E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2023-0103; FRL-10689-01-OCSPP]

Modernizing the Approach to the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Oversight of Certain Products; Notice of Public Meeting and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA)'s Office of Chemical Safety and Pollution Prevention (OCSPP) is co-hosting a virtual public meeting with the U.S. Food and Drug Administration (FDA)'s Center of Veterinary Medicine (CVM) on March 22, 2023. Additionally, EPA has opened a docket for the agencies to receive public comment on their current approach to the oversight of various products regulated as either pesticides by EPA or new animal drugs by FDA, with a focus on parasite treatment products applied topically to animals and in genetically engineered pest animals for use as pest control tools. The agencies are also announcing the availability of and soliciting comment on a document entitled, "WHITEPAPER: A Modern Approach to EPA and FDA Product Oversight" that describes the current challenges and highlights the potential benefits of a modernized approach for oversight of these products. EPA and FDA are considering how best to update their respective oversight responsibilities for specific products in an efficient and transparent manner and in alignment with each agency's expertise, with the goal of improving protection of human, animal, and environmental health. The purpose of the public comment period and virtual public meeting is to obtain feedback from stakeholders on the whitepaper and ideas for modernizing EPA and FDA's approach to product oversight.

DATES: *Virtual Public Meeting*: March 22, 2023, from 1:00 PM to 4:00 PM (EDT). Registration to attend the virtual public meeting is required on or before March 15, 2023. See the

additional details and instructions for registration that appear in Unit III.

Written Comments: Submit your comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. As described in Unit III., you may also register to make oral comments during the virtual public meeting.

Special accommodations: Requests for special accommodations should be submitted as instructed under **ADDRESSES** on or before March 15, 2023, to allow EPA and FDA time to process these requests.

ADDRESSES: *Virtual Public Meeting*: You must register online to receive the webcast meeting link and audio teleconference information on or before the date set in the **DATES** section. Please follow the registration instructions that is available through a link on the Office of Pesticide Programs (OPP) website available at: *https://www.epa.gov/pesticides*. For additional instructions, see Unit III.

Written Comments: Submit written comments, identified by docket identification (ID) No. EPA-HQ-OPP-2023-0103, through the Federal eRulemaking Portal at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not electronically submit any information you consider Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

Special accommodations: For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact Paul Di Salvo, listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Paul Di Salvo, Office of Chemical Safety and Pollution Prevention, Registration Division (7505T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-2597; email address: *disalvo.paul@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This notice is directed to the general public and may be of specific interest to persons (e.g., industry, non-governmental organizations (NGOs), animal owners, veterinarians, and academia) who are or may be interested in regulation of parasite treatment products applied topically to animals or in genetically engineered pest animals for use as pest control tools. Because other entities may also be interested in this notice, the agencies have not attempted to describe all entities that may be interested in this subject.

B. Where can I access information about this meeting?

Information about this meeting is available through a link on the OPP website available at: *https://www.epa.gov/pesticides*. Supporting materials are available in the docket for this meeting, identified by docket ID No. EPA-HQ-OPP-2023-0103, at *https://www.regulations.gov*.

C. What should I consider as I prepare my comments?

1. *Submitting CBI*. Do not submit CBI information through *https://www.regulations.gov* or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the individual listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see Tips for Effective Comments at *https://www.epa.gov/dockets*.

II. Background

A. Why are EPA and FDA hosting this public meeting and soliciting public comment?

Currently, EPA and FDA determine regulatory oversight of pesticides and new animal drugs based on the rationale described in a Memorandum of Understanding (MOU) between the agencies signed in 1971 and revised in 1973. Since that time, pesticide and animal drug technologies—and both agencies' understanding of these technologies—have evolved.

For example, parasite treatment products applied topically to animals generally are regulated by EPA if they remain on the skin to control only external parasites (e.g., fleas, ticks) and by FDA if they are absorbed systemically into the bloodstream to control internal parasites (e.g., intestinal worms). The agencies now understand that many of the topically administered products currently regulated by EPA do not remain on the skin and are actually absorbed into the bloodstream, highlighting challenges with the current approach and raising different safety concerns than originally anticipated.

