problems, product use errors, and therapeutic failure (therapeutic inequivalence). Reporting is supported for all FDA-regulated human medical care products, including drugs, biologicals, medical devices, special nutritional products, dietary supplements, cosmetics, and nonprescription (OTC) human drug products marketed without an approved application.

Qualitative assessment by social scientists, and comments and feedback from the public, have recognized that Form FDA 3500 is written and formatted at a literacy/comprehensibility level that far exceeds the level recommended for the general public by health literacy experts and does not conform to recommendations in the Plain Writing Act of 2010 (*http://www.gpo.gov/fdsys/pkg/PLAW–111publ274/pdf/PLAW–111publ274.pdf*).

The proposed consumer version of the voluntary Form FDA 3500 will request no new data from the voluntary reporter not already included in the existing Form FDA 3500 that is currently used for reporting from both health care professionals and consumers (patients). Certain existing fields, not considered essential data for the consumer report but present on the standard (i.e., health care professional) version of Form FDA 3500, have been eliminated to facilitate and expedite consumer submissions and reduce reporting burden. The formatting and the plain language used is compatible with the intent of the Plain Writing Act and is expected to provide non-health care professionals with a second option to the existing Form FDA 3500 that will reduce the burden of reporting by facilitating their understanding of the requested data and further clarify the voluntary reporting process.

The proposed consumer version of Form FDA 3500 evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies and with extensive input from consumer advocacy groups and the general public. The Agency recognizes that many consumer reporters have a preference for accessing a copy of the voluntary reporting form on the Internet or submitting to FDA using an electronic version of the form. The Agency currently supports voluntary reporting with the forms submitted by mail, by FAX, by telephone via the toll free 800 number and online at *http://www.fda.gov/medwatch/report.htm* . It is the Agency's expectation that an approved consumer version of the voluntary form will be provided for consumer use by these same channels.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

| FDA Center FDA Form (21 CFR Section) | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research: | | | | | |
| Form 3500 | 28,952 | 1 | 28,952 | 0.6 | 17,371 |
| Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80) | 599 | 96 | 57,504 | 1.1 | 63,254 |
| Center for Devices and Radiological Health: | | | | | |
| Form 3500 | 4,585 | 1 | 4,585 | 0.6 | 2,751 |
| Form 3500A (§ 803) | 1,485 | 225 | 334,125 | 1.1 | 367,538 |
| Center for Food Safety and Applied Nutrition: | | | | | |
| Form 3500 | 297 | 1 | 297 | 0.6 | 178 |
| Form 3500A | 1,039 | 1 | 1,039 | 1.1 | 1,143 |
| Total | | | | | 452,235 |

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

## VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Kessler, D.A., ''Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems,'' *Journal of the American Medical Association,* vol. 269, pp. 2765–2768, 1993.

Dated: September 6, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–23094 Filed 9–8–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0625]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for filing objections and requests for a hearing on a regulation or order.

**DATES:** Submit either electronic or written comments on the collection of information by November 8, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the

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., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12—(OMB Control Number 0910–0184)—Extension**

The regulations in 21 CFR 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)), set forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d) (21 CFR 12.20(d)). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection for which a hearing has been requested must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

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 |
|---|---|---|---|---|---|
| 12.22 | 3 | 1 | 3 | 20 | 60 |

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

The burden estimate for this collection of information is based on past filings. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order estimate approximately three requests are received by the Agency annually, with each requiring approximately 20 hours of preparation time.

Dated: September 2, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–23106 Filed 9–8–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–D–0480]**

### Draft Guidance for Industry: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products.'' This draft guidance document is intended to assist persons submitting warning plans to FDA under the Comprehensive Smokeless Tobacco Health Education Act, as amended by the Family Smoking Prevention and Tobacco Control Act; and under the Federal Cigarette Labeling and Advertising Act, as amended by the Family Smoking Prevention and Tobacco Control Act, when that requirement takes effect.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 8, 2011.

Submit either electronic or written comments on the proposed collection of information by November 8, 2011.

**ADDRESSES:** Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug