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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on commonly asked questions about HUDs and HDE applications.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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet.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* 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This draft guidance refers to previously approved collections of information found in FDA regulations.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.

[FR Doc. 2014–05900 Filed 3–17–14; 8:45 am]

BILLING CODE 4160–01–P

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.*

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

an NDA. This guidance document is not intended to provide recommendations on studies conducted in support of demonstrating comparability or biosimilarity for biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

Studies to measure BA and/or establish BE of a product are important elements in support of INDs, NDAs, and NDA supplements. BA means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action (21 CFR 320.1(a)). BA data provide an estimate of the fraction of the drug absorbed, as well as provide information related to the pharmacokinetics of the drug. BA for orally administered drug products can be documented by a systemic exposure profile obtained by measuring concentrations of active ingredients and/or active moieties over time and, when appropriate, active metabolites over time in samples collected from the systemic circulation as compared to that of a suitable reference.

BE means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study (21 CFR 320.1(e)). Studies to establish BE between two products are important for certain formulation or manufacturing changes occurring during the drug development and postapproval stages. In BE studies, the systemic exposure profile of a test drug product is compared to that of a reference drug product.

In the **Federal Register** of March 19, 2003 (68 FR 13316), FDA announced the availability of a final guidance entitled ''Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations'' (March 2003 BA and BE guidance). Since the March 2003 guidance was issued, FDA has determined that separating guidances according to application type will be beneficial to sponsors. Thus, FDA is issuing this draft BA and BE guidance for NDAs, and has also issued a draft guidance entitled ''Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA'' (draft BE guidance for ANDAs) (December 5, 2013; 78 FR 73199). This draft BA and BE guidance for NDAs revises those parts of the March 2003 BA and BE guidance relating to BA and BE studies for INDs, NDAs, and NDA supplements. This draft guidance also provides additional information in the section on modified-release products, and adds new sections including the following topics: (1) Concomitant administration of drug products and combination drug products, (2) alcoholic beverage effects on modified-release dosage forms, (3) endogenous substances, and (4) drug products with high intrasubject variability. This draft guidance should be useful for applicants planning to conduct BA and/or BE studies during the IND period for submissions to an NDA, and BA and BE studies conducted in the postapproval period for certain changes in NDAs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on conducting BA and BE studies for INDs and NDAs. 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 requirement 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 collection of information submitted under 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910–0014. The collection of information submitted under 21 CFR part 314 (new drug applications) has been approved under OMB control number 0910–0001.

IV. Electronic Access

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

Dated: March 12, 2014.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2014–05849 Filed 3–17–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of April 2014.

The National Advisory Committee on Rural Health will convene its seventy fifth meeting in the time and place specified below:

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Time: April 28, 2014, 8:45 a.m.–5:30 p.m. April 29, 2014, 9:00 a.m.–5:00 p.m. April 30, 2014, 8:30 a.m.–10:30 a.m.

Place: University of Nebraska Medical Center, Michael F. Sorrell Center for Health Science Education, 649 South 42nd Street, Omaha, NE 68105, (402) 559–8550.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services (the Committee) provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Monday morning, at 8:45 a.m., the meeting will be called to order by the Chairperson of the Committee: the Honorable Ronnie Musgrove. The Committee will assess how rural residents are served by the new insurance coverage opportunities afforded by the Affordable Care Act. The Committee will also examine the issue of rural homelessness. The day will conclude with a period of public comment at approximately 5:00 p.m.

Tuesday morning at approximately 9:00 a.m., the Committee will break into Subcommittees and depart for site visits to health care and human services' providers in Iowa and Nebraska. One panel from the Health Subcommittee will visit Nemaha County Hospital in Auburn, Nebraska. Another panel from the Health Subcommittee will visit Myrtue Medical Center in Harlan, Iowa. The Human Services Subcommittee will visit the Northeast Nebraska Community Action Partnership, in Fremont, Nebraska. The day will conclude at the Sorrell Center for Health Science Education with a period