

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial 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 recently approved for marketing the human biologic product *STELARA* (ustekinumab). *STELARA* is indicated for treatment of adult patients with severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for *STELARA* (U.S. Patent No. 6,902,734 and 7,166,285) from Centocor Ortho Biotech Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 24, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of *STELARA* 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 *STELARA* is 3,165 days. Of this time, 2,498 days occurred during the testing phase of the regulatory review period, while 667 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:* January 27, 2001. The applicant claims December 28, 2000 as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was January 27, 2001, 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):* November 29, 2007. FDA has verified the applicant's claim that the biologics license application (BLA) for *STELARA* (BLA 125261/0) was initially submitted on November 29, 2007.

3. *The date the application was approved:* September 25, 2009. FDA has verified the applicant's claim that BLA 125261/0 was approved on September 25, 2009.

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 425 or 510 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 February 4, 2011. 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 June 6, 2011. 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. It is no longer necessary to send three copies of mailed 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 regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

**Jane A. Axelrad,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2009–E–0584]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; **BESIVANCE**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for *BESIVANCE* and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims 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 *BESIVANCE* (besifloxacin hydrochloride). *BESIVANCE* is indicated for treatment of bacterial conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for *BESIVANCE* (U.S. Patent No. 5,447,926) from Bausch & Lomb Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 10, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of *BESIVANCE* 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 *BESIVANCE* is 2,271 days. Of this time, 1,910 days occurred during the testing phase of the regulatory review period, while 361 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:* March 12, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 12, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 2, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for

*Besivance* (NDA 22-308) was submitted on June 2, 2008.

3. *The date the application was approved:* May 28, 2009. FDA has verified the applicant's claim that NDA 22-308 was approved on May 28, 2009.

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 application for patent extension, this applicant seeks 1,316 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 February 4, 2011. 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 June 6, 2011. 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. It is no longer necessary to send three copies of mailed 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 regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

**Jane A. Axelrad,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Oncologic Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Oncologic Drugs Advisory Committee.

*General Function of the Committee:*

To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 9, 2011, from 8 a.m. to 12:30 p.m.

*Location:* FDA White Oak Campus, Building 31 Conference Center, the Great Room (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must have a valid driver's license or other picture ID, and must enter through Building 1.

*Contact Person:* Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301 847-8533, e-mail: [Nicole.vesely@fda.hhs.gov](mailto:Nicole.vesely@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.