



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: August 28, 2015
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: The One Minute Miracle Inc. [Dietary Supplements]

AFFECTED PRODUCT: Miracle Diet 30, capsules and Miracle Rock 48

SUMMARY: Unclassified Recall; The recall for Miracle Diet 30 has been initiated because it has been found to contain undeclared phenolphthalein and Miracle Rock 48 has been found to contain undeclared thiosildenafil. These undeclared ingredients make Miracle Diet 30 and Miracle Rock 48 unapproved drugs.

Miracle Diet 30 capsules is marketed as a dietary supplement to support appetite control and lose weight and is packaged in 30-count plastic bottles. The affected Miracle Diet 30 Lot Number 150416, Expiration 04/15/2018.

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. The affected Miracle Rock 48 Lot Number 20150602, Expiration 06/01/2018.

Both recalled products were distributed via the internet nationwide.

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 the oneminutemiracle@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:



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

(305)947-6244 or
email theoneminutemiracle@gmail.com

FOR IMMEDIATE RELEASE - August 27, 2015, North Miami Beach, Florida - The One Minute Miracle Inc. is voluntarily recalling one lot each of **Miracle Diet 30**, capsules and **Miracle Rock 48**.

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 Diet 30 capsules is marketed as a dietary supplement to support appetite control and lose weight and is packaged in 30-count plastic bottles. The affected Miracle Diet 30 Lot Number 150416, Expiration 04/15/2018. Product was distributed via internet nationwide in the United States.

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.

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. The affected Miracle Rock 48 Lot Number 20150602, Expiration 06/01/2018. Product was distributed via internet nationwide in the United States.

These undeclared ingredients make Miracle Diet 30 and Miracle Rock 48 unapproved drugs.

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

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: <http://www.fda.gov/medwatch/report.htm> Regular Mail or Fax: Download form <http://www.fda.gov/MedWatch/getforms.htm> or call 1-800-FDA-0178.

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

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*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
Photos*



THE 1 MINUTE MIRACLE

MIRACLE ROCK 48

**BLUE NATURAL
MIRACLE PILL**

Fast Acting Maximum Strength

Rock for 48 Hours

HERBAL SUPPLEMENT

4 Capsules

MALE SEXUAL ENHANCEMENT

www.Theoneminutemiracleinc.com

