Tobacco Product Reporting Violation Form (OMB Control Number 0910–NEW)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321 *et seq.*) 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 OMB approval for a new collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

As part of its enforcement strategy, FDA created a Tobacco Call Center (with a toll-free number: 1–877–CTP–1373) to accept information from the public about violations of the Tobacco Control Act. Callers are able to report potential violations of the Tobacco Control Act and FDA will conduct targeted followup investigation based on information received. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation happened, the product type (*e.g.*, cigarette, smokeless, roll-your-own, *etc.*), tobacco brand, type of potentially violative promotional materials, potential violation type, who potentially violated, and the name, address, phone number, and e-mail address of the potential violator. The caller will also be asked to list the potential violator's Web site (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation. FDA has developed a form that will be used to solicit this information from the caller (FDA Form 3779, Tobacco Product Violations Reporting), which is expected to eventually replace current form FDA Form 3734 for Cigarette Flavor Ban Violations. This new form will be posted on FDA's Web site, and information may be submitted by filling out the form online (or the public can request a copy of Form 3779 by contacting the Center for Tobacco Products (CTP)). In addition, FDA has developed a smartphone application for use with iPhones, Android, etc. to allow consumers to report potential violations to FDA via their smartphone. Others may simply choose to send a letter to FDA with their information. In summary, the public will be able to report information regarding possible violations of the Tobacco Control Act through the following methods: calling the Tobacco Call Center using CTP's toll-free number; using a fill-able form found on FDA's Web site; using FDA's tobacco violation reporting smartphone application, and sending a letter to FDA's Center for Tobacco Products.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and FDA Form 3779	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act by telephone, Internet form, smartphone application, or mail	1,000	1	1,000	0.167	167

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

FDA estimates that submitting the information (by phone, Internet form, smartphone application, or mail) will take 10 minutes. Since a similar type of reporting went into effect for the cigarette flavor ban, FDA has received several reports via the Internet or e-mail. Judging from the rate of reporting for the cigarette flavor ban, FDA estimates the number of respondents will be 1,000 who will submit 1 report each annually by phone, Internet form, smartphone application, or mail. Because of the variety of products regulated by FDA under the authority of the FD&C Act, as amended by the Tobacco Control Act, FDA expects the rate of calls and reports received to remain steady over the next 3 years.

Dated: August 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Arthritis Advisory Committee; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the Arthritis Advisory Committee meeting scheduled for September 13, 2011. This meeting was announced in the **Federal Register** of July 19, 2011 (76 FR 42715). The postponement is due to the fact that the Agency recently received submissions from some of the investigational new drug (IND) application holders for anti-nerve growth factor (Anti-NGF) antibody drug products that contain large quantities of new information that will require additional time for Agency review prior to the advisory committee meeting.

FOR FURTHER INFORMATION CONTACT: Philip A. Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX 301–827–8533, *e-mail: AAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: August 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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