U.S. FOOD & DRUG ADMINISTRATION

FDA REQUESTED RECALL

December 18, 2017

James D. Weir, President and Chief Executive Officer
Primus Pharmaceuticals, Inc.
7373 N. Scottsdale Road, Suite B-200
Scottsdale, AZ 85253

Dear Mr. Weir:

This letter is to request that you cease distribution and immediately initiate a recall of all lots within expiry of the following products:

- Limbrel (flavocoxid) 250 mg capsules
- Limbrel250 (250 mg flavocoxid with 50 mg citrated zinc bisglycinate) capsules
- Limbrel (flavocoxid) 500 mg capsules
- Limbrel500 (500 mg flavocoxid with 50 mg citrated zinc bisglycinate) capsules

The FDA has determined that these Limbrel products are unapproved new drugs and represent a serious health hazard. Between January 1, 2007, and November 9, 2017, FDA received 194 adverse event reports associated with the use of Limbrel products. The adverse event reports identified a close relationship between the use of Limbrel and adverse events involving the development of drug-induced liver injury (DILI), pancreatitis, and hypersensitivity pneumonitis (HP). Any of these conditions can present in patients with varying degrees of severity, ranging from mild to life-threatening. These conditions may go unnoticed by the patient until symptoms develop that require hospitalization, such as respiratory failure. FDA continues to review data and information related to these products as they become available. This FDA action is necessary to protect the public health and welfare.

In addition, your Limbrel products are unapproved new drugs distributed in violation of sections 301(d) and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 331(d) and 355(a)]. The claims on your product labeling, such as for the "clinical dietary management of the metabolic processes of osteoarthritis," establish that the Limbrel products are drugs under section 201(g)(1)(B) of the FD&C Act [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The Limbrel products are not generally recognized as safe and effective for their intended uses and, therefore, are "new drugs" under section 201(p) of the FD&C Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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Furthermore, under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)], the Limbrel products are misbranded drugs because their labeling is false or misleading. Use of the phrase "medical food" in the labeling of the Limbrel products renders your products' labels misleading because the products do not meet the definition of a medical food, as described below. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

These Limbrel products are labeled and marketed as medical foods but do not meet the definition of a medical food as defined in the Orphan Drug Act [21 U.S.C. § 360ee(b)(3)] or the criteria set forth in Title 21, Code of Federal Regulations (CFR), section 101.9(j)(8) [21 CFR 101.9(j)(8)]. The Orphan Drug Act defines "medical food" as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

The Limbrel products are promoted as medical foods for the clinical dietary management of the metabolic processes of osteoarthritis. However, FDA is not aware of any distinctive nutritional requirements for individuals with osteoarthritis. More specifically, there is no distinctive nutritional requirement relative to catechin (derived from Acacia catechu) or baicalin (derived from Scutellaria baicalensis), which are identified as the primary ingredients in Limbrel. Therefore, the Limbrel products do not meet the definition of a medical food in the Orphan Drug Act [21 U.S.C. § 360ee(b)(3)] or the criteria set forth in 21 CFR 101.9(j)(8).

We acknowledge your posting of a Limbrel Safety Update on your website, dated November 22, 2017, advising Limbrel prescribers to limit Limbrel use only to established patients and not provide it to new patients. In this update, your firm committed to discontinue the new patient program which includes halting distribution of blister sample packs. However, that does not address those products that are still available for sale and products already in consumer possession.

FDA anticipates classifying this recall as a Class I recall, and believes that pursuing this recall request is necessary at this time to address the ongoing public health risk. A Class I recall represents a serious health hazard which may be life-threatening. FDA recommends level A (100%) effectiveness checks be performed by your firm to the retail level.

FDA's recall policy and guidance is found in Title 21 CFR, Part 7. FDA's Division of Pharmaceutical Quality Operations IV (ORAPHARM4) will provide guidance on implementing and assuring the effectiveness of your recall of these products, including reviewing the proposed recall communication to your consignees. We are requesting that you work closely with ORAPHARM4 and that you provide all necessary information regarding the recall in a timely manner. Title 21 CFR, Part 7 provides for, among other things, publishing your recall in an upcoming issue of the weekly FDA Enforcement Report.

Please respond to this letter within 24 hours of receipt. Your response to this letter should be directed to:

CDR Steven E. Porter, Division Director
Division of Pharmaceutical Quality Operations IV
19701 Fairchild
Irvine, CA 92612-2445
Phone (949) 608-4448, Fax (949) 608-4415

Due to the seriousness of this situation, FDA is updating our public notification today, advising consumers of the FDA Requested Recall letter and again warning consumers and retailers to discontinue use or sale of these products and of the health risk associated with the use of these products.

Failure to comply with this request can result in further regulatory action being taken against you, your firm, and the misbranded and unapproved new drug products distributed by your firm.

Sincerely,

Melinda K. Plaisier, MSW
Associate Commissioner for Regulatory Affairs