METFORMIN INFORMATION RELEASE

May 30, 2020

Ascend wants to re-assure all patients, consumers, physician prescribers, and pharmacists that as of today it has not been contacted by FDA regarding any initiative to recall any of its Metformin products.

Ascend markets both an immediate release metformin in 500mg, 850, and 1000mg strengths and an extended release metformin in 500mg and 750mg strengths.

Recently, tests were conducted by an independent laboratory, not associated with FDA, claiming an impurity NDMA, which has been labeled a probable human carcinogen by the WHO, was found in excessive amounts in samples of metformin they tested. An article from earlier this week published by Bloomberg states that FDA, after conducting its own tests, has found no excess levels in any Immediate Release Metformin but had found some in samples of Extended Release Metformin. This result has caused FDA to request recalls by five companies. Ascend is not one of these companies and has not been contacted by FDA to take any recall action on its product.

As a result of this attention Ascend will implement further testing specifically aimed at detecting any NDMA in its finished product. Ascend is also working with its API (Active Pharmaceutical Ingredient) vendor to insure that the drug product also conforms to FDA specifications with regard to NDMA.