



February 21 2017

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
Submitted via Regulations.gov FDA-2016-D-4482-0001

Re: Regulation of Mosquito-Related Products; Draft Guidance for Industry; Availability  
[Docket ID No. FDA-2016-D-4482-0001] 82 Fed. Reg. 6574 (Jan. 19 2017).

To whom it may concern:

CropLife America (CLA) appreciates the opportunity to provide comment on the Food and Drug Administration (FDA or Agency)'s recent request for comment on the Regulation of Mosquito-Related Products; Draft Guidance for Industry; Availability; 82 Fed. Reg. 6574. Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all of the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners.

FDA has announced the availability of a draft guidance for industry (GFI) entitled, "Regulation of Mosquito-Related Products," which provides information for industry and other stakeholders regarding regulatory oversight of mosquito-related products. This guidance is intended to clarify regulatory oversight of mosquito-related products, including but not limited to those produced through biotechnology.

Under the Federal Insecticide, Fungicide and Rodenticide Act (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)].

FDA is clarifying that its interpretation 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 Federal Food, Drug and Cosmetic Act (FFDCA) 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.

**Representing the Crop Protection Industry**

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While the FFDCA defines “articles (other than food) intended to affect the structure or any function of the body of man or other animals” as new drugs, which would include mosquitoes, under FIFRA, mosquitoes also fall within the definition of a “pest.” Before 1975 FDA and EPA each had the authority to regulate substances that controlled the mosquito population if they met both the definition of ‘new animal drug’ under the FFDCA, and the definition of ‘pesticide’ under FIFRA. However, owing to the confusion caused by the joint jurisdiction, Congress amended the FIFRA definition of pesticide in 1975 to exclude any article that is a “new animal drug” within the meaning of the FFDCA. Since that time, EPA has registered, as pesticides, articles that control the population of mosquitoes by killing them or interfering with their reproduction, consistent with FDA and EPA’s general agreement that articles or categories of articles that control the population of mosquitoes are most appropriately regulated as pesticides.

Given this history, FDA intends to clarify that the phrase “articles (other than food) intended to affect the structure or any function of the body of man and other animals” in the FFDCA 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.

CLA strongly supports this move by FDA given EPA’s historic role in regulating pesticides under, FIFRA, as amended [7. U.S.C. 136-136y].

Should you have any questions or wish to discuss this matter further, please contact me directly by email [[jjcollins@croplifeamerica.org](mailto:jjcollins@croplifeamerica.org)] or telephone [+1-202-833-4474].

Thank you for your consideration of these comments.

Respectfully,



Janet E. Collins, Ph.D., R.D.  
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