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

received no comments on the draft guidance. The guidance announced in this notice finalizes the draft guidance dated June 2015.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on oncology drugs for companion animals. 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. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously 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 514.1 and 514.8 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: August 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17855 Filed 8–22–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0804; FDA–2013–N–1163; FDA–2013–N–1393; FDA–2017–N–0084; FDA–2013–N–0731; FDA–2009–D–0008; FDA–2013–N–0868; FDA–2013–D–0117; FDA–2016–N–2066; FDA–2017–N–0366]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Premarket Notification Submission 510(k), Subpart E	0910–0120	6/30/2020
Institutional Review Boards	0910–0130	6/30/2020
Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions	0910–0233	6/30/2020
Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))	0910–0471	6/30/2020
Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products	0910–0543	6/30/2020
Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act	0910–0679	6/30/2020
Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion	0910–0681	6/30/2020
Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act	0910–0762	6/30/2020
Certification of Identity for Freedom of Information Act and Privacy Act Requests	0910–0832	6/30/2020
FDA Advisory Committee Membership Nominations	0910–0833	6/30/2020

Dated: August 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17871 Filed 8–22–17; 8:45 am]

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