DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–E–0264; FDA–2013–E–0263; and FDA–2013–E–0218]

Determination of Regulatory Review Period for Purposes of Patent Extension; RECUVYRA; Affirmation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of affirmation.

DATES: August 23, 2017

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, 301–796–9148.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is affirming the signature date for a notice that appeared in the **Federal Register** on August 21, 2017 (82 FR 39587). The document announced FDA's determination for the regulatory review period for RECUVYRA. The document published with an incorrect date for the signature. We affirm that the document was signed on August 15, 2017.

Dated: August 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17961 Filed 8–21–17; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1248]

Oncology Drugs for Companion Animals; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry #237 entitled ''Oncology Drugs for Companion Animals.'' The guidance provides recommendations for sponsors of investigational oncology drugs for use in companion animals (*e.g.,* dogs, cats, and horses), discusses the contents of a new animal drug application for certain oncology drugs, and provides recommendations on how to address human user safety concerns.

DATES: The announcement of the guidance is published in the **Federal Register** on August 23, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1248 for ''Oncology Drugs for Companion Animals.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Christopher Loss, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., Rm. N310, Rockville, MD 20855, 240–402–0619, *christopher.loss@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 10, 2016 (81 FR 37605), FDA published the notice of availability for a draft guidance entitled ''Oncology Drugs for Companion Animals'' giving interested persons until August 9, 2016, to comment on the draft guidance. FDA