and reported by SLHs participating in ACL-funded Model Approaches projects will be comparable from one SLH to another and apply standard/uniform terminology consistently across Model Approaches projects. The consistent and uniform data will be used to illustrate the effectiveness of Model Approaches states in reaching key target populations under the OAA with much needed ''priority'' legal assistance through SLHs. The data collected will also inform and drive ongoing ACL policy related to increasing the number of states that have a SLH as a sustained, and permanent feature of integrated and cost effective legal service delivery systems targeted to those most in need. Anticipated data collection and reporting requirements would apply to SLHs operating as lead partners in 2014 Model Approaches Phase I and Phase II, with a total of 11 SLHs operational during the 3 year project period.

ACL estimates the burden of this collection of information as follows: 11 SLHs would be asked to respond annually pursuant to data collection tools that should require an average burden of 2.5 hours per SLH per year or a total 27.5 hours for all complying SLHs operating under Model Approaches projects. The proposed data collection tools may be found on the CERA Web site for review at: *http://www.legalhotlines.org/uploads/1/6/9/1/16912868/reportingguidelinesforseniorlegalhelplines.pdf.*

Dated: July 31, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014–18463 Filed 8–4–14; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1161]

Design Considerations for Devices Intended for Home Use; Guidance for Industry 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 guidance entitled ''Design Considerations for Devices Intended for Home Use.'' This document is intended to assist manufacturers in designing and developing home use medical devices that comply with applicable standards of safety and effectiveness and other regulatory requirements. Devices used in the home or other non-clinical environments are associated with unique risks created by the interactions among the user (often a layperson), the use environment, and the device. This document identifies several factors that manufacturers should consider, especially during device design and development, and provides recommendations for minimizing these unique risks.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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 guidance document entitled ''Design Considerations for Devices Intended for Home Use'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Alternatively, you may submit written requests for single copies of the guidance to 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 the office that you are ordering from to assist that office in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For information concerning the guidance as it relates to devices regulated by CDRH:* Mary Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5426, Silver Spring, MD 20993–0002, 301–796–6089.

For information concerning the guidance as it relates to devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

For a variety of reasons, use of devices outside professional healthcare facilities is on the rise. First, the U.S. population is aging, and the elderly are more likely to live with chronic diseases that require daily medical care at home. Second, due to medical advancements, many individuals with chronic diseases are living longer but are dependent on home medical care. Finally, an increasing focus on reducing healthcare costs for patients of all ages has spurred the growth of the home health care market. Integral to the home health care market are home use devices. Although home use devices provide significant benefits to patients and families, including quality of life improvements and cost savings, they are also associated with unique risks. Minimizing the risks posed by home use devices can greatly improve the public health.

This guidance provides recommendations for designing and developing medical devices intended for home use through considerations involving the physical environment, the user, the device or system, the labeling, and human factors. This should result in a safe and easier-to-use device, minimize use error, and reduce the likelihood that adverse events will occur. The recommendations in the guidance apply to both prescription and over-the-counter medical devices that are intended for use in the home or other non-clinical environments.

In the **Federal Register** of December 13, 2012 (77 FR 74195), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by March 13, 2013. FDA reviewed the comments and revised the guidance as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on design considerations for devices intended for home use. 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 guidance may do so by downloading an electronic copy from 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.* Persons unable to download an electronic copy of ''Design Considerations for Devices Intended for Home Use'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1750 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to currently 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 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; 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 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in Form FDA 3500A have been approved under OMB control number 0910–0291.

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: July 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18470 Filed 8–4–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1165]

Draft Guidance for Industry on Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the Public Health Service Act; 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 ''Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act.'' This draft guidance is intended to assist sponsors developing biological products, sponsors holding biologics license applications (BLAs), and other interested parties in providing information and data that will help the Agency determine the date of first licensure for a reference product under 351(k)(7)(C) of the Public Health Service Act (PHS Act), as added by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act amends the PHS Act and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product.

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 October 6, 2014. Submit either electronic or written comments concerning the proposed collection of information by October 6, 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, or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, 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 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: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act.'' This draft guidance is intended to assist sponsors who are developing biological products, sponsors of BLAs, and other interested parties in providing information that will help the Agency determine the date of first licensure for a reference product under 351(k)(7)(C) of the Public Health Service Act (PHS Act) as added by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

The BPCI Act amends the PHS Act and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). Section 351(k)(7) of the PHS Act, entitled ''Exclusivity for Reference Product,'' describes reference product exclusivity, the period of time in which a 351(k) sponsor is not permitted to submit and FDA is not permitted to license a 351(k) application that references a reference product, the single biological product licensed under section 351(a) of the PHS Act against which a biological product is evaluated in a 351(k) application. Under this section, exclusivity for the reference product is described in terms