

entitled "Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability", published in the **Federal Register** of December 30, 2014. In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments.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DATES: FDA is reopening and extending the comment period on the draft guidance.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 Submit written requests for a single hard copy of the draft guidance document entitled "Radiation Biodosimetry Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological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Submit electronic comments on the draft guidance to 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of December 30, 2014 (79 FR 78448), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry and FDA staff entitled "Radiation Biodosimetry Devices".

The Agency received a request for an extension of the comment period for the draft guidance (Docket No. FDA-2014-D-2065-0005).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the draft guidance for 30 days.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 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.

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.

The meropenem docket remained opened for public comment from February 27, 2012, until March 28, 2012. There were no comments submitted to the docket during that time. The key findings of this final clinical study report are:

The submitted study was an open-label, non-comparative, multicenter, prospective, multiple pharmacokinetic (PK) and safety study in infants less than 91 days of age. The study enrolled 200 infants with a median postnatal age of 21 days (range 1 to 92 days) and a median gestation age (GA) of 27.8 weeks (range 22.5 to 40 weeks). Infants with complicated intra-abdominal infections who were receiving meropenem based on local standard of care were eligible for enrollment. Complicated intra-abdominal infections were defined per the protocol as physical, radiologic, or bacteriologic findings of complicated intra-abdominal infection to include peritonitis, necrotizing enterocolitis (NEC) grade II or higher by Bell's criteria, Hirschsprung's disease with perforation, spontaneous perforation, meconium ileus with perforation, bowel obstruction with perforation, as evidenced by free peritoneal air on abdominal radiograph, intestinal pneumatosis, or portal venous gas on abdominal radiographic examination, or possible NEC.

The study was not statistically powered to establish efficacy because the Division of Anti-Infective Products agreed that extrapolation of efficacy to pediatric populations from adult populations was acceptable. However, clinical efficacy endpoints were also evaluated. The efficacy assessment included a comparison of the clinical status at study baseline and at day 28 or after a minimum of 7 days of treatment, using a combination of an assessment using the Score for Neonatal Acute Physiology II tool and other protocol specified outcome criteria. The clinical endpoint was defined as the patient being alive, with negative bacterial cultures from a sterile body fluid, and a presumptive clinical cure. Clinical failure was defined as death, change in antibiotic therapy while on study drug, or lack of presumptive clinical cure. The addition of treatment directed against Gram-positive pathogens from a non-abdominal source was not considered to represent treatment failure. Using these criteria, 195/200 patients or 97.5 percent were considered to have achieved the clinical endpoint. Of the 195 patients included in the efficacy population, 192 (98.5 percent) were evaluated for efficacy. The overall efficacy success rate for the study was 84.4 percent (95

percent confidence interval, 78.5 to 89.2 percent).

Analysis of safety was a primary objective of the study. The following assessments were included in the study: Monitoring for adverse events, serious adverse events, and death; documentation of seizures; acute abdominal complications; development of resistant bacterial infection or candidiasis; treatment failure; physical examination; clinical laboratory values; cultures from sterile sites, and concomitant medications. There were 11 deaths in the study; all occurred in patients less than 32 weeks GA. The most common cause of death was multi-organ failure. None of the deaths were related to meropenem administration. The following adverse events occurred with a frequency in the study that differed from that seen in previous pediatric and adult studies: Convulsion (seizures), 5 percent, hyperbilirubinemia, 4.5 percent and vomiting, 2.5 percent. Study oversight included a safety committee and an independent data safety monitoring board.

The Division of Anti-Infective Products agreed that meropenem was well-tolerated in the pediatric population enrolled in the study. Of the 10 patients with seizures, 8 patients were adjudicated to have developed seizures possibly due to the study medication. Because cerebrospinal fluid was only evaluated in a limited number of patients with seizures, it is not possible to determine if the seizure threshold may have changed due to possible underlying meningitis and the administration of meropenem.

II. Recommendation

This study supports the use of meropenem in neonates and infants less than 91 days of age for complicated intra-abdominal infections. However, infants with complicated intra-abdominal infections are anticipated to have different physiological characteristics than patients with meningitis that may impact the PK of meropenem; as such, it may not be appropriate to apply the PK findings from this population to a patient population with meningitis. The Division recommended that the evaluation of meropenem in infants less than 91 days of age be limited to the treatment of complicated intra-abdominal infections at this time.

FDA's requested labeling changes, including dosing recommendations for the use of meropenem in neonates and infants less than 91 days of age for complicated intra-abdominal infections, are available on the FDA Web site at

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm379088.htm> and in the docket (Ref. 1).

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-2015-N-0012]

Molecular Characterization of Multiple Myeloma Black/African Ancestry Disparity

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the efforts of the Center for Drug Evaluation and Research (CDER). FDA is announcing its intent to accept and consider a single-source application for the award of a grant to the Multiple Myeloma Service of Memorial Sloan Kettering Cancer Institute. The goal of the cooperative agreement between CDER and the Multiple Myeloma Service of Memorial Sloan Kettering Cancer Institute is to support the development of appropriate methodologies to conduct clinical trial design evaluation and determine extrapolation of findings from the general population to the U.S. Black population.

DATES: Important dates are as follows:

1. The application due date is July 20, 2015.
2. The anticipated start date is August 2015.
3. The opening date is May 18, 2015.
4. The expiration date is July 21, 2015.

ADDRESSES: Submit electronic applications to: <http://www.Grants.gov>. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Dickran Kazandjian, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2320, Silver Spring, MD 20993-0002, 240-402-5272; or Vieda Hubbard, Division of Acquisition Support and Grants (HFA-500), Food and Drug