Protection of Human Subjects and Institutional Review Boards

OMB Control Number 0910–0130—Revision

This information collection supports FDA regulations governing requirements for informed consent and IRBs that are intended to protect the rights and safety of human subjects involved in FDA-regulated clinical investigations (parts 50 and 56 (21 CFR parts 50 and 56)). A ''clinical investigation'' is any experiment that involves a test article and one or more human subjects and is subject to requirements for prior submission to FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i) or 360j(g)), or is not subject to requirements for prior submission to FDA under these sections of the FD&C Act, but the results of which are intended to be submitted later to, or held for inspection by, FDA as part of an application for a research or marketing permit (§ 50.3).

Under § 50.54, FDA will accept IRB referrals of clinical investigations involving children as subjects that are not otherwise approvable by an IRB under part 50 subpart D. The collections of information in parts 50 and 56 are currently approved under OMB control number 0910–0130; however, the submission of records to FDA as part of an IRB referral under § 50.54, as recommended in the draft guidance document, is not called for in the regulations themselves. We are therefore revising the information collection to include submissions of records to the Agency that may occur under § 50.54. Based on a review of Agency data regarding the frequency of IRB referrals under § 50.54, we expect that fewer than one such submission would be made annually. The records that the draft guidance recommends be sent to FDA as part of an IRB's referral are records that are kept by IRBs in the ordinary course of their business, and where necessary, information collections related to the creation and retention of these documents are already approved under OMB control number 0910–0130. We assume that no more than 1 hour would be needed to complete the task of transmitting this existing information to FDA in accordance with the draft guidance recommendations. We invite comment on our estimate and assumptions.

This draft guidance also refers to previously approved collections of information by HHS' OHRP under OMB control numbers 0990–0481 and 0990–0260. Specifically, on February 14, 2022, OMB approved the collection of information identified with the OMB control number 0990–0481 without change. The approved collection of information consists of a requirement that IRB records be submitted when an IRB or its institution request an HHS consultation process for proposed research involving, respectively: (1) pregnant women, human fetuses or neonates; (2) prisoners; or (3) children, as subjects that are not otherwise approvable by an IRB.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.regulations.gov.*

Dated: March 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06649 Filed 3–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0606]

Infectious Otitis Externa Drugs for Topical Use in Dogs; Draft 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 draft guidance for industry (GFI) #281 entitled ''Infectious Otitis Externa Drugs for Topical Use in Dogs.'' This draft guidance provides recommendations to help sponsors complete the effectiveness, target animal safety, and labeling technical sections of a new animal drug application (NADA) for infectious otitis externa drugs for topical use in dogs.

DATES: Submit either electronic or written comments on the draft guidance by May 30, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2023–D–0606 for ''Infectious Otitis Externa Drugs for Topical Use in Dogs.'' 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, 7500 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lea Cranford, Center for Veterinary Medicine (HFV–118), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0615, *lea.cranford@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #281 entitled ''Infectious Otitis Externa Drugs for Topical Use in Dogs.'' This draft guidance provides recommendations to help sponsors complete the effectiveness, target animal safety, and labeling technical sections of an NADA for infectious otitis externa drugs for topical use in dogs.

This level 1 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 ''Infectious Otitis Externa Drugs for Topical Use in Dogs.'' 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. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06380 Filed 3–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2613]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by May 1, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0686. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Advertising

OMB Control Number 0910–0686—Revision

This information collection supports FDA implementation of Agency regulations and associated guidance. Section 502(n) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352(n)) requires that manufacturers, packers, and distributors (firms) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. FDA's prescription drug advertising regulations in § 202.1 (21 CFR 202.1) describe requirements and standards for print and broadcast advertisements. Section 202.1 applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements