## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0813]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance

**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 January 4, 2013.

**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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0699. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

### Applications for Food and Drug Administration Approval To Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance—(OMB Control Number 0910–0699)—Reinstatement

FDA published an interim final rule on December 19, 2011 (76 FR 78530), amending its postmarketing reporting regulations implementing certain provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act). The provisions of the FD&C Act require manufacturers who are the sole manufacturers of certain drug products to notify FDA at least 6 months before discontinuance of manufacture of the products. The interim final rule modified the term ''discontinuance'' and clarified the term ''sole manufacturer'' with respect to notification of discontinuance requirements. The broader reporting resulting from these changes will enable FDA to improve its collection and distribution of drug shortage information to physician and patient organizations and to work with manufacturers and other stakeholders to respond to potential drug shortages.

Sections 314.81(b)(3)(iii) and 314.91 (21 CFR 314.81(b)(3)(iii) and 314.91) of FDA's regulations implement section 506C of the FD&C Act (21 U.S.C. 355c). Section 314.81(b)(3)(iii) requires entities who are the sole manufacturers of certain drug products to notify us at least 6 months before discontinuance of manufacture of the product. For the regulations to apply, a product must meet the following three criteria:

1. The product must be life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition;
2. The product must have been approved by FDA under section 505(b) or 505(j) (21 U.S.C. 355(b) or 355(j)) of the FD&C Act; and
3. The product must not have been originally derived from human tissue and replaced by a recombinant product.

Under § 314.81(b)(3)(iii)(c), FDA will publicly disclose information about drug products subject to section 506C that are to be discontinued. Section 314.91 allows us to reduce the 6-month notification period if we find that good cause exists for the reduction. A manufacturer may request that we reduce the notification period by certifying that good cause for the reduction exists.

FDA added §§ 314.81(b)(3)(iii) and 314.91 to its regulations in the **Federal Register** of October 18, 2007 (72 FR 58993). Sections 314.81(b)(3)(iii) and 314.91 require two new reporting requirements to FDA that are subject to OMB approval under the PRA: Notification of Discontinuance and Certification of Good Cause. The December 19, 2011, interim final rule added two new definitions to § 314.81(b)(3)(iii): ''Discontinuance'' and ''sole manufacturer.'' The interim final rule clarified the scope of manufacturers required to report and expanded the range of circumstances required to be reported to the Agency under § 314.81(b)(3)(iii), but did not change the substantive content of the reports required to be submitted to the Agency. This PRA analysis covers the information collection resulting from the October 18, 2007, final rule and also includes estimates of how the number of Notifications of Discontinuance and Certifications of Good Cause may increase as a result of the interim final rule.

*A. Notification of Discontinuance*

Under § 314.81(b)(3)(iii), at least 6 months before a sole manufacturer intends to discontinue manufacture of a drug product subject to section 506C of the FD&C Act, the manufacturer must send us notification of the discontinuance. The notification of discontinuance generally contains the name of the manufacturer, the name of the product to be discontinued, the reason for the discontinuance, and the date of discontinuance. FDA will work with relevant manufacturers during the 6-month notification period to help minimize the effect of the discontinuance on patients and health care providers, and to distribute appropriate information about the discontinuance to physician and patient organizations. The interim final rule added definitions of ''discontinuance'' and ''sole manufacturer'' to § 314.81(b)(3)(iii). The inclusion of these definitions expands notification requirements under § 314.81(b)(3)(iii) to additional discontinuance circumstances and clarifies the scope of manufacturers who must report discontinuances. The interim final rule also required that notifications of discontinuance be submitted either electronically or by telephone according to instructions on FDA's Drug Shortage Web site at *http://www.fda.gov/Drugs/DrugSafety/DrugShortages.* This change ensures that the appropriate offices are timely notified of all relevant discontinuances. It also reflects existing practice for submitting notices of discontinuance, and reduces the burden on industry to submit multiple copies of the notification.

*B. Certification of Good Cause*

FDA may reduce the 6-month notification period if we find good cause for the reduction. As described in § 314.91, a manufacturer can request a reduction in the notification period by submitting written certification that good cause exists to the following designated offices: (1) The Center for Drug Evaluation and Research (CDER) Drug Shortage Coordinator at the address of the Director of CDER; (2) the CDER Drug Registration and Listing Team, Division of Compliance Risk Management and Surveillance in CDER; and (3) the director of either the CDER

division or the Center for Biologics Evaluation and Research office that is responsible for reviewing the application. The following circumstances may establish good cause:

- A public health problem may result from continuation of manufacturing for the 6-month period (§ 314.91(d)(1));
- A biomaterials shortage prevents the continuation of manufacturing for the 6-month period (§ 314.91(d)(2));
- A liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period (§ 314.91(d)(3));
- Continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer (§ 314.91(d)(4));
- The manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code (§ 314.91(d)(5));
- The manufacturer can stop making the product but still distribute it to satisfy existing market need for 6 months (§ 314.91(d)(6)); or
- Other good cause exists for a reduction in the notification period (§ 314.91(d7) (7)).

With each certification described previously, the manufacturer must describe in detail the basis for its conclusion that such circumstances exist. We require that the written certification that good cause exists be submitted to the offices identified previously to ensure that our efforts to address the discontinuance take place in a timely manner. The interim final rule made no changes to the requirements or process for certification of good cause.

*Description of Respondents:* An applicant that is the sole manufacturer and who is discontinuing manufacture of a drug product that meets the following criteria: (1) Is life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition; (2) was approved by FDA under section 505(b) or (j) of the FD&C Act; and (3) was not originally derived from human tissue and replaced by a recombinant product.

*Burden Estimate:* The table below provides an estimate of the annual reporting burden for notification of a product discontinuance and certification of good cause under §§ 314.81(b)(3)(iii) and 314.91, as amended by the interim final rule.

*Notification of Discontinuance:* Based on data collected from the CDER Drug Shortage Coordinator since December 17, 2007, when §§ 314.81(b)(3)(iii) and 314.91 went into effect, one manufacturer during each year reported to FDA a discontinuance of one drug product meeting the criteria of section 506C and its implementing regulations (i.e., the drug product was approved under section 505(b) or (j) of the FD&C Act, the drug product was ''life-supporting, life-sustaining or intended for use in the prevention of a debilitating disease or condition,'' the drug product was produced by a sole manufacturer, and the drug product was permanently discontinued). CDER's Drug Shortages Coordinator tracked 220 drug shortages between January and October of 2011. The Agency estimates that 30 percent (66) of these shortages would relate to discontinuances subject to mandatory reporting under section 506C of the FD&C Act as a result of the interim final rule. Adjusting to include an additional 2 months of reporting (November and December), we estimate that FDA will receive a total of 80 notifications of a discontinuance per year under section 506C of the FD&C Act, as amended by the interim final rule. Based on experience, a manufacturer submits only one notification of a discontinuance per year, thus the total number of manufacturers who would be required to notify us of a discontinuance would be 80. Therefore, the number of respondents is estimated to be 80. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a notification of product discontinuance, including the time it takes to gather and copy the statement. Based on experience in working with manufacturers to submit notifications under § 314.81(b)(3)(iii), we estimate that approximately 2 hours on average are needed per response. We do not expect the changes in the interim final rule to affect the number of hours per response. Therefore, we estimate that respondents will spend 160 hours per year notifying us of a product discontinuance under these regulations.

