DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2474]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Designated New Animal Drugs for Minor Use and Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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.

DATES: Submit written comments (including recommendations) on the collection of information by February 6, 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 0910–0605. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species—21 CFR Part 516

OMB Control Number 0910–0605—Extension

The Federal Food, Drug, and Cosmetic Act authorizes FDA to implement regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species (21 U.S.C. 360ccc). This statutory authority provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors who have had their drugs designated by FDA under section 573 of the Minor Use and Minor Species Animal Health Act of 2004 (Pub. L. 108–282) (MUMS Act). Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species, for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees.

MUMS-drug designation is completely optional for drug sponsors. The associated reporting only applies to those sponsors who request and are subsequently granted MUMS-drug designation status. Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS-drug designation as well as the annual reporting requirements for MUMS designees. Sponsors use FDA's ''eSubmitter'' system to fill out a series of system generated screens to submit their request and annual report electronically. To access the ''eSubmitter'' system, sponsors will use a previously established account. Additional information about this system is available on our website at: *https://www.fda.gov/industry/fda-esubmitter.*

Description of Respondents: The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

In the **Federal Register** of August 1, 2022 (87 FR 46961), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.20; content and format of MUMS-drug designation request	5	2	10	16	160
516.26; requirements for amending MUMS-drug designation	3	1	3	2	6
516.27; change in sponsorship of MUMS-drug designation	1	1	1	1	1
516.29; termination of MUMS-drug designation	2	1	2	1	2
516.30; requirements of annual reports from sponsor(s) of MUMS-designated drugs	26	2	52	2	104
516.36; consequences for insufficient quantities of MUMS-designated drugs	1	1	1	3	3
Total					276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection reflects an overall adjustment decrease of 88 responses and 1,086 burden hours. Upon further review since publication of the 60-day notice, we determined that the number of respondents for new designation requests decreased (from 15 to 5 respondents) due to changes in industry, while the number of respondents for annual reports increased (from 15 to 26 respondents), due to an increase in the number of sponsors holding active MUMS designations since the last renewal of this collection. We also decreased the

number of responses per respondent for both the new designation request and the annual report (from five to two), based on our experience over the last 3 years.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00015 Filed 1–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

DoNation Campaign Collaboration Projects

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: HRSA's Health Systems Bureau (HSB), Division of Transplantation (DoT) solicits requests from non-federal public and private sector organizations and entities who wish to collaborate on the DoNation Campaign. DoNation collaboration projects will involve executing a series of activities that elevate the benefits and importance of organ, eye, and tissue donation and increase organ donor registrations among the public with a focus on individuals from diverse racial and ethnic backgrounds. Potential collaborating organizations must have demonstrated interest in and experience with coordinating activities that address key public health issues, be capable of managing the day-to-day operations associated with the proposed activity(ies), and be willing to participate substantively in the execution of the proposed activity(ies), not just providing funding or logistical support.

DATES: A request to participate as a collaborating organization must be received via email or postmarked mail at the addresses listed below by 5 p.m. EST on Tuesday, January 31, 2023.

ADDRESSES: Proposals for DoNation Campaign collaborations may be submitted via email to *DoNation@hrsa.gov*. Proposals may also be sent to Frank Holloman, Director, DoT; 5600 Fishers Lane; Rockville, MD 20852. Requests will meet the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date. Private metered postmarks will not be accepted as proof of timely mailing. Hand-delivered requests must be received by 5 p.m. EST on Tuesday, January 31, 2023. Requests that are received after the deadline will be returned to the sender.

FOR FURTHER INFORMATION CONTACT: Lauren Darensbourg, DoT, HSB, HRSA; 5600 Fishers Lane, Rockville, MD 20852; Telephone (301) 443–3737. Email: *DoNation@hrsa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Division of Transplantation (DOT), within HRSA's Heath Systems Bureau, is the primary federal entity responsible for oversight of the nation's organ and blood stem cell transplant systems and the implementation of programs and initiatives that increase organ and blood stem cell donations in the United States. DoT's mission is to protect public health and extend and enhance the lives of individuals with end-stage organ failure for whom an organ transplant is the most appropriate therapeutic treatment. DoT, on behalf of the Secretary of Health and Human Services, is authorized under 42 U.S.C. 274f–1(a) to establish a public education program on organ donation and the need for more organ donors. Specifically, the authority provides, ''[t]he Secretary shall, directly or through grants or contracts, establish a public education program in cooperation with existing national public awareness campaigns to increase awareness about organ donation and the need to provide for an adequate rate of such donations.''

The DoNation Campaign is an initiative of DoT with the goal of improving awareness about the importance of organ donation and transplantation as well as increasing organ donor registrations from the public, especially among those in racially and ethnically diverse communities. The DoNation Campaign recruits and engages workplaces of all sizes and across all industries in efforts to educate their employees and communities about organ, eye, and tissue donation and to encourage organ donor registration. The DoNation Campaign was built on the foundation of DoT's Workplace Partnership for Life Hospital Campaign, which encouraged thousands of hospitals and workplaces to educate and register more than 630,000 people as organ donors since 2011.

Requirements of the Collaboration

DoT is seeking organizations capable of managing the development and execution of activities (such as campaign amplification and workplace recruitment) and identifying ways to enhance campaign activities and participation. Approved proposals will require a co-sponsorship agreement signed by both participants that outlines the terms and parameters of the collaboration. The co-sponsorship will be in place for a period of 1 year from the date at which it bears all parties' signatures. No funding will be provided by DoT for any organization's involvement in this collaboration other than sharing existing layouts and files of relevant DoNation Campaign materials and the staff time needed to carry out activities in the co-sponsorship agreement.

DoNation Campaign Projects

Proposed DoNation Campaign projects will develop and implement activities that amplify the availability of the DoNation Campaign; recruit workplaces to participate in the campaign; and encourage organ, eye, and tissue donor registration. The collaborating organization shall help promote the DoNation Campaign through outreach activities that may include using social media, exhibiting at conferences or speaking at events, and recognizing campaign partners throughout the campaign and at the conclusion of the campaign year. The collaborating organization shall identify and recommend ways to enhance the delivery and outreach of the DoNation Campaign. Upon signing the above-referenced co-sponsorship agreement, and as long as the activation/activity meets all requirements, DoT will grant collaborating organizations the use of its DoNation-branded materials to promote the project and will highlight the collaboration via its digital and social media platforms, as deemed appropriate. Use of DoNation-branded materials should not imply any federal endorsement of the collaborating organization's general policies, activities, or products.

Eligibility for Collaborating Organizations

To be eligible, a requester shall: (1) have a demonstrated interest in, understanding of, and experience with managing the development and execution of programs, or other activities related to addressing key public health issues; (2) participate substantively in the proposed DoNation Campaign project (not just provide funding or logistical support); (3) demonstrate an organizational commitment and/or focus to increasing the number of registered organ, eye, and tissue donors in the United States; (4) demonstrate a willingness and ability to