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Determination That TESSALON (Benzonatate) Capsules and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

Application No.	Drug	Applicant
ANDA 088762	PROMETH W/DEXTROMETHORPHAN (dextromethorphan hydrobromide; promethazine HCl) Syrup; Oral 15 mg/5 mL; 6.25 mg/5 mL.	G&W Laboratories Inc.,111 Coolidge St., South Plainfield, NJ 07080.

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: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17730 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–2007–D–0369]

Bioequivalence Recommendations for Lubiprostone; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry on lubiprostone capsules entitled ''Bioequivalence Recommendations for Lubiprostone.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for lubiprostone capsules.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 18, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for lubiprostone capsules.

FDA initially approved new drug application (NDA) 021908 for AMITIZA capsules in January 2006. There are no approved ANDAs for this product. In August 2010, we issued a draft guidance for industry on BE recommendations for generic lubiprostone capsules. We are now issuing a revised draft guidance for industry on BE recommendations for generic lubiprostone capsules (''Bioequivalence Recommendations for Lubiprostone'').

In January 2014, Sucampo Pharma Americas, LLC, manufacturer of the reference listed drug, AMITIZA, submitted a citizen petition requesting that FDA revise the BE requirements for any new drug product that references AMITIZA and seeks approval by means of demonstrating BE to AMITIZA. FDA has reviewed the issues raised in the petition and is responding to the petition (Docket No. FDA–2014–P–0144).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for lubiprostone capsules. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments 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.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*