4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1196]

List of Bulk Drug Substances That May Be Used by an Outsourcing Facility to Compound Drugs for Use in Animals; Extension of Nomination Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of nomination period.

SUMMARY: The Food and Drug Administration (FDA) is extending the nomination period for the notice that appeared in the Federal Register of May 19, 2015. In the notice, FDA requested nominations for a list of bulk drug substances that may be used by facilities registered as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to compound animal drugs from bulk substances, in accordance with FDA's draft guidance for industry (GIF) #230, "Compounding Animal Drugs from Bulk Drug Substances." The FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit nominations.

DATES: Submit either electronic or written nominations for the bulk drug substances list by November 16, 2015.

ADDRESSES: You may submit nominations by any of the following methods:

Electronic Submissions

Submit electronic nominations in the following way:

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

Written Submissions

Submit written nominations 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-N-1196. All nominations received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting nominations, see the "Request for Nominations" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or nominations 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: Neal Bataller, Center for Veterinary Medicine, Food and Drug Administration (HFV-210), 7519 Standish Pl., Rockville, MD 20855, 240-402-5745, neal.bataller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of May 19, 2015 (80 FR 28622), FDA published a notice with a 90-day nomination period for the list of bulk drug substances that may be used by a facility registered as an outsourcing facility under section 503B of the FD&C Act (21 U.S.C. 353B) to

compound drugs for use in animals in accordance with FDA's draft GFI #230, "Compounding Animal Drugs from Bulk Drug Substances." That notice describes the information that should be provided to the FDA in support of each nomination.

FDA has received a request for a 90-day extension of the nomination period as the requestor wanted more time to nominate drugs to the list and to provide supporting data. FDA has considered the request and is extending the nomination period for 90 days, until November 16, 2015. The FDA believes that a 90-day extension allows adequate time for interested persons to submit nominations without significantly delaying consideration of these nominations.

II. Nomination Process

The process for nominations for bulk drug substances that may be used by facilities registered as outsourcing facilities under section 503B of the FD&C Act to compound animal drugs from bulk drug substances is described in the previous notice published May 19, 2015. FDA cannot guarantee that all drugs nominated during the nomination period will be considered for initial inclusion in Appendix A at the time of its initial publication. Nominations submitted during the nomination period (ending on November 16, 2015) that are not evaluated and included in Appendix A at the time of its initial publication will receive consideration for later addition to Appendix A. In addition, individuals and organizations may petition FDA, in accordance with 21 CFR 10.30, to make additional amendments to Appendix A after the nomination period.

III. Request for Nominations

Interested persons may submit either electronic nominations to http://www.regulations.gov or written nominations to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of nominations. Identify nominations with

the docket number found in brackets in the heading of this document. Received nominations 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 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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