

Dated: March 29, 2012.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0153]

#### Guidance for Industry and Food and Drug Administration Staff; Food and Drug Administration and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act." This guidance document establishes the procedures for the submission, FDA review, and FDA response to requests for information regarding the class in which a device has been classified.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8419. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Bob Gatling, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1640, Silver Spring, MD 20993-0002, 301-796-6560; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining FDA's views about the classification and the regulatory requirements that may be applicable to a particular device. This guidance describes procedures for the submission, FDA review, and FDA response to requests for information with respect to the classification of a device or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) requests for information. FDA's response to section 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

In the **Federal Register** of April 29, 2010 (75 FR 22599), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by July 28, 2010. No comments were received. The guidance announced in this notice finalizes the draft guidance of the same title.

Additionally, the FD&C Act, as amended by the FDA Amendments Act of 2007 (FDAAA) (Pub. L. 110-85), requires FDA to collect user fees for section 513(g) requests for information. Elsewhere in this issue of the **Federal Register**, FDA is publishing a document announcing the availability of a guidance entitled "Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information."

##### II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on procedures regarding section 513(g) requests. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive "Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act," you may either send an email request to [ds mica@fda.hhs.gov](mailto:ds mica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8419 to receive a hard copy. Please use the document number 1671 to identify the guidance you are requesting.

##### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection(s) of information in this guidance was approved under OMB control number 0910-0705.

This guidance also refers to currently approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; and the collections of information in 21 CFR 860.123 have been approved under OMB control number 0910-0138.

##### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is

only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 29, 2012.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2011-E-0245 and FDA-2011-E-0246]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; TEFLARO

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for TEFLARO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product. **ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's

regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product TEFLARO (ceftaroline fosamil). TEFLARO is indicated for the treatment of the following infections caused by designated susceptible bacteria: Acute bacterial skin and skin structure infections; and community-acquired bacterial pneumonia. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for TEFLARO (U.S. Patent Nos. 6,417,175 and 6,906,055) from Takeda Pharmaceutical Company Limited, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 8, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TEFLARO represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TEFLARO is 2,118 days. Of this time, 1,814 days occurred during the testing phase of the regulatory review period, while 304 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* January 12, 2005. FDA has verified the

applicant's claim that the date the investigational new drug application became effective was on January 12, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 30, 2009. FDA has verified the applicant's claim that the new drug application (NDA) for TEFLARO (NDA 200-327) was submitted on December 30, 2009.

3. *The date the application was approved:* October 29, 2010. FDA has verified the applicant's claim that NDA 200-327 was approved on October 29, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,049 days or 1,211 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 5, 2012. 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 by October 3, 2012. To meet its burden, the petition must 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on [www.regulations.gov](http://www.regulations.gov) may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 19, 2012.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

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