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*.

IV. Electronic Access

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

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20228 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–2818]

Rare Diseases: Common Issues in Drug Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Rare Diseases: Common Issues in Drug Development.'' The purpose of this draft guidance is to advance and facilitate the development of drugs and biologics to treat rare diseases. Drug development for rare diseases has many challenges related to the nature of these diseases. This draft guidance is intended to assist sponsors of drug and biological products for treating rare diseases in conducting more efficient and successful development programs.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 16, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Office of Communication, Outreach, and Development, 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: Jonathan Goldsmith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6480, Silver Spring, MD 20903–0002, 240–402–9959; or 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

FDA is announcing the availability of a draft guidance for industry entitled ''Rare Diseases: Common Issues in Drug Development.'' This guidance is intended to assist sponsors of drug and biological products for treating rare diseases in conducting more efficient and successful development programs through a discussion of selected issues commonly encountered in rare disease drug development. Although these issues are encountered in other drug development programs, they are frequently more difficult to address in the context of a rare disease than a common disease for which there is greater and more widespread medical experience. These issues are also more acute with increasing rarity of the disorder. A rare disease is defined by the Orphan Drug Act as a disorder or condition that affects less than 200,000 persons in the United States; however, most rare diseases affect far fewer persons.

Most rare disorders are serious conditions with no approved treatments, and rare disease patients have considerable unmet medical needs. Collectively, rare diseases are highly diverse. FDA is committed to helping sponsors of drugs for rare diseases create successful programs that address the particular challenges posed by each disease.

This guidance addresses the following important components of drug development:

- Adequate description and understanding of the disease's natural history
- Adequate understanding of the pathophysiology of the disease and the drug's proposed mechanism of action
- Nonclinical pharmacotoxicology considerations to support the proposed clinical investigation(s)
- Standard of evidence to establish safety and effectiveness
- Drug manufacturing considerations during drug development

Early consideration of these issues allows sponsors to efficiently and adequately address them during the course of drug development, from drug discovery to confirmatory efficacy and safety studies, and to have productive meetings with FDA.

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 current thinking of FDA on common issues in drug development for rare diseases. 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. The Paperwork Reduction Act of 1995

This 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 collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

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*.

IV. Electronic Access

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

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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/*.