annualized cost to respondents is estimated at $3,793.00. There are no capital costs to report. There are no operating or maintenance costs to report.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, *Attention:* Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection reports and instrument, contact Kathy Kranzfelder, Director, NIDDK Office of Communications and Public Liaison, Building 31, Room 9A06, MSC2560, Bethesda, MD 20852 or e-mail your request, including your address to: *KranzfelderK@mail.nih.gov.* To request more information on the proposed project or to obtain a copy of the data collection reports and instrument, contact Kathy Kranzfelder, Director, NIDDK Office of Communications and Public Liaison, Building 31, Room 9A06, MSC2560, Bethesda, MD 20852. You may also submit comment and data by electronic mail (e-mail) at *KranzfelderK@mail.nih.gov.*

Dated: June 14, 2010.

Lynell Nelson,

NIDDK Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–14793 Filed 6–17–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–E–0268 and FDA–2008–E–0267]

Determination of Regulatory Review Period for Purposes of Patent Extension; BYSTOLIC; U.S. Patent Nos. 5,759,580 and 6,545,040

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BYSTOLIC 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 drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. 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.

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 human drug product 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 BYSTOLIC (nebivolol hydrochloride). BYSTOLIC is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for BYSTOLIC (U.S. Patent Nos. 5,759,580 and 6,545,040) from Forest Laboratories, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibilities for patent term restoration. In a letter dated June 10, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BYSTOLIC 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 BYSTOLIC is 6,790 days. Of this time, 5,463 days occurred during the testing phase and 1,327 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (U.S.C. 355 (i)) involving this drug product became effective*: May 17, 1989. The applicant claims July 6, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND originally became effective on May 17, 1989, which was 30 days after FDA receipt of the original IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: April 30, 2004. The applicant claims April 29, 2004, as the date the new drug application (NDA) for BYSTOLIC (NDA 21–742) was initially submitted. However, FDA records indicate that NDA 21–742 was submitted on April 30, 2004.

3. The date the application was approved: December 17, 2007. FDA has verified the applicant's claim that NDA 21–742 was approved on December 17, 2007. 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 1,828 days of patent term extension for U.S. Patent No. 5,759,580 and 619 days of patent term extension for U.S. Patent No. 6,545,040.

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 August 17, 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 December 15, 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: May 10, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–14814 Filed 6–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control

Special Emphasis Panel (SEP): Cooperative Agreement Program for the National Academic Centers of Excellence in Youth Violence Prevention (U01), Funding Opportunity Announcement (FOA) CE10–004, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Times and Dates: 8 a.m.–5 p.m., July 22, 2010 (Closed). 8 a.m.–5 p.m., July 23, 2010 (Closed).

Place: Embassy Suites Atlanta—Buckhead, 3285 Peachtree Road, NE., Atlanta, Georgia 30305, Telephone: 404–261–7733.

Status: The meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Matters to be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Cooperative Agreement Program for the National Academic Centers of Excellence in Youth Violence Prevention (U01), FOA CE10–004."

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: J. Felix Rogers, Ph.D., M.P.H., NCIPC/ERPO, CDC, 4770 Buford Highway, NE., M/S F63, Atlanta, Georgia 30341–3724, Telephone (770) 488–4334. The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 10, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–14772 Filed 6–17–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0295]

Web-Based Public Meeting To Discuss Issues Related to the Development of an Enforcement Action Plan; Request for Data, Information, and Views

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Web-based public meeting; request for data, information, and views.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products is announcing that it is hosting a Web-based public meeting to discuss issues regarding the development of an enforcement action plan to enforce restrictions on promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities. FDA is seeking participation in the Web-based public meeting and data, information, and views from all interested parties, including, but not limited to, public health organizations, minority community groups and leaders, other stakeholders with demonstrated expertise and experience in serving minority communities, groups serving youth, patient groups, advertising agencies, the regulated industry, and other interested parties. This Web-based public meeting and the data, information, and views we receive are intended to help FDA in developing an enforcement action plan. FDA is seeking input on a number of specific issues, but is interested in other pertinent information as well.

DATES: The Web-based public meeting will be held on June 30, 2010, from 9 a.m. to 5 p.m. EDT. Persons interested in participating in the Web-based public meeting must submit written or electronic registration by close of business on June 23, 2010. Submit written and electronic data, information, and views by August 2, 2010.

ADDRESSES: Submit data, information, and views electronically to *http://www.regulations.gov*. Submit written data, information, and views to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic registration to *CTPCompliance@fda.hhs.gov*. Submit written registration to Anthony W. Lee, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Anthony W. Lee, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373, email: *AnthonyW.Lee@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111–31; 123 Stat. 1776) was enacted on June 22, 2009, providing FDA with the authority to regulate tobacco products in order to protect the public health generally and to reduce tobacco use by minors. Tobacco products are responsible for more than 440,000 deaths each year in the United States (Ref. 1). In enacting the Tobacco Control Act, Congress found, among other things, that the use of tobacco products by children is a pediatric disease and virtually all new users of tobacco products are under the minimum legal age to purchase such products (sections 2(1) and (4) of the Tobacco Control Act). Advertising, marketing, and promotion of tobacco products have been "especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth" (section 2(15) of the Tobacco Control Act).

Additionally, the rates of tobacco use and tobacco-related mortality are higher among certain racial and ethnic groups, including American Indian and Alaska Natives, and African-American men. As the National Cancer Institute (NCI) noted in Monograph 19, "[t]argeting of various population groups—including * * * specific racial and ethnic