*Certification of Good Cause:* Based on data collected from the CDER drug shortage coordinator since 2007, one manufacturer each year reported a discontinuance of one drug product under section 506C of the FD&C Act and its implementing regulations. Each manufacturer has the opportunity under § 314.91 to request a reduction in the 6-month notification period by certifying to us that good cause exists for the reduction. The Agency has received no certifications of good cause since 2007. Although we expect we will receive an increase in the number of reports of discontinuances as a result of the changes in the interim final rule, because of the limited circumstances under which good cause can be requested or would be appropriately granted, we do not expect a correspondingly large increase in the number of manufacturers requesting a certification of good cause. We estimate that only five manufacturers will request a certification of good cause each year. Therefore, the number of respondents is estimated to be five. The total annual responses are the total number of certifications of good cause that are expected to be submitted to us in a year. We estimate that the total annual responses will remain small, averaging one response per respondent. The hours per response is the estimated number of hours that a respondent spends preparing the detailed information certifying that good cause exists for a reduction in the notification period, including the time it takes to gather and copy the documents. We estimate that approximately 16 hours on average are needed per response. Therefore, we estimate that 80 hours will be spent per year by respondents certifying that good cause exists for a reduction in the 6-month notification period under § 314.91.

In the **Federal Register** of August 1, 2012 (77 FR 45619), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Notification of Discontinuance (314.81(b)(3)(iii) | 80 | 1 | 80 | 2 | 160 |
| Certification of Good Cause (314.91) | 5 | 1 | 5 | 16 | 80 |

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

| 21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Total | ..... | ..... | ..... | ..... | 240 |

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

Dated: November 30, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No FDA–2012–N–0273]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Review; Experimental Study of Graphic Cigarette Warning Labels

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a reinstatement 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 (the PRA).

**DATES:** Fax written comments on the collection of information by January 4, 2013.

**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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0668. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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.

The Tobacco Control Act (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

The purpose of this submission is to request OMB approval to conduct Web-based surveys to evaluate the relative effectiveness of various graphic health warnings on cigarette packs, which will inform the Agency's efforts to implement the mandatory graphic warnings required by the Tobacco Control Act.

**Experimental Study of Graphic Cigarette Warning Labels (OMB Control Number 0910–0668—Reinstatement)**

The current approval for this information collection expired October 31, 2012. FDA seeks to reinstate the collection and to reflect that there is no change in the reporting burden. At this time, the Agency is not collecting the information, but awaits OMB review and approval, and therefore believes that we are not in violation of the PRA.

Tobacco products are responsible for more than 400,000 deaths each year. The Centers for Disease Control and Prevention report that approximately 46 million U.S. adults smoke cigarettes in the United States, even though this behavior will result in death or disability for half of all regular users. Paralleling this enormous health burden is the economic burden of tobacco use, which is estimated to total $193 billion annually in medical expenditures and lost productivity. Curbing the significant adverse consequences of tobacco use is one of the most important public health goals of our time.

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act, which amends section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), requires FDA to issue ''regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1).'' The study proposed here is an effort by FDA to collect data concerning graphic warnings on cigarette packages and their impact on consumer perceptions, attitudes, and behavior with respect to smoking.

On June 22, 2011, FDA issued a final rule in the **Federal Register** of June 22, 2011 (76 FR 36628), entitled ''Required Warnings for Cigarette Packages and Advertisements,'' which specified nine graphic images to accompany the new textual warnings for cigarettes. Although the rule was scheduled to become effective 15 months after it issued, a panel of the U.S. Court of Appeals of the District of Columbia held, on August 24, 2012, that the rule in its current form violates the First Amendment. FDA expects that the information that FDA proposes to collect will be relevant to FDA's regulation of cigarette warnings no matter the final outcome of the current litigation.

This study, the Experimental Study of Graphic Cigarette Warning Labels, is a voluntary annual experimental survey of consumers. The purpose of the study is to assess the effectiveness of various graphic warnings on cigarette packs for achieving three communication goals: (1) Conveying information about various health risks of smoking; (2) encouraging cessation of smoking among current smokers; and (3) discouraging initiation of smoking among youth and former smokers. The study will collect data from various groups of consumers, including current smokers aged 13 years and older, former smokers aged 13 years and older, and non-smokers aged between 13 and 25 years who may be susceptible to initiation of smoking. The study goals are to: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to graphic warning labels; (2) determine whether consumer responses to graphic warning labels differ across various groups based on smoking status, age, or other demographic variables; and (3) evaluate the relative effectiveness of various graphic images associated with each of the nine warning statements specified in