P140003) was initially submitted on March 20, 2014.

3. *The date the application was approved:* March 23, 2015. FDA has verified the applicant's claim that PMA P140003 was approved on March 23, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,796 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 29, 2017.

Anna K. Abram,

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

[FR Doc. 2017–21436 Filed 10–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4482]

Clarification of the Food and Drug Administration and Environmental Protection Agency Jurisdiction Over Mosquito-Related Products; 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 guidance for industry #236 entitled ''Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products.'' This 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 the Food and Drug Administration (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: The announcement of the guidance is published in the **Federal Register** on October 5, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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 Dockets Management Staff 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 Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 guidance document.

FOR FURTHER INFORMATION CONTACT: Laura R. Epstein, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–8558, *Laura.Epstein@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 19, 2017 (82 FR 6574), FDA published the notice of availability for a draft guidance entitled ''Regulation of Mosquito-Related Products'' giving interested persons until February 21, 2017, to comment on the draft guidance. FDA has finalized that draft guidance and is issuing final guidance entitled ''Clarification of FDA and EPA Jurisdiction over Mosquito-Related Products.'' This 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 guidance to clarify the regulatory jurisdiction 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 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.

FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Some comments on the draft guidance expressed confusion about how the intended use of a product can determine whether a product is a drug or a pesticide. The definition of ''drug'' in the FD&C Act depends upon the ''intended use'' of a product. A product is a drug if it is intended to do certain things (*i.e.,* if it is ''intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . .'' and ''to affect the structure or any function of the body . . .'' and for use as a component of such a product. (21 U.S.C. 321(g)(1)). Even when considering products subject only to the FD&C Act, the same product may be classified differently depending on the intended use. For example, an article that is intended to treat disease in an animal is an animal drug, while the same article if intended to control mold growth in animal feed could be a food additive (*i.e.,* a substance ''the intended use of which results . . . in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately been shown . . . to be safe. . . .''). Similarly, whether a product is a ''pesticide'' under FIFRA also depends upon intended use (''pesticide'' means, among other things, any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest). As a commenter pointed out, this means that the same product can be a drug when intended for one use (*i.e.,* diagnosing, curing, mitigating, treating, or preventing disease) and a pesticide when intended for another use (*i.e.,* preventing, destroying, repelling, or mitigating a pest). We have updated the guidance document in response to these comments (see section III.C. of the guidance document). We have also revised the title of the guidance document to better reflect the scope of the document.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Clarification of FDA and EPA Jurisdiction Over 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. This guidance clarifies regulatory jurisdiction and is not a significant regulatory action subject to Executive Order 12866. Because FDA is clarifying that the definition of ''drug'' in the FD&C Act does not include articles intended to function as pesticides by preventing, destroying, repelling, or mitigating mosquitoes for population control purposes, it is a deregulatory action on the part of FDA in that it clarifies that the manufacturers of such articles will no longer be subject to FDA's regulatory jurisdiction.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: October 2, 2017.

Anna K. Abram,

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

[FR Doc. 2017–21494 Filed 10–4–17; 8:45 am]

BILLING CODE 4164–01–P