



DATE: March 11, 2015
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: UltraZx, Labs, L.L.C. - [Drug]

AFFECTED PRODUCT: "UltraZx" weight loss supplements

SUMMARY: Unclassified Recall; The recall has been initiated because this product has been found to contain undeclared Sibutramine and phenolphthalein.

UltraZx weight loss supplement is marketed as a dietary supplement used as a weight loss aid and is packaged in bottles of thirty (30) capsules of 300mg. The affected UltraZx weight loss supplement, includes all lots/bottles/packages. The products were distributed from September 2014 until February 2015.

The recalled product was distributed nationwide.

SUGGESTED ACTION: For consumer inquiry only. Consumers with questions regarding this recall can contact UltraZx Labs, L.L.C. at (305) 904-9393, Monday through Friday from 9:00am – 5:00pm EST.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Ultra ZX LABS, L.L.C. Issues Voluntary Nationwide Recall of Ultra ZX Since It Contains Undeclared Sibutramine and Phenolphthalein

Contact:
Consumer:
(305) 904-9393

FOR IMMEDIATE RELEASE — March 10, 2015 — Miami, Florida — UltraZx, Labs, L.L.C. is voluntarily recalling "UltraZx" weight loss supplements. This product has been found to contain undeclared Sibutramine and phenolphthalein.

FDA laboratory analysis of confirmed that UltraZx contains sibutramine and phenolphthalein. Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons. 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. Phenolphthalein is a chemical that is not an active ingredient in any approved drug in the United States. Studies have indicated that it presents a cancer causing risk. This product may also interact, in life-threatening ways, with other medications a consumer may be taking.

Ultra ZX LABS, L.L.C. has not received any reports of adverse events related to this recall. UltraZx weight loss supplement is marketed as a dietary supplement used as a weight loss aid and is packaged in bottles of thirty (30) capsules of 300mg. The affected UltraZx weight loss supplement, includes all lots/bottles/packages. The products were distributed from September 2014 until February 2015.

UltraZx Labs, L.L.C. is notifying its distributors and customers by letter and is arranging for return of all recalled products. Consumers and distributors that have product which is being recalled should stop using the product and return the product to UltraZx Labs, L.L.C.

Consumers with questions regarding this recall can contact UltraZx Labs, L.L.C. at (305) 904-9393, Monday through Friday from 9:00am – 5:00pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

This recall is being conducted with the knowledge of the Food and Drug Administration (FDA).

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
- **Regular Mail or Fax:** Download form 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.

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Ultra ZX LABS, L.L.C. Issues Voluntary Nationwide Recall of Ultra ZX Since It Contains Undeclared Sibutramine and Phenolphthalein
Photo





Modo de uso: Tomar una capsula diario, 45 minutos antes de la primera comida. Para mejores resultados acompaña ULTRAax con un dieta balanceada y ejercicio. ULTRAax está designado para ayudar a la pérdida y control de peso.

INFORMACIÓN NUTRICIONAL
*CANTIDAD DE LA PORCIÓN 1 CAPSULA
#PARTIONES POR ENVASE 30 CAPSULAS

Extracto de Naranja Amarga	70	28%
Extracto de semilla de Sen	47.6	20%
Lágrima de Coix	42	18%
Almidón Medico	84	34%

*Valor de referencia no establecido

Lote 030114FL — FV 03/20/2020

Almacenar a una temperatura inferior a 30°C y en un lugar seco.

ESTE PRODUCTO ES UN SUPLEMENTO DIETARIO, NO ES UN MEDICAMENTO Y NO SUPLE UNA ALIMENTACIÓN EQUILIBRADA. Manténgase fuera del alcance de los niños. NO CONSUMIR EN ESTADO DE EMBARAZO Y LACTANCIA.

Advertencias: No exceder el consumo establecido. No apto para menores de 18 y mayores de 60, tampoco lo deben consumir personas con problemas de coagulación con alguna condición médica. No combinar con medicamentos. Antes de consumir este suplemento consultar con su doctor.



Modo de uso: Tomar una capsula diaria 45 minutos Antes de la primera comida. Para mejores resultados acompaña ULTRAzx con un dieta balanceada y ejercicio. ULTRAzx está designado para ayudar a la pérdida y control de peso.

INFORMACIÓN NUTRICIONAL

■ TAMAÑO DE LA PORCIÓN 1 CAPSULA
■ PORCIONES POR ENVASE 30 CAPSULAS

Extracto de Naranja Amarga	70	28%
Extracto de semilla de Sen	47.6	20%
Lagrima de Colix	42	18%
Almidón Medico	84	34%

*Valor de referencia no establecido

Lote 030114FL — FV 03/20/2015

Almacenar a una temperatura inferior a 30°C y evitar la humedad. ESTE PRODUCTO ES UN SUPLEMENTO ALIMENTICIO.

Alimento 35%

*Valor de referencia no establecido

Lote 030114FL ——— FV 03/20/2016

Almacenar a una temperatura inferior a 30°C y 65% de humedad

ESTE PRODUCTO ES UN SUPLEMENTO DIETARIO, NO ES UN MEDICAMENTO Y NO SUPLE UNA ALIMENTACIÓN EQUILIBRADA. Manténgase fuera del alcance de los niños. NO CONSUMIR EN ESTADO DE EMBARAZO Y LACTANCIA.

Advertencias: No exceder el consumo establecido. No apto para menores de 18 y mayores de 60, tampoco lo deben consumir personas con problemas de corazón con alguna condición médica. No combinar con medicamentos. Antes de consumir este u otro suplemento consultar con su doctor.



