

Michael R. Pence Governor

Jerome M. Adams, MD, MPH State Health Commissioner

DATE:

August 26, 2015

TO:

All Local Health Departments

Attp: Chief Food Inspection Officer

FROM:

Laurie Kidwell, RRT Supervisor

Food Protection Program

SUBJECT:

Novacare, LLC – RECALL [Dietary Supplements]

AFFECTED

PRODUCT:

Dietary Supplements

SUMMARY:

Unclassified Recall; The recall has been initiated because sample analysis by the FDA has revealed that these products contain the undeclared drug ingredient salicylic acid making these unapproved new drugs.

Salicylic acid is acutely toxic, not recommended for oral use and is harmful if swallowed.

Name*	Brand Name	Quantity	<u>UPC</u>	<u>Dates of</u> <u>Manufacture</u>
Thin & Slim	Fataway Ultimate Stack	120 capsules	853002003025	2/21/2011- 3/16/2011
ThermoFX	ThermoFX<	90 capsules	793573902665	4/5/2011
Thin and Slim	MaxOut Body	60 capsules	N/A	10/24/2011- 2/11/2014
Metabolic Accelerator	Metabolic Accelerator	120 capsules	637687114593	2/23/2011- 3/18/2013
Thin and Slim	Burn Fat Now>	90 capsules	N/A	10/29/2011- 10/29/2014
Thin and Slim	Thermogenic Fat Burner	90 capsules	020025500095	10/29/2011- 10/29/2014
TruTrim		Bulk		11/30/2011
Thin and Slim Naturally AM	Thin and Slim Naturally	90 capsules	637687019003	10/29/2011- 10/29/2014
Thin and Slim	Extreme Stack	90 capsules	637687019133	1/30/2012, 3/20/2012
Xcellerator		Bulk		10/27/2011- 3/26/2012
Asia Black	Asia Black	100 capsules	859613274229	5/19/2011- 5/13/2014
Black Widow	Black Widow 25	100 capsules	859613252258	1/25/2011- 8/10/2014
Methyldrene	Methyldrene Original 25	100 capsules	859613638496	1/19/2011- 6/28/2013



These products were distributed nationwide to distributors.

SUGGESTED

ACTION:

For consumer inquiry only. Consumers with questions regarding this recall can contact Novacare, LLC directly at (801) 261-2252, Monday through Friday from 10:00 am – 4:00 pm MST.

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.

Novacare, LLC Issues Voluntary Nationwide Recall of Dietary Supplements Due to Undeclared Salicylic Acid

Contact:

Consumer: 801-261-2252

FOR IMMEDIATE RELEASE — August 24, 2015 — Murray, UT — Novacare, LLC of Murray, Utah is voluntarily recalling all lots of the following dietary supplements to the consumer level:

Name*	Brand Name	Quantity	<u>UPC</u>	<u>Dates of</u> <u>Manufacture</u>
Thin & Slim	Fataway Ultimate Stack	120 capsules	853002003025	2/21/2011- 3/16/2011
ThermoFX	ThermoFX<	90 capsules	793573902665	4/5/2011
Thin and Slim	MaxOut Body	60 capsules	N/A	10/24/2011- 2/11/2014
Metabolic Accelerator	Metabolic Accelerator	120 capsules	637687114593	2/23/2011- 3/18/2013
Thin and Slim	Burn Fat Now>	90 capsules	N/A	10/29/2011- 10/29/2014
Thin and Slim	Thermogenic Fat Burner	90 capsules	020025500095	10/29/2011- 10/29/2014
TruTrim		Bulk		11/30/2011
Thin and Slim Naturally AM	Thin and Slim Naturally	90 capsules	637687019003	10/29/2011- 10/29/2014
Thin and Slim	Extreme Stack	90 capsules	637687019133	1/30/2012, 3/20/2012
Xcellerator		Bulk		10/27/2011- 3/26/2012
Asia Black	Asia Black	100 capsules	859613274229	5/19/2011- 5/13/2014
Black Widow	Black Widow 25	100 capsules	859613252258	1/25/2011- 8/10/2014
Methyldrene	Methyldrene Original 25	100 capsules	859613638496	1/19/2011- 6/28/2013

^{* -} Pictures of the product labels are included herewith for easier identification.

Sample analysis by the FDA has revealed that these products contain the undeclared drug ingredient salicylic acid making these unapproved new drugs.

Salicylic acid is acutely toxic, not recommended for oral use and is harmful if swallowed. Nausea, vomiting, gastrointestinal irritation, loss of hearing, sweating to severe reactions of blurred vision, mental confusion, cerebral edema and cardiorespiratory arrest which could be life-threatening may occur. Since the labeling does not state salicylic acid is contained it the product, individuals who are allergic, elderly, have a history of stomach ulcers or bleeding problems, consume ≥ 3 alcoholic drinks per day, or take concomitant medications containing salicylates are at higher risk for toxicity. No illnesses from these products have been reported to date.

These products are marketed as dietary supplements aiding in weight loss, produced in capsule form, and were sold in bottles. These products were distributed nationwide to distributors.

Novacare, LLC is notifying its distributors and customers by certified mail and is arranging for return of all recalled product. Consumers/distributors/retailers that have the aforementioned products that are being recalled should stop using, distributing, or selling them and return them to:

Novacare, LLC Returns Dept.: MS# 2000 913 West 2900 South Salt Lake City, UT 84119

Consumers with questions regarding this recall can contact Novacare, LLC directly at (801) 261-2252, Monday through Friday from 10:00 am – 4:00 pm MST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking any of the aforementioned products.

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.

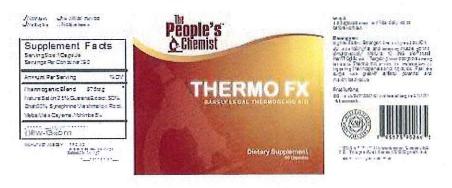
- Complete and submit the report Online:www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

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Photo







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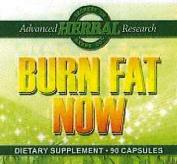
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Thermogenic Fat Burner

Suppreses Appetite Boosts Energy Levels Burns Fat

Dietary Supplement . 60 Capsules

Supplement Facts

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