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; CBER 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In the Federal Register of April 15, 2013 (72 FR 22269), FDA published a notice announcing the availability of a draft guidance entitled “M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.”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


Dated: May 20, 2015.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2015–12752 Filed 5–27–15; 8:45 am]

BILLING CODE 4164–01–P
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.

ADDITIONAL INFORMATION: 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 (see ADDRESSES). It is only necessary to submit one set of comments. 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, 301–796–9850, email: lori.gorski@fda.hhs.gov.

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 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.

[FR Doc. 2015–12854 Filed 5–27–15; 8:45 am]

BILLING CODE 4164–01–P

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.

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.