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 the FDA Unified Registration Listing System (FURLS.) Firms that prefer to submit a paper notification in a format of their own choosing will 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 via FURLS.

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.

| 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>
<thead>
<tr>
<th>Table 1—Estimated Annual Reporting Burden 1</th>
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<tbody>
<tr>
<td>21 CFR section</td>
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<tr>
<td>101.93</td>
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</table>

1 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 FURLS 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 hours to gather the information needed and prepare a communication, we calculate a total of 2,767.5 hours (3,690 total annual responses × 0.75 hours).

Dated: February 1, 2019.

Lowell J. Schiller,
Acting Associate Commissioner for Policy.

[FR Doc. 2019–01380 Filed 2–6–19; 8:45 am]
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–0125 for “Oncologic Drugs Advisory Committee; Notice of Meeting: Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see the ADDRESSES section), 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.” FDA 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 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 the 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. Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Lauren D. Tesh, 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: 301–847–8533, email: ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 FDA’s website at https://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:
Agenda: The committee will discuss new drug application (NDA) 212306 for selinexor tablets, application submitted by Karyopharm Therapeutics Inc. The proposed indication (use) for this product is in combination with dexamethasone, for the treatment of patients with relapsed/refractory multiple myeloma who have received at least three prior therapies and whose disease is refractory to at least one proteasome inhibitor, at least one immunomodulatory agent, and an anti-CD38 monoclonal antibody.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s website after the meeting. Background material is available at https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the ADDRESSES section) on or before February 22, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 3 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 19, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 20, 2019.

Persons attending FDA’s advisory committee meetings are advised that FDA is not responsible for providing access to electrical cooling devices. For press inquiries, please contact the Office of Media Affairs at fdaamo@fda.hhs.gov or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Lauren D. Tesh (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the meeting. FDA is committed to the orderly conduct of its advisory committee
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3404]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Drug User Fee Cover Sheet

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 11, 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. All comments should be identified with the OMB control number 0910–0727. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna-Lynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRAS staff@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.

Generic Drug User Fee Coversheet

OMB Control Number 0910–0727—Extension

On July 9, 2012, the President signed the Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112–144, Title III) into law. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to the industry. Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f, et seq.), as added by GDUFA, authorized FDA to assess and collect the fees related to generic drugs, beginning fiscal year (FY) 2013 and expiring at the close of FY 2017 on September 30, 2017. GDUFA was reauthorized on August 18, 2017 (GDUFA II), and is effective beginning October 1, 2017, through September 30, 2022. GDUFA II enables FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications.

Form FDA 3794, the Generic Drug User Fee Cover Sheet available at https://www.ipqpubs.com/wp-content/uploads/2012/09/GDUFA-cover-sheet.pdf, requests the minimum necessary information from applicants to account for and track user fees and to determine the amount of the fee required. Applicants complete the cover sheet. It also notes the correct user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct FY user fee assessment that is due for the submission/program. FDA requests that applicants submit a copy of this completed cover sheet along with the abbreviated new drug application, and other GDUFA fees, so FDA can verify that the applicant has paid the correct user fee.

Respondents to the collection of information are potential or actual generic drug application holders or related Active Pharmaceutical Ingredient and Finished Dosage Form manufacturers. Companies with multiple user fee obligations will submit a cover sheet for each user fee obligation.

In the Federal Register of September 25, 2018 (83 FR 48430), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received asking whether the information was “essential for FDA to conduct its duties,” and whether “there is a way to reduce burden” on respondents. We appreciate this feedback. As discussed in both the 60-day notice and this notice, the information collection implements statutory provisions FDA must fulfill under GDUFA II. The information requested from respondents on Form FDA 3794 represents what we consider to be the minimum necessary for us to efficiently and electronically assess, collect, and track user fees associated with generic drug applications.

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

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<td>Form FDA 3794</td>
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<tr>
<td>Generic Drug User Fee Cover Sheet</td>
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</tbody>
</table>

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