**Medical Devices; Exception From General Requirements for Informed Consent—21 CFR 50.23 (OMB Control Number 0910–0586)—Extension**

In the **Federal Register** of June 7, 2006 (71 FR 32827), FDA issued an interim final rule (hereinafter referred to as the June 7, 2006, interim final rule) to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The agency took this action because it was concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

Section 50.23(e)(1) (21 CFR 50.23(e)(1)) provides an exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device. This exception will apply to those situations in which the in vitro investigational diagnostic device is used to prepare for and respond to a chemical, biological, radiological, or nuclear terrorism event or other public health emergency, if the investigator and an independent licensed physician make the determination and later certify in writing that: (1) There is a life-threatening situation necessitating the use of the investigational device; (2) obtaining informed consent from the subject is not feasible because there was no way to predict the need to use the investigational device when the specimen was collected and there is not sufficient time to obtain consent from the subject or the subject's legally authorized representative; and (3) no satisfactory alternative device is available. Under the June 7, 2006, interim final rule these determinations are made before the device is used, and the written certifications are made within 5 working days after the use of the device. If use of the device is necessary to preserve the life of the subject and there is not sufficient time to obtain the determination of the independent licensed physician in advance of using the investigational device, § 50.23(e)(2) provides that the certifications must be made within 5 working days of use of the device. In either case, the certifications are submitted to the Institutional Review Board (IRB) within 5 working days of the use of the device.

Section 50.23(e)(4) provides that an investigator must disclose the investigational status of the device and what is known about the performance characteristics of the device at the time test results are reported to the subject's health care provider and public health authorities, as applicable. Under the June 7, 2006, interim final rule, the investigator provides the IRB with the information required by § 50.25 (21 CFR 50.25) (except for the information described in § 50.25(a)(8)) and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED AVERAGE ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency of Responses | Total Annual Responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| 50.23(e)(1)(2) | 150 | 3 | 450 | 2 | 900 |
| 50.23(e)(4) | 150 | 3 | 450 | 1 | 450 |
| Total | | | | | 1350 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

From its knowledge of the industry, FDA estimates that there are approximately 150 laboratories that could perform testing that uses investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents. FDA estimates that in the United States each year there are approximately 450 naturally occurring cases of diseases or conditions that are identified in Centers for Disease Controls's list of category "A" biological threat agents. The number of cases that would result from a terrorist event or other public health emergency is uncertain. Based on its knowledge of similar types of submissions, FDA estimates that it will take about 2 hours to prepare each certification.

Based on its knowledge of similar types of submissions, FDA estimates that it will take about 1 hour to prepare a report disclosing the investigational status of the in vitro diagnostic device and what is known about the performance characteristics of the device and submit it to the health care provider and, where appropriate, to public health authorities.

This interim final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 50.25 have been approved under 0910–0130.

Dated: February 4, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–3025 Filed 2–17–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0496]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Product Standard on Flavored Cigarettes

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 22, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0647. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Tobacco Product Standard on Flavored Cigarettes—(OMB Control Number 0910–0647)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

FDA is requesting an extension of an existing collection of information pertaining to section 907(a)(1)(A) of the act (21 U.S.C. 397(a)(1)(A), as amended by the Tobacco Control Act, which provides a general tobacco standard special rule for cigarettes that became effective on September 22, 2009. This special rule for cigarettes states in part that "* * * a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke."

As part of our enforcement strategy, FDA created a Tobacco Call Center (with a toll-free number) to accept information from the public about violations of this provision, known as the cigarette flavor ban. Callers are able to report violations of the cigarette flavor ban and FDA will determine whether to conduct targeted followup investigations based on information the agency receives. Members of the public who wish to report a violation will be asked for certain information: Name and contact information, which are optional, date that the caller observed or purchased the alleged violative product, description of the tobacco product, and address of the retail outlet or Internet address where the violative product was available. FDA developed a form (FDA Form 3734) that Tobacco Call Center representatives use to record this information. Additionally, this form is posted on FDA's Internet at *http://www.accessdata.fda.gov/scripts/email/TobaccoProducts/flavoredCigarettes.cfm)* which allows the public to report violations of the cigarette flavor ban by filling out the form online. Others may simply choose to send a letter to FDA. (Information about how to contact FDA's Center for Tobacco Products is posted at *http://www.fda.gov/TobaccoProducts/default.htm)*.

FDA described how to report information about possible violations in a **Federal Register** notice reminding regulated industry of the effective date of the ban on certain flavored cigarettes (74 FR 48974, September 25, 2009). FDA also included this information in the following outreach materials:

- Letter to our tobacco control partners announcing the cigarette flavor ban and soliciting information on possible violations,
- Press release announcing the effective date of the cigarette flavor ban,
- Flavored tobacco products fact sheet, and
- Flavored tobacco products parental advisory.

In the **Federal Register** of October 26, 2009 (74 FR 55050), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment in response to the 60-day notice soliciting public comment on the extension of OMB approval for this information collection generally supporting "the extension of this collection of information regarding the enforcement of the cigarette flavor ban and submits that the extension of data collection is critical to the 'proper performance of FDA's functions' and that it will have great 'practical utility'." Although FDA did not receive comment on the estimated number of respondents, FDA is adjusting this estimate based on current reporting experience to 170 respondents.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Activity and Form FDA 3734 | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Minutes Per Response | Total Hours |
|---|---|---|---|---|---|
| Reporting violations of section 907(a)(1)(A) of the act | 170 | 1 | 170 | 10 (0.167 hours) | 28 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 12, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–3036 Filed 2–17–10; 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): Translating Research Into Action for Diabetes (TRIAD) Legacy Study, Funding Opportunity Announcement (FOA) DP 10–005, 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:

*Time and Date:* 11 a.m.–5 p.m., March 31, 2010 (Closed).

*Place:* Teleconference.

*Status:* The meeting 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 Public Law 92–463.

*Matters To Be Discussed:* The meeting will include the initial review, discussion, and evaluation of applications received in response to "TRIAD Legacy Study, FOA DP 10–005."

*Contact Person for More Information:* Don Blackman, PhD, Scientific Review Officer, National Center for Chronic Disease and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K–92, Atlanta, GA 30341, telephone: (770) 488–3023, e-mail: *DBlackman@cdc.gov.*

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: February 10, 2010.

**Elaine L. Baker,**

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

[FR Doc. 2010–3064 Filed 2–17–10; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### National Center for Injury Prevention and Control/Initial Review Group, (NCIPC/IRG)

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 following meeting of the aforementioned review group:

*Time and Date:* 12:30 p.m.–4 p.m., March 3, 2010 (closed).

*Place:* Teleconference.

*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.

*Purpose:* This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct research that will build the scientific base for the prevention of unintentional poisonings from drug overdoses in the adult population.

*Matters to be Discussed:* The meeting will include the review, discussion, and evaluation of applications intended to encourage exploratory/developmental research in unintentional childhood injury. Requests for Applications are related to the following individual research announcement: CE10–002 Unintentional Poisoning from Prescription Drug Overdoses in Adults (R21).

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* J. Felix Rogers, PhD, M.P.H., Telephone (770) 488–4334, NCIPC, CDC, 4770 Buford Highway, NE., Mail Stop F63, Atlanta, Georgia 30341–3724. 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: February 4, 2010.

**Elaine L. Baker,**

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

[FR Doc. 2010–3047 Filed 2–17–10; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0001]**

### Pediatric 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*: Pediatric 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 Monday, March 22, 2010, from 8 a.m. to 6 p.m.

*Location*: Bethesda Marriott Hotel, 5151 Pooks Hill Rd., Bethesda, MD., 20814.

*Contact Person*: Doreen Kezer, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane (HF–33), rm. 14–65, Rockville, MD 20857, 301–827–1249, e-mail: *Doreen.Kezer@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. 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.

*Agenda*: The Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, for: Anthelios 40, Cardiolite (technetium Tc-99), Nasacort AQ (triamcinolone), Viramune