presented supports the conclusion that the conduct upon which Dr. Brancato's debarment was based is unlikely to recur. For these reasons, the Agency finds that termination of Dr. Brancato's debarment serves the interest of justice and will not pose a threat to the integrity of the drug approval process.

Under section 306(d)(4)(D) of the FD&C Act, the period of debarment of an individual who qualifies for special termination may be limited to less than permanent but to no less than 1 year. Dr. Brancato's period of debarment, which commenced on January 6, 1994, has lasted more than 1 year. Accordingly, the Director of the Office of Enforcement and Import Operations, under section 306(d)(4) of the FD&C Act and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that David J. Brancato's application for special termination of debarment should be granted, and that the period of debarment should terminate immediately, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application. The Director of Enforcement and Import Operations further finds that because the Agency is granting Dr. Brancato's application, an informal hearing under section 306(d)(4)(C) of the FD&C Act is unnecessary.

As a result of the foregoing findings, Dr. David J. Brancato's debarment is terminated effective (see **DATES**) (21 U.S.C. 335a(d)(4)(C) and (d)(4)(D)).

Dated: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17712 Filed 7–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1196]

List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals; Extension of Nomination Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of nomination period.

SUMMARY: The Food and Drug Administration (FDA) is extending the nomination period for the notice that appeared in the **Federal Register** of May 19, 2015. In the notice, FDA requested nominations for a list of bulk drug substances that may be used by facilities registered as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to compound animal drugs from bulk substances, in accordance with FDA's draft guidance for industry (GIF) #230, ''Compounding Animal Drugs from Bulk Drug Substances.'' The FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit nominations.

DATES: Submit either electronic or written nominations for the bulk drug substances list by November 16, 2015.

ADDRESSES: You may submit nominations by any of the following methods:

Electronic Submissions

Submit electronic nominations in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written nominations in the following ways:

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

Instructions: All submissions received must include the Docket No. FDA–2015–N–1196. All nominations received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting nominations, see the ''Request for Nominations'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or nominations received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine, Food and Drug Administration (HFV–210), 7519 Standish Pl., Rockville, MD 20855, 240–402–5745, *neal.bataller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 19, 2015 (80 FR 28622), FDA published a notice with a 90-day nomination period for the list of bulk drug substances that may be used by a facility registered as an outsourcing facility under section 503B of the FD&C Act (21 U.S.C. 353B) to compound drugs for use in animals in accordance with FDA's draft GFI #230, ''Compounding Animal Drugs from Bulk Drug Substances.'' That notice describes the information that should be provided to the FDA in support of each nomination.

FDA has received a request for a 90-day extension of the nomination period as the requestor wanted more time to nominate drugs to the list and to provide supporting data. FDA has considered the request and is extending the nomination period for 90 days, until November 16, 2015. The FDA believes that a 90-day extension allows adequate time for interested persons to submit nominations without significantly delaying consideration of these nominations.

II. Nomination Process

The process for nominations for bulk drug substances that may be used by facilities registered as outsourcing facilities under section 503B of the FD&C Act to compound animal drugs from bulk drug substances is described in the previous notice published May 19, 2015. FDA cannot guarantee that all drugs nominated during the nomination period will be considered for initial inclusion in Appendix A at the time of its initial publication. Nominations submitted during the nomination period (ending on November 16, 2015) that are not evaluated and included in Appendix A at the time of its initial publication will receive consideration for later addition to Appendix A. In addition, individuals and organizations may petition FDA, in accordance with 21 CFR 10.30, to make additional amendments to Appendix A after the nomination period.

III. Request for Nominations

Interested persons may submit either electronic nominations to *http://www.regulations.gov* or written nominations to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of nominations. Identify nominations with the docket number found in brackets in the heading of this document. Received nominations may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17729 Filed 7–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2412]

Determination That TESSALON (Benzonatate) Capsules and 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: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993–0002, 301–796–8363.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors 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. ANDAs 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 are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 050448 for GRIFULVIN (griseofulvin) Oral Suspension in the **Federal Register** of August 16, 2001 (66 FR 43017)).

Application No.	Drug	Applicant
NDA 011210	TESSALON (benzonatate) Capsule; Oral 200 milligrams (mg)	Pfizer Inc., 1 Giralda Farms, Madison, NJ 07940.
NDA 012093	ISORDIL (isosorbide dinitrate) Tablet; Oral 10 mg, 20 mg, 30 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 018702	ACLOVATE (alclometasone dipropionate) Ointment; Topical 0.05%.	Fougera Pharmaceuticals Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747.
NDA 018707	ACLOVATE (alclometasone dipropionate) Cream; Topical 0.05%.	Do.
NDA 018936	SARAFEM (fluoxetine hydrochloride (HCl)) Capsule; Oral Equivalent to (EQ) 10 mg Base, EQ 20 mg Base.	Eli Lilly and Co., Lilly Corp. Ctr., Indianapolis, IN 46285.
NDA 018988	VASOCIDIN (prednisolone sodium phosphate; sulfacetamide sodium), Solution/Drops; Ophthalmic, EQ 0.23% phosphate; 10%.	Novartis Pharmaceuticals Corp., 105 Eisenhower Pky., 280 Corporate Center, Roseland, NJ 07068.
NDA 019898	PRAVACHOL (pravastatin sodium) Tablet; Oral 10 mg	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 020092	DILACOR XR (diltiazem HCl) Capsule, Extended-Release; Oral 120 mg, 180 mg, 240 mg.	Actavis Laboratories UT, Inc., 577 Chipeta Way, Salt Lake City, UT 84108.
NDA 021551	HALFLYTELY (polyethylene glycol 3350; potassium chloride; sodium bicarbonate; sodium chloride) For Solution and bisacodyl Delayed-Release Tablets); Oral 210 grams (g); 0.74 g; 2.86 g; 5.6 g; 5 mg.	Braintree Laboratories, Inc., 60 Columbia St., P.O. Box 850929, Braintree, MA 02185.
NDA 021871	LOESTRIN 24 FE (ethinyl estradiol; norethindrone acetate) Tablet; Oral 0.02 mg; 1 mg.	Warner Chilcott Co. LLC, Union Street Rd. 195 KM 1.1., Fajardo, Puerto Rico 00738.
NDA 050448	GRIFULVIN V (griseofulvin, microcrystalline) Suspension; Oral 125 mg/5 milliliters (mL).	Johnson & Johnson Consumer Products Co., 199 Grandview Rd., Skillman, NJ 08558.
NDA 050719	HELIDAC (bismuth subsalicylate; metronidazole; tetracycline HCl) Tablet, Chewable, Tablet, Capsule; Oral 262.4 mg; 250 mg, 500 mg.	Prometheus Laboratories Inc., 9410 Carroll Park Dr., San Diego, CA 92121.
ANDA 040454	PROMETHAZINE HYDROCHLORIDE (promethazine HCl) Injectable; Injection 25 mg/mL, 50 mg/mL.	Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044.
ANDA 062483	GRIFULVIN V (griseofulvin, microsize) Suspension; Oral 125 mg/5 mL.	Valeant Pharmaceuticals Luxembourg S.a.r.l, C/O Valeant Pharmaceuticals North America LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.