Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03460 Filed 2–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0079]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Generic Drug User Fee Act Cover Sheet

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 the paperwork burden of animal drug sponsors to fill out the Animal Generic Drug User Fee Act (AGDUFA) cover sheet.

DATES: Submit either electronic or written comments on the collection of information by April 21, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Form FDA 3728, Animal Generic Drug User Fee Act Cover Sheet—21 U.S.C. 379j–21 (OMB Control Number 0910–0632)—Revision

Section 741 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j–21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). Because concurrent submission of user fees with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728 is the AGDUFA cover sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

The Animal Generic Drug User Fee Amendments of 2013, signed by the President on June 13, 2013 (AGDUFA II) (Title II of Pub. L. 113–14), amended the FD&C Act authorizing FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. To implement changes under the reauthorization by their effective date of October 1, 2013, FDA sought and received OMB approval to update its Form FDA 3728 as described here:

On page 1 of the electronic questions under ''Select an Application Type'' users must select ''Original'' and then choose either, ''Abbreviated New Animal Drug Application (ANADA)—under provisions of 512(b)(2) of the FD&C Act (21 U.S.C. 360b(b)(2))''; or ''Abbreviated New Animal Drug Application—for certain combination pioneer products approved under provisions of 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)).'' If they select the first ANADA type, they will be charged 100 percent of the application fee. If they select the second ANADA type, then they will be charged at rate of 50 percent of the original application fee. To facilitate the application process in this regard, on Form FDA 3728 we have added a line in Section 3 that allows applicants to select the option, ''3.2 Original Abbreviated New Animal Drug Application—for certain combination pioneer products approved under provisions of 512(d)(4) of the FD&C Act.''

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3728	20	2	40	.08	3.2

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

Respondents to this collection of information are generic animal drug applicants. Based on data for the past 3 years, FDA estimates there are approximately 20 submissions annually and a total of 3.2 burden hours.

Dated: February 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03352 Filed 2–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0948]

Determination That STAVZOR (Valproic Acid) Delayed-Release Capsules, 125 Milligrams, 250 Milligrams, and 500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined that STAVZOR (valproic acid) delayed-release capsules, 125 milligrams (mg), 250 mg, and 500 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for valproic acid, delayed-release capsules, 125 mg, 250 mg, and 500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Na'Im R. Moses, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6223, Silver Spring, MD 20993–0002, 240–402–3990.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, is the subject of NDA 22–152, held by Banner Pharmacaps Inc., and initially approved on July 29, 2008. STAVZOR is indicated for acute treatment of manic or mixed episodes associated with bipolar disorder (with or without psychotic features), monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures, adjunctive therapy in patients with multiple seizure types that include absence seizures, and prophylaxis of migraine headaches.

In a letter dated June 25, 2013, Banner Pharmacaps Inc. notified FDA that STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Pharmaceutics International, Inc., submitted a citizen petition dated August 7, 2013 (Docket No. FDA–2013–P–0948), under 21 CFR 10.30, requesting that the Agency determine whether STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03455 Filed 2–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0161]

Determination That GANITE (Gallium Nitrate) Injectable and Five Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined