Primus Pharmaceuticals – Recall of Limbrel®

- On January 29, 2018, the FDA announced a user level recall of all unexpired lots of Primus' Limbrel products due to rare but serious and reversible side effects associated with Limbrel.

- All lots within expiry of the following products are included in the recall:

Product Description	NDC #
Limbrel (flavocoxid) 250 mg capsules	68040-601-16
Limbrel250 (250 mg flavocoxid with 50 mg citrated zinc bisglycinate) capsules	68040-605-16
Limbrel (flavocoxid) 500 mg capsules	68040-602-16
Limbrel500 (500 mg flavocoxid with 50 mg citrated zinc bisglycinate) capsules	68040-606-16

- In an effort to cooperate with the FDA, Primus voluntarily ceased its promotion and distribution of Limbrel on December 21, 2017, and is now recalling Limbrel as the FDA has requested.

- Limbrel has been marketed since 2004 as a medical food available only by prescription for patients under active and ongoing supervision of a physician for the dietary management of osteoarthritis.

- Between January 1, 2007, and November 9, 2017, the FDA received 30 adverse event reports of elevated liver function tests or acute hypersensitivity pneumonitis associated with the use of Limbrel products.

    — These conditions present in rare cases with varying degrees of severity in patients taking Limbrel for the first time in the initial weeks of exposure, and may go unnoticed by the patient until they consult with their physician or until symptoms develop that require hospitalization.
    — To date, there have been no deaths reported with the use of Limbrel, and in all reported cases adverse effects resolved without residual effects after discontinuing use of the product.

- Primus retained independent medical and former senior FDA safety experts to conduct a further investigation of these cases and the ingredients in Limbrel. It is the opinion of these experts based on a thorough review of the medical literature, adverse event reports to the FDA, and the FDA's health hazard evaluation that there is no basis on which to conclude that Limbrel potentially causes life-threatening adverse effects, and that none of the reported adverse events show liver failure or respiratory failure.

- Primus is notifying its distributors and is arranging for the return of all recalled products. Retail pharmacies that have Limbrel products should return them to the wholesale distributor.

- The FDA recommends that patients who have the recalled Limbrel products should stop its use.

- Patients should contact their physician or healthcare provider if they have experienced any adverse event that may be related to taking Limbrel.

- Patients who wish to return unopened bottles or who have questions regarding this recall can go to Limbrel.com or contact Primus at **1-480-483-1410**.

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- Primus is working with the FDA to return Limbrel to the market as quickly as possible.