

Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance emphasizes considerations of both safety and quality risk management in establishing levels of mutagenic impurities that are expected to pose negligible carcinogenic risk. It outlines recommendations for assessment and control of mutagenic impurities that reside or are reasonably expected to reside in a final drug substance or product, taking into consideration the intended conditions of human use. The guidance is intended to provide guidance for new drug substances and new drug products during their clinical development and subsequent applications for marketing.

**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 Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. 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 to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* Aisar Atrakchi, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, Rm. 4118, Silver Spring, MD 20993-0002, 301-796-1036.

*Regarding the ICH:* Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1174, Rockville, MD 20993-0002, 301-796-8377.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of April 15, 2013 (72 FR 22269), FDA published a notice announcing the availability of a draft guidance entitled "M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk." The notice gave interested persons an opportunity to submit comments by June 14, 2013. Changes made to the guidance took into consideration written comments received. Minor editorial changes were made to improve clarity.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three

participating regulatory agencies in June 2014.

The guidance provides guidance on the regulation of genotoxic impurities in new drug substances and drug products.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance 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.

**II. 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>.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: May 20, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-D-2065]

**Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period**

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

**ACTION:** Notice; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for an additional 30 days, for the notice of availability

entitled "Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability", published in the **Federal Register** of December 30, 2014. In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is reopening and extending the comment period on the draft guidance. Submit either electronic or written comments by June 29, 2015.

**ADDRESSES:** An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Radiation Biodosimetry Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

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:** Jennifer Dickey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5262, Silver Spring, MD 20993-0002, 301-796-5028.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of December 30, 2014 (79 FR 78448), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry and FDA staff entitled "Radiation Biodosimetry Devices".

The Agency received a request for an extension of the comment period for the draft guidance (Docket No. FDA-2014-D-2065-0005). The request conveyed concern that the current 90-day comment period does not allow sufficient time to respond. FDA has considered the request and is reopening and extending the comment period for

the draft guidance for 30 days. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this guidance document.

**II. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Radiation Biodosimetry Devices" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1400045 to identify the guidance you are requesting.

**III. 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: May 21, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0918]

**Pediatric Studies of Meropenem Conducted in Accordance With the Public Health Service Act; Availability of Summary Report and Requested Labeling Changes**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a summary report of the pediatric studies

of meropenem conducted in accordance with the Public Health Service Act (the PHS Act) and is making available requested labeling changes for meropenem. The Agency is making this information available consistent with the PHS Act.

**FOR FURTHER INFORMATION CONTACT:** Lori Gorski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6415, Silver Spring, MD 20993-0002, 301-796-2200, FAX: 301-796-9855, email: [lori.gorski@fda.hhs.gov](mailto:lori.gorski@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Meropenem Summary Review**

In the **Federal Register** of August 13, 2003 (68 FR 48402), meropenem was identified as a drug that needed further study in pediatrics. The approved labeling lacked adequate information on dosing, pharmacokinetic, tolerability, and safety data in newborns and young infants with complicated intra-abdominal infections.

A written request for pediatric studies of meropenem was issued on September 10, 2004, to AstraZeneca Pharmaceuticals, the holder of the new drug application (NDA) for meropenem. FDA did not receive a response to the written request. Accordingly, the National Institutes of Health (NIH) issued a request for proposals to conduct the pediatric studies described in the written request on August 15, 2005, and awarded funds to Duke University and Stanford University on September 28, 2007, to complete the studies described in the written request.

On completion of the studies, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) submitted a final clinical study report for meropenem to FDA for review under investigational new drug application (IND) 101043: (NICHD-2005-18) "A Multiple Dose PK Study of Meropenem In Young Infants (less than 91 days of age) With Suspected or Complicated Intra-abdominal Infections."

In the **Federal Register** of February 27, 2012 (77 FR 11556), FDA announced the opening on February 17, 2012, of docket FDA-2011-N-0918 for submission of data from pediatric studies of meropenem. The data submitted to the docket by NIH were submitted in accordance with section 409I of the PHS Act (42 U.S.C. 284m) and were the same data submitted to IND 101043, with the exception that personal privacy information had been redacted from the data submitted to the docket.