

events/improving-implementation-risk-based-monitoring-approaches-clinical-trials.

Transcripts: Please be advised that transcripts of the public workshop will not be available.

Dated: May 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-11411 Filed 5-30-19; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0032]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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 July 1, 2019.

**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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0331. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@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.

**Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93**

OMB Control Number 0910-0331—Extension

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(r)(6)) and § 101.93 (21 CFR 101.93) of our regulations require that, no later than 30 days after the first marketing, we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act. In accordance with these requirements, submissions must include: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via an electronic system. We are upgrading our current

system (the FDA Unified Registration Listing System known as FURLS) to deploy the Food Applications Regulatory Management (FARM) system. FARM is modeled after FURLS and collects the same information, but improves our operational efficiency. A web link of the FARM system can be found here: <https://www.fda.gov/Food/DietarySupplements/IndustryInfo/ucm485532.htm>. Firms that prefer to submit a paper notification in a format of their own choosing still have the option to do so; however, Form FDA 3955 prompts respondents to include certain elements in their structure/function claim notification (SFCN) described in § 101.93 in a standard electronic format and helps respondents organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. The electronic form, and any optional elements prepared as attachments to the form (e.g., label), can be submitted in electronic format. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act.

In the **Federal Register** of February 7, 2019 (84 FR 2528), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

**Description of Respondents:** Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93 .....	3,690	1	3,690	0.75 (45 minutes) .....	2,767.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our burden estimate reflects an overall increase of 1,117.5 hours (from 1,650 hours) and a corresponding increase of 1,490 responses (from 2,200

responses). We attribute this adjustment to an increase in the average number of notification submissions we received over the preceding 12 months, which

we expect will continue over the next 3 years. We believe gathering information to satisfy the notification requirements of section 403(r)(6) of the FD&C Act by

submitting information regarding section 403(r)(6) of the FD&C Act statements on labels or in labeling of dietary supplements imposes minimal burden on respondents. We expect the information needed is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We believe also that submission via the FARM system will facilitate reporting for respondents. We estimate that, each year, approximately 3,690 firms will submit the information required by section 403(r)(6) of the FD&C Act. Assuming firms require 0.75 hour to gather the information needed and prepare a communication, we calculate a total of 2,767.5 hours (3,690 total annual responses  $\times$  0.75 hour).

Dated: May 28, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-1845]

#### **Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate-Release Opioid Analgesics for Treatment of Acute Pain; Establishment of a Public Docket; Request for Comments**

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the establishment of a docket to solicit public comment on a potential modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) to require that certain solid, oral dosage forms of immediate-release (IR) opioid analgesics commonly prescribed for treatment of acute pain be made available in fixed-quantity unit-of-use blister packaging for outpatient dispensing. This could reduce the amount of unused opioid analgesics, thereby reducing opportunities for misuse, abuse, inappropriate access, and overdose, and possibly reducing the development of new opioid addiction.

**DATES:** Submit either electronic or written comments by July 30, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. Electronic comments must be submitted on or before July 30, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 30, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2019-N-1845 for "Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate-Release Opioid Analgesics for Treatment of Acute Pain; Establishment of a Public Docket; Request for Comments." Received

comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6260, Silver Spring, MD 20993, 301-796-3522, [Patrick.Raulerson@fda.hhs.gov](mailto:Patrick.Raulerson@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In 2017, opioid-involved overdoses killed more than 47,000 people, with