

Michael R. Pence Governor

Jerome M. Adams, MD, MPH State Health Commissioner

DATE:

September 14, 2015

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

Laurie Kidwell, RRT Supervisor

Food Protection Program

SUBJECT:

The One Minute Miracle Inc. – RECALL [Drug]

AFFECTED

PRODUCT:

Miracle Diet 30, capsules and Miracle Rock 48, capsules

SUMMARY:

Unclassified Recall; The recall has been initiated because Miracle Diet 30 has been found to contain undeclared phenolphthalein, phenolphthalein was an ingredient used in over-the counter laxatives but was removed from the market because of concerns of carcinogenicity. Miracle Rock 48 has been found to contain undeclared thiosildenafil, thiosildenafil is an analogue of sildenafil which is an approved drug used for the treatment of male sexual enhancement.

Miracle Diet 30 capsules is marketed as a dietary supplement to support appetite control and weight loss and is packaged in 30-count plastic bottles. All lots of Miracle Diet 30 through the expiration date of 04/15/2018 are affected.

Miracle Rock 48 capsules is marketed as a dietary supplement for male sexual enhancement and is packaged in two blister packages of 2- count capsules, 4 capsules per box. All lots of Miracle Rock 48 through the expiration date of 06/01/2018 are affected.

Products were distributed via nationwide in the United States.

In addition to the voluntary recall of the above products, The One Minute Miracle Inc. has chosen to voluntarily withdraw the following products from the marketplace to provide its customers with the certainty of safety. Those products include all sizes and lots of Miracle Cholesterol, Miracle Night Time, Miracle Joint-Flex, Miracle Stud 72, Miracle Magic Man, Male Mint Gum, Miracle 48 Hrs, Miracle Magic Woman, Miracle Cougar, Miracle Cougar Gum, Miracle Cougar G-Spot, Miracle G-Spot, Vagina Rejuvenation, Miracle Anti-Wrinkle, Miracle Stud Delay, Miracle Male Stud Spray, Miracle Male Stud Coffee, Miracle Male Coffee, Male 10, Miracle Male Stud Sublingual, Male 72 Hr, Miracle Tongue Sublingual, Miracle Tongue and Master Blaster.

SUGGESTED ACTION:

For consumer inquiry only. Consumers with questions regarding this recall can contact The One Minute Miracle Inc. by phone (305)947-6244 or email theoneminutemiracle@gmail.com Monday through Friday,

9:00am through 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.

The One Minute Miracle Inc. Issues Voluntary Nationwide Recall of MIRACLE DIET 30 Due to Presence of Undeclared Phenolphthalein & MIRACLE ROCK 48 Due to Presence of Undeclared Thiosildenafil

Contact:

Consumer: Rene Castillo (305) 947-6244 www.theoneminutemiracleinc.com

FOR IMMEDIATE RELEASE — September 11, 2015 — North Miami Beach, Florida — The One Minute Miracle Inc. is voluntarily recalling all lots of *Miracle Diet 30*, capsules and *Miracle Rock 48*, capsules to the consumer level. These products have been recalled due to FDA analysis revealing that these dietary supplements contain undeclared drug products making them unapproved drugs.

Miracle Diet 30 has been found to contain undeclared phenolphthalein, phenolphthalein was an ingredient used in over-the counter laxatives but was removed from the market because of concerns of carcinogenicity. There is a reasonable probability that the health risks of long term phenolphthalein consumption could include serious gastrointestinal disturbances, irregular heartbeat, and cancer with long term use.

Miracle Rock 48 has been found to contain undeclared thiosildenafil, thiosildenafil is an analogue of sildenafil which is an approved drug used for the treatment of male sexual enhancement. Based on the similarity of chemical structures thiosildenafil, the analogue of sildenafil is likely to have a similar pharmacological effect as sildenafil and there is a reasonable probability that concomitant use of this dietary supplement and nitrates could cause a sudden and significant drop in blood pressure that may be life threatening.

The company has received no reports of illness associated with these products to date.

Miracle Diet 30 capsules is marketed as a dietary supplement to support appetite control and weight loss and is packaged in 30-count plastic bottles. All lots of Miracle Diet 30 through the expiration date of 04/15/2018 are affected. Product was distributed via internet nationwide in the United States.

Miracle Rock 48 capsules is marketed as a dietary supplement for male sexual enhancement and is packaged in two blister packages of 2- count capsules, 4 capsules per box. All lots of Miracle Rock 48 through the expiration date of 06/01/2018 are affected. Product was distributed via nationwide in the United States.

In addition to the voluntary recall of the above products, The One Minute Miracle Inc. has chosen to voluntarily withdraw the following products from the marketplace to provide its customers with the certainty of safety. Those products include all sizes and lots of Miracle Cholesterol, Miracle Night Time, Miracle Joint-Flex, Miracle Stud 72, Miracle Magic Man, Male Mint Gum, Miracle 48 Hrs, Miracle Magic Woman, Miracle Cougar, Miracle Cougar Gum, Miracle Cougar G-Spot, Miracle G-Spot, Vagina Rejuvenation, Miracle Anti-Wrinkle, Miracle Stud Delay, Miracle Male Stud Spray, Miracle Male Stud Coffee, Miracle Male Coffee, Male 10, Miracle Male Stud Sublingual, Male 72 Hr, Miracle Tongue Sublingual, Miracle Tongue and Master Blaster

The One Minute Miracle is notifying its customers via U.S. Postal Service and is arranging for return of recalled products. Consumers that have Miracle Diet 30 and/or Miracle Rock 48 which are being recalled should stop using and return product(s) immediately to: The One Minute Miracle Inc. 3322 NE 166 Street, North Miami Beach, FL 33160

Consumers with questions regarding this recall can contact The One Minute Miracle Inc. by phone (305)947-6244 or email theoneminutemiracle@gmail.com Monday through Friday, 9:00am through 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 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
- 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.

###



MIRACLE DIET 3

MARCINIA CAMBOURABLES

BUPPOWTH APPETRY CONTRO

HE ALTHY MEXICA



SECRETARIA SECRETARIA

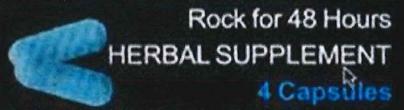
Bridge Street Control of American



MIRACLE ROCK 48

BLUE NATURAL MIRACLE PILL

Fast Acting Maximum Strength



MALE SEXUAL ENHANCEMENT www.Theoreminutemiracleinc.com

		av variable.
		7.000.000.000
		,
		THE PROPERTY OF THE PROPERTY O
		TOTAL CONTRACTOR OF THE CONTRA