

submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product, ENTYVIO (vedolizumab). ENTYVIO is indicated for adult ulcerative colitis and adult Crohn's disease. Subsequent to this approval, the USPTO received a patent term restoration application for ENTYVIO (U.S. Patent No. 7,147,851) from Millenium Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 6, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ENTYVIO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ENTYVIO is 5,066 days. Of this time, 4,731 days occurred during the testing phase of the regulatory review period, while 335 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 8, 2000. The applicant claims August 18, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 8, 2000, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* June 20, 2013. FDA has verified the applicant's claim that the biologics license application (BLA) for ENTYVIO (BLA 125476) was initially submitted on June 20, 2013.

3. *The date the application was approved:* May 20, 2014. FDA has verified the applicant's claim that BLA 125476 was approved on May 20, 2014.

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 1,526 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 ask for a redetermination (see **DATES**). Furthermore, 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 be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (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 <http://www.regulations.gov>, Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: September 12, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

### Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing a public workshop regarding "Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices (ASTs)." This public workshop is intended to facilitate discussion between drug sponsors and device manufacturers who

are planning to develop new antimicrobial drugs or ASTs and who wish to coordinate development of these products, such that the AST device could be cleared either at the time of new drug approval or shortly thereafter. The input from this public workshop will also help in developing topics for future discussion.

**DATES:** *Dates and Times:* The public workshop will be held on September 29, 2016, from 9 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

**ADDRESSES:** *Location:* The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's phone number is 301-589-0800.

### FOR FURTHER INFORMATION CONTACT:

*Contact Persons:* Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.

*Registration:* Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email your registration information (including name, title, firm name, address, telephone number, and fax number) to [AntimicrobialSusceptibilityTestingWorkshop2016@fda.hhs.gov](mailto:AntimicrobialSusceptibilityTestingWorkshop2016@fda.hhs.gov). Persons without access to the Internet can call 301-796-1300 to register.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see *Contact Persons* above) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** FDA is announcing a public workshop pertaining to the coordinated development of antimicrobial drugs and ASTs. Discussions will focus on assisting drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs or ASTs and who seek to coordinate development of these products.

The goals of the workshop are to: (1) Outline the regulatory considerations for submitting separate applications to the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health for antimicrobial drugs and ASTs, respectively; (2) identify the challenges related to obtaining data supporting the clearance of an AST device coincident with or soon after antimicrobial drug approval; and (3) discuss ideas for addressing these challenges.

The Agency encourages individuals, industry, device manufacturers, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop. Workshop updates will be made available on the internet at <http://www.fda.gov/Drugs/NewsEvents/ucm512519.htm>.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available either in hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm512519.htm> approximately 45 days after the workshop.

Dated: September 9, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2004-D-0045]

#### Waivers From the Requirement To Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles; Draft Revised 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 revised guidance for industry (GFI) #171 entitled "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." This draft revised guidance document describes how the Center for Veterinary Medicine (CVM) intends to evaluate requests for waiving the requirement for submitting data demonstrating the bioequivalence of animal drugs in soluble powder oral dosage form products and Type A medicated articles. It expands upon

CVM's Bioequivalence Guidance,<sup>1</sup> particularly the section on Criteria for Waiver of In Vivo Bioequivalence Study. This guidance is applicable to generic investigational new animal drug (JINAD) files and abbreviated new animal drug applications (ANADAs). Although the recommendations in this guidance reference generic drug applications, the general principles described may also be applicable to new animal drug applications (NADAs), investigational new animal drug (INAD) files, and supplemental NADAs.

**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 revised guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft revised guidance by November 15, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-2004-D-0045 for "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://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 <http://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 <http://www.regulations.gov> and insert the docket number, found in brackets in the

<sup>1</sup> CVM Guidance for Industry #35, "Bioequivalence Guidance," November 8, 2006 (see page 7): <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052363.pdf>.