Additionally, genetically engineered ("GE") pest animals, which are gaining interest as a pest control tool, were not envisioned 50 years ago when the original regulatory approach was developed. As agreed in the 2016 National Strategy for Modernizing the Regulatory System for Biotechnology Products, EPA and FDA have considered how to update their respective responsibilities with the goal of developing an efficient, transparent, and predictable approach for overseeing GE insects. Recently, Executive Order 14081, issued September 12, 2022, has further directed the agencies to improve the clarity and efficiency of the regulatory process for biotechnology products, underscoring the need for continued coordination between the agencies on biotechnology.

The agencies' current approach to determining whether EPA or FDA is the appropriate regulator of certain products does not effectively reflect or accommodate scientific advancement, and it has become clear in some cases that the current approach has resulted in misalignment between product characteristics and the agency better equipped to regulate the product. A modernized approach would ensure that the oversight of these products better aligns with each agency's expertise, accounts for scientific advancement, avoids redundancy, better protects animal health and safety, and improves regulatory clarity for regulated entities, animal owners, veterinarians, and other stakeholders.

Additional information on each of these key areas is provided in the whitepaper in the docket.

B. What feedback do EPA and FDA hope to gain from the public meeting and comments?

The virtual public meeting will focus on the whitepaper and the following questions. We are not seeking input or comments about any specific products, other federal agencies' product oversight, or other topics outside the scope of the whitepaper and the questions below. We are particularly interested in receiving comments from the public on the following:

1. What do you perceive as the strengths and weaknesses of each agency in regulating these types of products?

2. Are there additional or different challenges that EPA and FDA did not identify in the whitepaper?

3. How can EPA and FDA communicate with their stakeholders about the regulation of these products in a clearer and more transparent manner?

4. For regulated entities, how have you historically determined which agency to approach first to bring your product to market?

5. For consumers, do you know who is regulating the products you use on your animal(s)? If you have a concern or complaint about a specific product, do you know which agency to contact?

6. How should EPA and FDA modify product oversight to better align with each agency's mission and expertise?

7. What difficulties would you envision if EPA and FDA were to modify product oversight to better align with each agency's mission and expertise, and how could they be mitigated?

C. How are EPA and FDA seeking public comments?

EPA and FDA are seeking public comments through several planned activities including:

• Through this *Federal Register* document, EPA is announcing that it is co-hosting a virtual public meeting with FDA on the date identified in **DATES** to seek input from stakeholders on the agencies' current approaches to the oversight of various products regulated

as either pesticides by EPA or new animal drugs by FDA. The agenda and instructions for registration for this meeting are available through a link on the OPP website available at: *https://www.epa.gov/pesticides*.

• EPA and FDA are announcing the availability of and are soliciting comment on the whitepaper and the questions posed in Unit II.B.

• Following the public meeting and the close of the comment period, EPA and FDA will consider comments received in determining next steps.

D. How can I access the documents?

The whitepaper is available in the docket at *https://www.regulations.gov*; identified as docket ID No. EPA-HQ-OPP-2023-0103. In addition, EPA and FDA may include additional background documents in the docket as the materials become available.

III. Public Participation Instructions

To participate in the virtual public meeting, please follow the instructions in this unit.

A. How can I provide comments?

To ensure proper receipt of comments, it is imperative that you identify docket ID No. EPA-HQ-OPP-2023-0103 in the subject line on the first page of your comments.

1. *Written comments*. You are encouraged to provide written comments that are submitted using the instructions in **ADDRESSES** and Unit I.B. and C., on or before the date set in the **DATES** section.

2. *Oral comments*. If you want to make brief oral comments during the virtual public meeting, please indicate this interest during registration for the virtual public meeting on or before March 15, 2023. Please follow the registration instructions available through a link on the OPP website available at: *https://www.epa.gov/pesticides.*

After the agencies receive all registrations for oral comments, they will determine the amount of time to allot to each commenter and email that information to all commenters.

B. How can I participate in the virtual public meeting?

This meeting is virtual and will occur via webcast. For information on how to register and then view the webcast, please refer to the registration instructions available through a link on the OPP website available at: *https://www.epa.gov/pesticides*.

Authority: 7 U.S.C. 136 *et seq*.

Dated: February 17, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemicals Safety and Pollution Prevention.

[FR Doc. 2023-03739 Filed: 2/22/2023 8:45 am; Publication Date: 2/23/2023]