Contains Nonbinding Recommendations

#236

Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products

Guidance for Industry

This version of the guidance replaces the version made October 2017. This revision provides updated contact information.

Submit comments on this guidance at any time. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments on the guidance at https://www.regulations.gov/. All written comments should be identified with the Docket No. FDA-2016-D-4482.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and may be viewed on the Internet at either https://www.fda.gov/AnimalVeterinary/default.htm or https://www.regulations.gov/.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
August 2025

Table of Contents

Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides information for industry and other stakeholders regarding regulatory oversight of articles, including substances, for use in or on mosquitoes ("mosquito-related products"). We are providing this guidance to clarify circumstances under which such products are regulated by the Food and Drug Administration (FDA) as new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other circumstances under which such products are regulated by the Environmental Protection Agency (EPA) as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in the Agency's guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Both FDA and EPA regulate products intended for use in or on animals. FDA is charged with protecting the public health by, among other things, ensuring that animal drugs are safe and effective [21 U.S.C. §393(b)(2)(B)]; under FIFRA, EPA is charged with protecting human health and the environment by ensuring registered pesticide products, when used according to the label directions, result in no unreasonable adverse effects to man or the environment. [7 U.S.C. §136a(c)(5)].

A. New Animal Drugs

The FD&C Act defines the term "drug" as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." [21 U.S.C. §321(g)(1)]. With very limited exceptions for animal drugs that are generally recognized as safe and effective or are subject to a "grandfather" clause, the FD&C Act defines drugs that are intended for use for animals as "new animal drugs." As such, these drugs

are subject to applicable pre-market approval and/or other review requirements. [21 U.S.C. §321(v); 21 U.S.C. §360b; 21 U.S.C. §360ccc; 21 U.S.C. §360ccc-1].

B. Pesticides

FIFRA defines the term "pesticide" to mean, in part, "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest…except that the term 'Pesticide' shall not include any article that is a 'new animal drug' within the meaning of section 321([v]) of title 21…" [7 U.S.C. §136(u)]. Generally speaking, pesticides must be registered with EPA prior to distribution or sale, unless they are otherwise excluded or exempted from regulation (e.g., they meet the specific conditions or criteria in 40 CFR § 152.6; or they qualify for an exemption as, for instance, a minimum risk pesticide under 40 CFR § 152.25(f)).

III. DISCUSSION

A. Scope of Guidance

This guidance provides information for industry and other stakeholders regarding regulatory oversight of mosquito-related products. This guidance is important in light of the public health urgency of countering the spread of mosquito-borne disease, such as that caused by the Zika virus. Vector control is a critical element of the effort to combat the spread of mosquito-borne disease.[1] Novel mosquito control technologies have gained greater attention as an element of this effort; however, there has been some confusion with respect to FDA's and EPA's respective jurisdiction over such mosquito-related products.

Given the public health implications of mosquito control, FDA, working collaboratively with EPA, is providing this guidance to clarify the regulatory oversight of mosquito-related products, including but not limited to those produced through biotechnology.[2]

B. FDA and EPA Jurisdiction Over Mosquito-Related Products[3]

The FD&C Act's definition of "drug" includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21

---

[1] See "*A Strategy for Integrating Best Practices with New Science to Prevent Disease Transmission by Aedes Mosquito Vectors*," available online at: https://www.hsdl.org/?abstract&did=797520.

[2] We also note that FDA, EPA, and USDA have committed to clarifying how the U.S. Federal Government intends to regulate genetically engineered insects. *National Strategy for Modernizing the Regulatory System for Biotechnology Products*, released by the White House Office of Science and Technology Policy, September 16, 2016.

[3] Developers may need to comply with additional requirements for import or interstate movement of certain mosquito-related products, including those contained in mosquitoes. To ensure you are in compliance with applicable requirements, contact APHIS at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_contact_brs/ct_contact_brs; and CDC at https://www.cdc.gov/phpr/ipp/index.htm.

U.S.C. §321(g)(1). However, mosquitoes, which are animals, also fall within the FIFRA definition of "pest."[4]

FIFRA's definition of "pesticide" includes "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest" and "any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." 7 U.S.C. §136(u). Pesticide products for mosquitoes, which are intended to prevent, destroy, repel, or mitigate mosquitoes, necessarily affect the structure or function of the body of the mosquito.

Before 1975, FDA and EPA each had authority to regulate substances that controlled mosquito population if they met both the definition of "new animal drug" under the FD&C Act and the definition of "pesticide" under FIFRA. Because of concern that this dual jurisdiction created regulatory burden and confusion about which Agency had primary jurisdiction, Congress amended FIFRA's definition of "pesticide" in 1975 to exclude any article that is a "new animal drug" within the meaning of the FD&C Act. Since the FIFRA definition of pesticide was amended in 1975, EPA has registered, as pesticides, articles that control the population of mosquitoes by killing them or interfering with their reproduction, which is consistent with FDA's and EPA's general agreement that articles or categories of articles that control the population of mosquitoes are most appropriately regulated as pesticides. This general agreement arises from a careful consideration of Congressional intent.

Given this history, FDA is clarifying that the phrase "articles (other than food) intended to affect the structure or any function of the body of man or other animals" in the FD&C Act's drug definition [21 U.S.C. 321 (g)(1)(C)] does not include articles intended to function as pesticides by preventing, destroying, repelling, or mitigating mosquitoes for population control purposes. FDA believes that this interpretation is consistent with congressional intent and provides a rational approach for dividing responsibilities between FDA and EPA in regulating mosquito-related products.

1. Examples of New Animal Drugs – Regulated by FDA

a. Products intended to reduce the virus/pathogen load within a mosquito, including reduction in virus/pathogen replication and spread within the mosquito and/or reduction in virus/pathogen transmissibility from mosquitoes to humans.

b. Products intended to prevent mosquito-borne disease in humans or animals.

[4] FIFRA defines a "pest" broadly to include "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other animals)." 7 U.S.C. § 136(t). EPA's regulation at 40 CFR 152.5 expands in more specific detail on precisely what constitutes a pest for purposes of FIFRA.

2. Example of Pesticide Products – Regulated by EPA

Products intended to reduce the population of mosquitoes (for example, by killing them at some point in their life cycle, or by interfering with their reproduction or development).[5]

C. Guidance for Sponsors/Manufacturers of Products Intended for use in Mosquitoes

FDA encourages sponsors of mosquito-related products, other than those that are intended to prevent, destroy, repel, or mitigate mosquitoes by controlling a mosquito population, to contact FDA early in the development process. If a developer has a jurisdictional question, for example, which agency or agencies would have oversight of a mosquito-related product that is expressly intended for both mosquito population control and human disease suppression, the developer may contact either or both agencies via the contacts listed in section IV of this guidance. The agencies will consult with each other on the jurisdictional question, as is already common practice. The agencies may also suggest a joint meeting among EPA, FDA, and the sponsor to discuss appropriate pathways to market.

IV. CONTACT INFORMATION

If you have any questions about how this interpretation may affect your regulated products, or products you have under development, you should contact the following:

FDA: AskCVMBiotech@fda.hhs.gov

EPA: fifra-biotech-questions@epa.gov

[5] This is true whether the product is a traditional chemical product or involves a different technology (e.g., a recombinant DNA construct or bacteria intended to reduce the population of mosquitoes).