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*.

IV. Electronic Access

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

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20235 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1176]

Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the document that appeared in the **Federal Register** of May 19, 2015. In the document, FDA requested comments on draft guidance for industry (GFI) #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published May 19, 2015 (80 FR 28624). Submit either electronic or written comments on the draft guidance by November 16, 2015.

ADDRESSES: You may submit comments by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written comments in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2015–D–1176. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Division of Compliance, Center for Veterinary Medicine, Food and Drug Administration (HFV–230), 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, *CVMCompliance@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 19, 2015, FDA published a document with a 90-day comment period for draft GFI #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' The draft guidance describes FDA's policies with regard to compounding animal drugs from bulk drug substances. When final, the guidance will reflect FDA's current thinking on the issues addressed by the guidance.

FDA has received a request for a 90-day extension of the comment period. 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 extending the comment period for 90 days, until November 16, 2015. FDA believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this guidance document.

II. Specific Topics for Comment

In addition to comments on the draft guidance as written, we are specifically requesting comments on the following issues:

- Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable (*e.g.,* disruptions in the manufacture or supply chain; business decisions to stop marketing the drug; drug is subject to Agency action based on safety, effectiveness, or manufacturing concerns)? If so:
  - How should these situations be addressed in the final guidance?
  - How should the final guidance define the terms ''shortage'' and ''unavailable''?
  - What criteria should FDA use to determine if an approved animal or human drug is in shortage or otherwise unavailable?
- Do United States Pharmacopeia and National Formulary (USP–NF) [1] chapters 795 and 797 provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?
- Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a State-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?
- Should the final guidance include a condition on the amount or percentage of compounded animal drugs that a pharmacy or outsourcing facility can ship in interstate commerce? If so, what would a reasonable amount be?
- Is additional guidance needed to address the repackaging of drugs for animal use?
  - How widespread is the practice of repackaging drugs for animal use?
  - What types of drugs are repackaged for animal use, and why are they repackaged?
  - Have problems been identified with repackaged drugs for animal use?
- Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under section 512(a)(4) or (a)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(a)(4) and (a)(5)) and 21 CFR part 530?
- Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?

[1] Chapters <795> ''Pharmaceutical Compounding—Nonsterile Preparations'' and <797> ''Pharmaceutical Compounding—Sterile Preparations'' can be found in both the *USP Compounding Compendium* and the combined *United States Pharmacopeia and National Formulary (USP–NF).* These compendia are available at *http://www.usp.org/*.

• As one condition under which FDA does not generally intend to take action for certain violations of the FD&C Act if this and the other conditions are followed, FDA is proposing that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from bulk drug substances to FDA within 15 days of becoming aware of the product defect or serious adverse event. Outsourcing facilities are required to report adverse events associated with the drugs they compound. FDA believes it is important to receive this information from State-licensed pharmacies and veterinarians because there are no other State Departments of Health or Federal Agencies (*e.g.,* the Centers for Disease Control and Prevention) charged with identifying and tracing animal injuries or disease associated with an animal drug compounded by these entities. FDA has the following specific questions with respect to this proposed condition:

○ How many State-licensed pharmacies and veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to FDA?

○ Are State-licensed pharmacies and veterinarians reporting the same or similar information to any State regulatory agency (*e.g.,* State boards of pharmacy, State boards of veterinary medicine)? If so, how many reports on average does each State-licensed pharmacy and veterinarian submit to these State agencies each year?

○ For purposes of the guidance, how should FDA define the terms ''product defect'' and ''serious adverse event?''

○ Can FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from a bulk drug substance through means other than product defect and serious adverse event reporting, and if so, what other means? For example, would reports of product defects alone achieve the same objective?

III. Request for 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm* or *http://www.regulations.gov.*

Dated: August 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20174 Filed 8–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2734]

Physiological Closed-Loop Controlled Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Physiological Closed-Loop Controlled (PCLC) Devices.'' The topic to be discussed is challenges related to the design, development, and evaluation of critical care PCLC devices. FDA considers PCLC devices an emerging technology and aims to hold a workshop focusing on design, development and performance evaluation of PCLC systems intended for use in critical care environments. Such devices include closed-loop anesthetic delivery, closed-loop vasoactive drug and fluid delivery, and closed-loop mechanical ventilation.

Dates and Times: The public workshop will be held on October 13 and 14, 2015, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Rm. 1503 (The Great Room), Silver Spring, MD 20993.

Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Bahram Parvinian, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2534, Silver Spring, MD 20993, 301–796–6445, email: *Bahram.Parvinian@fda.hhs.gov;* and Allison Kumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5402, Silver Spring, MD 20993, 301–796–6369, email: *Allison.Kumar@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., October 1, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Office of Communication and Education (OCE), Center for Devices and Radiological Health, Food and Drug Administration, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than September 29, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 4 p.m., October 1, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 7, 2015. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has