 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 sections 520(m) and 515A (21 U.S.C. 360e-1) of the FD&C Act and 613(b) of FDASIA have been approved under OMB control number 0910-0661; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437; 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 part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A, B, and C have been approved under OMB control number 0910-0231; the collections of

information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0755; 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 814, subpart H have been approved under OMB control number 0910-0332; and the collections of information in 21 CFR 10.30 have been approved under OMB control number 0910-0183.

## V. Comments

Interested persons may submit either electronic comments regarding this document 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: March 12, 2014.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0204]

#### Draft Guidance for Industry on Bioavailability and Bioequivalence Studies Submitted in New Drug Applications or Investigational New Drug Applications—General Considerations; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations" (draft BA and BE guidance for NDAs). The draft guidance provides recommendations to sponsors and/or applicants planning to include bioavailability (BA) and bioequivalence (BE) information for drug products in investigational new drug applications (INDs), new drug applications (NDAs), and NDA supplements. This draft guidance revises those parts of the

March 2003 guidance entitled "Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations" relating to BA and BE studies for INDs, NDAs, and NDA supplements.

**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 written or electronic comments on the draft guidance by May 19, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

**FOR FURTHER INFORMATION CONTACT:** Dakshina Chilukuri, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 3177, Silver Spring, MD 20993-0002, 301-796-5008, or [OCP@fda.hhs.gov](mailto:OCP@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance entitled "Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations." The draft guidance provides recommendations to sponsors and/or applicants planning to include BA and BE information for drug products in INDs, NDAs, and NDA supplements. The draft guidance is applicable to orally administered drug products and may also be applicable to non-orally administered drug products when reliance on systemic exposure measures is suitable to document BA and BE (e.g., transdermal delivery systems and certain rectal and nasal drug products). The guidance should be helpful for applicants conducting BA and BE studies during the IND period for an NDA and also for applicants conducting BE studies during the postapproval period for certain changes to drug products that are the subject of