

FDA Announces Atorvastatin Recall

A recent communication from the Food and Drug Administration (FDA) shared [details](#) of a recall of specific atorvastatin formulations distributed within the United States. The news of this recall has hit mainstream news sources and patients may be contacting you to discuss the issue.

The recall involved greater than 140,000 bottles of generic atorvastatin tablets of varying strengths, including 10mg, 20mg, 40mg, and 80mg tablets. The involved products were distributed from Ascend Laboratories, LLC, based out of New Jersey; the involved medications were produced by Akem Laboratories, Ltd. India. The manufacturer-initiated recall was issued after the involved atorvastatin tablets failed dissolution tests (in laboratory settings), resulting in concerns that the medication could be less effective than normally expected when ingested by humans. The FDA issued the recall as a *Class II risk level*, which classifies it as one that “*may cause temporary or medically reversible adverse health consequences;*” the risk of *serious* adverse health effects is felt to be low. Patients are not instructed to stop taking their atorvastatin, but should rather contact their pharmacy or medical provider if they feel they may have one of the recalled products.

Of note, pharmacies keep detailed records of medications dispensed to patients. When recalls are issued by the FDA or manufacturers, pharmacies are alerted if they received the product(s) in question. If recalled products were dispensed to patients, communication is initiated and actions are taken based on the recall and instructions provided.