

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention (CDC)****Announcement of Requirements and Registration for “Seeing My World through a Safer Lens: What Does Injury and Violence Look Like in My Community?” Video Contest**

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

Award Approving Official: Thomas R. Frieden, MD, MPH, Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry.

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) announces the launch of the *Seeing My World through a Safer Lens: What Does Injury and Violence Look Like in My Community?* video contest. The CDC National Center for Injury Prevention and Control (Injury Center) is reaching out to students, injury and violence professionals, and the general public throughout the United States to answer the question, “What does injury and violence prevention look like in my community?” Through the *Seeing My World through a Safer Lens* video contest, Contestants can create a short video that reflects injury and violence prevention activities that are in line with the Injury Center’s key topics and messages. This Challenge will raise awareness that, despite the fact that injuries and violence are serious public health issues, they are actually preventable. By having Contestants create personalized videos to submit to the video contest, we will show how proven prevention strategies are being implemented in various forms of communities. Further, by showcasing the winning videos in each category of submission (Student View, General Public View, and Injury and Violence Professional View), we will show that steps for injury and violence prevention can be taken by anyone and anywhere in the U.S.

DATES: Contestants can begin submission of videos on May 1, 2012, until the end of the submission period July 31, 2012. Judging will take place between August 1–31, 2012, and winners will be notified and prizes awarded September 10, 2012.

FOR FURTHER INFORMATION CONTACT: Rupal Mehta, National Center for Injury

Prevention and Control, Centers for Disease Control and Prevention, 4779 Buford Highway NE., Mailstop F–63, Atlanta, Georgia 30341, phone: 770–488–3984; email: Ien8@cdc.gov.

SUPPLEMENTARY INFORMATION:**Subject of Challenge Competition**

Entrants of the *Seeing My World through a Safer Lens* video contest will be asked to submit a short video that reflects how injury and violence prevention look like in their communities. Key prevention messages on Injury Center focus areas will be provided for inclusion in the videos. The videos should reflect positive prevention messaging and scenarios that students, injury and violence professionals, and the general public may face in their efforts to reduce injuries and violence where they live, work, study, or play.

Eligibility Rules for Participating in the Competition

The Challenge is open to any Contestant, defined as an individual or team of U.S. citizens or permanent residents of the United States who are 13 years of age or older (with the permission of a parent/guardian if under 18 years of age). Contestants may submit more than one entry if they have developed more than one video.

To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules promulgated by Centers for Disease Control and Prevention’s National Center for Injury Prevention and Control;

(2) Shall have complied with all the requirements under this section;

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States; and

(4) May not be a Federal entity or Federal employee acting within the scope of their employment. Federal employees seeking to participate in this contest outside the scope of their employment should consult their ethics official prior to developing their submission.

(5) May not be employees of the CDC Injury Center, judges of the Challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or their immediate family (spouse, parents or step-parents, siblings and step-siblings, and children and step-children).

(6) Shall not be an HHS employee working on their applications or submissions during assigned duty hours.

(7) Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

By participating in this Challenge, Contestants agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise. By participating in this Challenge, Contestants agree to indemnify the Federal Government against third party claims for damages arising from or related to Challenge activities.

Registration Process for Participants

The *Seeing My World through a Safer Lens* Challenge can be registered for through www.challenge.gov. Interested persons should read the official rules posted on the Challenge site, www.SaferLens.challenge.gov. Prior to entering a submission to the Challenge, Contestants must follow the Challenge before the end of the submission period.

Amount of the Prize

Each category of submission (Student View, Injury and Violence Professional View, and General Public View) shall be awarded ONE prize in the amount of \$500.00 after the notification of the winner.

Prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

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.

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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