# Ohio Department of Agriculture
# and
# Ohio Department of Health

| Mike DeWine | Jon Husted | Dorothy Pelanda | Amy Acton, M.D. |
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| Governor | Lieutenant Governor | ODA Director | ODH Director |

DATE: March 21, 2019

TO: Health Commissioners, Directors of Environmental Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2019-052

**Ata Int. Inc. Issues Voluntary Nationwide Recall of BLUEFUSION Capsules, due to presence of Undeclared Sildenafil, Tadalafil, Desmethyl carbodenafil, Dithiodesmethyl carbodenafil, Scutellarin and Daidzein**

Ata Int. Inc. is voluntarily recalling all lots within expiry of BLUEFUSION Capsules to the consumer level. FDA analysis has found the product to be tainted with sildenafil, tadalafil, desmethyl carbodenafil, dithiodesmethyl carbodenafil, scutellarin and daidzein. Sildenafil and tadalafil are FDA approved drugs for the treatment of male erectile dysfunction and are in a class of drugs called 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.

The presence of the undeclared active ingredients renders the product an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.

Consumption of a product with undeclared PDE-5 inhibitors may pose a threat to consumers 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. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates and may be the population most likely to be affected. To date, Ata Int. Inc. has not received any reports of adverse events related to this recall.

BLUE FUSION capsules were marketed as a dietary supplement for male enhancement and is packaged in 1-count blister packs, UPC code – 7.48252. 66460.0. All lots within expiry are being recalled. Product was distributed Nationwide in the USA between January 2015 and March 2019 to Retail stores and through the internet.

Consumers with questions regarding this recall can contact Ata Int. Inc. by 657-888-4041 or bluefusioncorp@gmail.com on Monday through Friday between the hours of 9 a.m. to 5 p.m. Pacific Standard Time for instructions on the disposition process. Consumers who purchased the product should stop consuming it and dispose it.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Ata Int. Inc. is notifying its customers by email and is arranging for return of all recalled products. Consumers, distributors, and retailers that have product which is being recalled should stop use or distribution and return to place of purchase. Ata Int. Inc. is committed to improving its products and avoiding future recall issues by sourcing higher quality raw ingredients and expanding testing. Ata Int. Inc. promises its customers the highest possible quality and welcomes the recall process as further evidence of our commitment to our consumers.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm1
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm2 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.