Basis Upon Which Winner Will Be Selected

Submissions to the Challenge will be assessed by an informed panel of judges of Injury Center program staff and external injury and violence professionals in compliance with the requirements of the America COMPETES Act. Judges will be named after the commencement of the Challenge. The judging panel will make decisions based on the following criteria:

(1) *Creativity:* Each entry will be judged on creative presentation of injury and violence prevention messages.

(2) *Use of Key Topics Message Boxes:* Key messages are provided for areas of Violence Prevention, Home and Recreational Safety, Motor Vehicle Safety, and Traumatic Brain Injury. One or more of the provided messages should be incorporated into the video, and be portrayed accurately.

(3) *Communication of Positive Injury and Violence Message:* Submissions will be judged on the expression of positive prevention injury and violence messages. The submissions should not show any acts of violence, profane language, inappropriate content, or personal or professional attacks.

(4) *Length of Video:* All submissions should be 90 seconds or less, and should use the required time to efficiently express the positive injury and violence prevention message.

(5) *Video and Audio Quality:* All types of videos will be accepted into the Challenge. However, effort to show quality content will be assessed.

Additional Information

Key injury and violence message boxes will be provided for use in each video on the topics of: Violence Prevention, Home and Recreational Safety, Motor Vehicle Safety, and Traumatic Brain Injury. More information on the topic areas can be found through *www.cdc.gov/injury.*

Regarding Copyright/Intellectual Property: Upon Submission, each Contestant warrants that he or she is the sole owner of the submission, that the Submission is wholly original with the Contestant and does not infringe on any copyright or any other rights of any third party of which the Contestant is aware.

Submission Rights: By participating in this Challenge, each Contestant grants to the CDC Injury Center an irrevocable, paid-up, royalty-free nonexclusive worldwide license to post, link to, share, and display publicly on the Web. All Contestants will retain all other intellectual property rights in their submissions.

Compliance With Rules and Contacting Contest Winners

Finalists and the Contest Winners must comply with all terms and conditions of these Official Rules, and winning is contingent upon fulfilling all requirements herein. The initial finalists will be notified by email, telephone, or mail after the date of the judging. Awards may be subject to Federal income taxes, and the Department of Health and Human Services will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Privacy

If Contestants choose to provide the CDC with personal information by registering or filling out the submission form through the Challenge.gov Web site, that information is used to respond to Contestants in matters regarding their submission, announcements of entrants, finalists, and winners of the Contest. Information is not collected for commercial marketing. Winners are permitted to cite that they won this contest.

General Conditions

The CDC reserves the right to cancel, suspend, and/or modify the Contest, or any part of it, for any reason, at CDC's sole discretion.

Participation in this Contest constitutes a contestant's full and unconditional agreement to abide by the Contest's Official Rules found at *www.Challenge.gov.*

Authority: 15 U.S.C. 3719

Dated: April 23, 2012.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2012–10548 Filed 5–1–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0663]

Determination of Regulatory Review Period for Purposes of Patent Extension; Alair Bronchial Thermoplasty System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Alair Bronchial Thermoplasty System 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 medical device.

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. 6284, 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Alair Bronchial Thermoplasty System. Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled

with inhaled corticosteroids and long-acting beta agonists. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Alair Bronchial Thermoplasty System (U.S. Patent No. 6,411,852) from Asthmatx, 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 February 17, 2011, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Alair Bronchial Thermoplasty System 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 Alair Bronchial Thermoplasty System is 1,743 days. Of this time, 1,259 days occurred during the testing phase of the regulatory review period, while 484 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* July 21, 2005. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective July 21, 2005.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* December 30, 2008. FDA has verified the applicant's claim that the premarket approval application (PMA) for Alair Bronchial Thermoplasty System (PMA P080032) was initially submitted December 30, 2008.

3. *The date the application was approved:* April 27, 2010. FDA has verified the applicant's claim that PMA P080032 was approved on April 27, 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 application for patent extension, this applicant seeks 1,114 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 *July 2, 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 24, 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 *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: April 16, 2012.

Jane A. Axelrad,

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

[FR Doc. 2012–10516 Filed 5–1–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–E–0333 and FDA–2010–E–0334]

Determination of Regulatory Review Period for Purposes of Patent Extension; KALBITOR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for KALBITOR 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 a patent which claims that human biological 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. 6284, 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 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 biological product KALBITOR (Ecallantide). KALBITOR is indicated for treatment of acute attacks of hereditary angioedema in patients 16 years of age and older. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for KALBITOR (U.S. Patent Nos. 5,795,685 and 7,276,480) from Dyax Corp., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In