Company Announcement

Fat Burners Zone Issues Voluntary Nationwide Recall of Zero Xtreme Due to Presence of Undeclared Sibutramine

For Immediate Release

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Contact

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Announcement

View Product Photos

Fat Burners Zone is voluntarily recalling 1 lot of Zero Xtreme, capsules to the consumer level. FDA analysis has found Zero Xtreme to be tainted with sibutramine. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market due to safety concerns. The presence of Sibutramine in Zero Xtreme renders it an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.

Risk Statement: Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and, subsequently, withdrawn from the U.S. market on December 21, 2010, after clinical data indicated Sibutramine poses an increased risk of heart attack and stroke.

The product poses a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. To date, Fat Burners Zone has not received any reports of adverse events related to this recall.

This tainted product is marketed as a dietary supplement for weight loss and is packaged in gray aluminum bottles with gray aluminum caps, 30 capsules per bottle. The affected Zero Xtreme lot, #1220062085, expires 03/2020. Zero Xtreme was distributed nationwide via internet through the website fatburnerszone.com.

Fat Burners Zone is notifying its distributors and customers by a recall letter sent by email and is arranging for return/replacement of all recalled products. Consumers that have Zero Xtreme, which is being recalled, should return to place of purchase and contact their doctor.

Consumers with questions regarding this recall can contact Fat Burners Zone at (305) 741-2562 or at **usa@fatburnerszone.com (mailto:usa@fatburnerszone.com)**. Monday through Friday from 9:00 AM to 5:00 PM, EST time zone. 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.

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.htm (http://www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** 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.

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