Generic Name:
Dietary supplement
Trade Name:
Blue Fusion
Company:
Ata Int. Inc.
Notes:

Ata Int. Inc. is voluntarily recalling all lots within expiry of Blue Fusion capsules because the product is tainted with sildenafil, tadalafil, desmethyl carbodenafil, dithiodesmethyl carbodenafil, scutellarin, and daidzein.

Sildenafil and tadalafil are FDA-approved drugs for treatment of male erectile dysfunction and are phosphodiesterase (PDE-5) inhibitors. Desmethyl carbodenafil and dithiodesmethyl carbodenafil are analogues of PDE-5 inhibitors and are likely to have the same pharmacological activity as PDE-5 inhibitors and thus carry the same clinical risks. Scutellarin and daidzein are derived from plants or herbs.

Presence of the undeclared active ingredients renders the product an unapproved drug for which safety and efficacy have not been established; therefore, the product is subject to recall.

Consumption of a product with undeclared PDE-5 inhibitors may pose a threat because the active ingredients may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels, which can be life threatening. Patients with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates and may be the population most likely to be affected.

Blue Fusion capsules were marketed as a dietary supplement for male enhancement and are packaged in 1-count blister packs (UPC code ? 7.48252. 66460.0). The product was distributed nationwide between January 2015 and March 2019 to retail stores and through the internet.

To date, Ata Int. Inc. has not received any reports of adverse events related to this recall.

Medication Monitor Categories:
Alerts and Recalls