

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Food Code Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Respondents	75	4	300	1	300

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's experience and the number of updates received in the past 3 years. FDA estimates that 75 respondents will provide four quarterly updates each, resulting in an estimated 300 total annual responses. The agency estimates that each quarterly update will take about 1 hour. Of the 75 respondents, those who amend their regulations with changes unrelated to the risk factors and interventions, and those who are not adopting model FDA Food Code provisions, but are incorporating certain Conference for Food Protection recommendations only, will likely need only annual contact.

Dated: April 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-8510 Filed 4-13-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-E-0413]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for AFINITOR 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 written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**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 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 AFINITOR (everolimus). AFINITOR is indicated for treatment of patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AFINITOR (U.S. Patent No. 5,665,772) from Novartis AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 2, 2009, FDA

advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of AFINITOR 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 AFINITOR is 4,486 days. Of this time, 4,212 days occurred during the testing phase of the regulatory review period, while 274 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 act) (21 U.S.C. 355(i)) became effective:* December 19, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 19, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* June 30, 2008. FDA has verified the applicant's claim that the new drug application (NDA) 22-334 was submitted on June 30, 2008.

3. *The date the application was approved:* March 30, 2009. FDA has verified the applicant's claim that NDA 22-334 was approved on March 30, 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 1,826 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**) written or electronic comments and ask for a redetermination by June 14, 2010. 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 12, 2010. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 22, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010-8443 Filed 4-13-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2009-E-0230 and FDA-2009-E-0231]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for SAVELLA 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 written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**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 (Public Law 98-417) and the Generic Animal Drug and

Patent Term Restoration Act (Public Law 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 SAVELLA (milnacipran hydrochloride). SAVELLA is indicated for the management of fibromyalgia. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for SAVELLA (U.S. Patent Nos. 6,602,911 and 6,992,110) from Cypress Bioscience, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SAVELLA 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 SAVELLA is 2,571 days. Of this time, 2,177 days occurred during the testing phase of the regulatory review period, while 394 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 act) (21 U.S.C. 355(i)) became effective:* January 2, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 2, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* December 18, 2007. FDA has verified the applicant's claim that the new drug application (NDA) 22-256 was submitted on December 18, 2007.

3. *The date the application was approved:* January 14, 2009. FDA has verified the applicant's claim that NDA 22-256 was approved on January 14, 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 435 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) written or electronic comments and ask for a redetermination by June 14, 2010. 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 12, 2010. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 22, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010-8518 Filed 4-13-10; 8:45 am]

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FEB 17 2011

Food and Drug Administration  
Rockville, MD 20857

Re: Afinitor  
Docket No. FDA-2009-E-0413

The Honorable David J. Kappos  
Under Secretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the patent term extension application for U.S. Patent No. 5,665,772 filed by Novartis AG under 35 U.S.C. § 156. The patent claims Afinitor (everolimus), new drug application (NDA) 22-334.

In the April 14, 2010, issue of the Federal Register (75 Fed. Reg. 19406), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before October 12, 2010, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Gregory C. Houghton  
Novartis Pharmaceuticals Corp  
Patents Pharma  
One Health Plaza, Bldg. 101  
East Hanover, NJ 07936-1080



MAY 31 2011

Gregory C. Houghton  
Novartis Pharmaceuticals Corp.  
Patents Pharma  
One Health Plaza, Bldg. 101  
East Hanover, NJ 07936-1080

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,665,772

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,665,772, claims of which cover the human drug product AFINITOR® (everolimus), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 14, 2010 (75 Fed. Reg. 19406), would be 2,248 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}
\text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2} (\text{TP} - \text{PGTP})^1 \\
&= 4,486 - 265 - 0 - \frac{1}{2} (4,212 - 265) \\
&= 2,248 \text{ days (6.2 years)}
\end{aligned}$$

Since the regulatory review period began December 19, 1996, before the patent issued (September 9, 1997), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From December 19, 1996, to and including September 9, 1997, is 265 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation,

<sup>1</sup> Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of 1/2 (TP - PGTP).

because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,665,772
Granted:	September 9, 1997
Original Expiration Date <sup>2</sup> :	September 9, 2014
Applicant:	Sylvain Cottens et al.
Owner of Record:	Novartis AG
Title:	O-Alkylated Rapamycin Derivatives and Their Use, Particularly as Immunosuppressants
Product Trade Name:	AFINITOR® (everolimus)
Term Extended:	5 years
Expiration Date of Extension:	September 9, 2019.

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<sup>2</sup>Subject to the provisions of 35 U.S.C. § 41(b).

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