

Review on the FDA-EPA's Technical Information on the Development of Fish Consumption Advice, available at <http://www.fda.gov/fishadvice> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

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Dated: January 11, 2017.

**Jeremy Sharp,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2016–D–4482]

#### Regulation of Mosquito-Related Products; Draft Guidance for Industry; Availability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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #236 entitled "Regulation of Mosquito-Related Products." This draft guidance provides information regarding regulatory oversight of mosquito-related products, defined as those articles for use in or on mosquitoes. We are clarifying circumstances under which such products are regulated by FDA as new animal drugs under the Federal Food, Drug, and Cosmetic Act (the 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).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 21, 2017.

**ADDRESSES:** You may submit comments 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):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–4482 for "Regulation of Mosquito-Related Products." 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **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 Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, 7519 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:** Laura R. Epstein, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-796-8558, [Laura.Epstein@fda.hhs.gov](mailto:Laura.Epstein@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry (GFI) #236 entitled “Regulation of Mosquito-Related Products.” This draft guidance provides information for industry and other stakeholders regarding regulatory oversight of mosquito-related products, defined as those articles for use in or on mosquitoes. Given the public health implications of mosquito control, FDA is providing this draft guidance to clarify the regulatory oversight of mosquito-related products, including but not limited to those produced through biotechnology. 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. 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. We are clarifying circumstances under which such products are regulated by FDA as new animal drugs under the FD&C Act and other circumstances under which such products are regulated by the EPA as pesticides under FIFRA. 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.

##### **II. Significance of Guidance**

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 Regulation of Mosquito-Related Products. 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.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: January 11, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2016-D-2285]

#### **Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling—Questions and Answers; 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 entitled “Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers.” This draft guidance provides information for manufacturers, packers, and distributors and their representatives (collectively “firms”) of drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs (collectively “medical products”), about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product. The Agency is issuing this draft guidance to explain FDA’s current thinking on commonly asked questions regarding such communications in order to provide clarity for firms.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2017.

**ADDRESSES:** You may submit comments 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