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]

BILLING CODE 4160–01–P

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That STAVZOR (Valproic Acid) Delayed-Release Capsules, 125 Milligrams, 250 Milligrams, and 500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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has determined that STAVZOR (valproic acid) delayed-release capsules, 125 milligrams (mg), 250 mg, and 500 mg, was not withdrawn from sale for reasons of safety or effectiveness.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]

BILLING CODE 4160–01–P

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

that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6207, Silver Spring, MD 20993–0002, 301–796–5418.

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 approved 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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application no.	Drug	Applicant
NDA 019961	GANITE (gallium nitrate) Injectable; Injection, 25 milligrams (mg)/milliliter (mL).	Chapter 7 Trustee of Genta Inc., 1628 John Kennedy Blvd., Philadelphia, PA 19103
NDA 020707	SKELID (tiludronate disodium) Tablet; Oral, Equivalent to (EQ) 200 mg Base.	Sanofi Aventis US LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 022023	EMEND (fosaprepitant dimeglumine) Powder; Intravenous, EQ 115 mg Base/Vial.	Merck and Co Inc., RY33 200, P.O. Box 2000, Rahway, NJ 07065.
NDA 050039	GARAMYCIN (gentamicin sulfate ophthalmic solution) Solution; Drops, EQ 0.3% Base.	Schering Plough Corp., 2000 Galloping Hill Rd., Mail Stop K 6 1, Kenilworth, NJ 07033.
NDA 202343	JUVISYNC (simvastin; sitagliptin phosphate) Tablet; Oral, 10 mg, EQ 100 mg Base; 20 mg, EQ 100 mg Base; 40 mg, EQ 100 mg Base; 10 mg, EQ 50 mg Base; 20 mg, EQ 50 mg Base; 40 mg, EQ 50 mg Base.	Merck Sharp and Dohme Corp., 351 North Sumneytown Pike, UG 2CD 015, P.O. Box 1000, North Wales, PA 19454.
ANDA 071259	TRIMETHOPRIM (trimethoprim) Tablet; Oral, 200 mg.	TEVA Pharmaceuticals USA Inc., 650 Cathill Rd., Sellersville, PA 18960–1512.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products 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. 2014–03458 Filed 2–14–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings With Food and Drug Administration Staff; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with