



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 17, 2014
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: Solgar, Inc., - RECALL [Drug]

AFFECTED PRODUCT: ABC Dophilus® Powder

SUMMARY: Unclassified Recall; The recall has been initiated because the product was found to contain Rhizopus oryzae, which may cause Mucormycosis.

Description: Solgar ABC Dophilus® Powder NET Wt. 1.75 oz (50 g)
UPC Code: 0 33984 00010 0
Label: Solgar
Lot# 074024-01R1, 074024-01, 074024-02 Expiration Date 7/31/15

This product was distributed to: Indiana, Illinois, Michigan, Ohio, and Kentucky through pharmacy, retail stores, wholesale, internet, etc.

SUGGESTED ACTION: For consumer inquiry only. Consumers with questions may contact the company at 888-534-6370, Monday-Friday, 9AM-7PM ET.

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.

Solgar, Inc. Issues Voluntary Class I Recall of ABC Dophilus® Powder

Contact
Consumer:
888-534-6370, Monday-Friday, 9AM-7PM ET



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To promote and provide
essential public health services.

Media:
Andrea Staub
631-200-7459

FOR IMMEDIATE RELEASE – November 14, 2014 – Solgar, Inc., of Leonia, NJ, is voluntarily recalling ABC Dophilus® Powder. The recall was initiated, out of an abundance of caution, because the product was found to contain *Rhizopus oryzae*, which may cause Mucormycosis. This is a rare infection that may cause health problems to consumers, particularly pre-mature infants/infants, children, and those with weakened immune systems. Although, it may also occur (rarely) in people who are otherwise healthy. Susceptible consumers should consult with their physician or health care provider if they have used this product.

Solgar is notifying consumers and customers not to consume this product.

This product was distributed to: AL, AR, AZ, CA, CT, CO, FL, IA, IL, IN, MI, ME, MO, MA, NC, NE, NY, NJ, NV, OH, OK, PA, PR, UT, TN, TX, VT, KY, WI, WA, UK and Israel through pharmacy, retail stores, wholesale, internet, etc.

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One complaint has been received to date.

Testing conducted by the Centers for Disease Control revealed the presence of *Rhizopus oryzae* in 1.75 oz (50 g) containers of Solgar ABC Dophilus Powder.

The distribution of the product has been suspended while FDA and the company continue to investigate the source of the problem.

Risk factors for developing Mucormycosis include: uncontrolled diabetes; cancer; organ transplant; neutropenia (low white blood cells); skin trauma (cuts, scrapes, punctures, or burns). Susceptible consumers should consult with their physician or health care provider.

Consumers who have purchased Solgar ABC Dophilus® Powder are urged not to consume the product and should return it to the place of purchase for a full refund. Consumers with questions may contact the company at 888-534-6370, Monday-Friday, 9AM-7PM ET.

Solgar, Inc. Issues Voluntary Class I Recall of ABC Dophilus® Powder Photos

Solgar® ABC Dophilus® Powder is a selective blend of beneficial friendly bacteria specially formulated for the infant and child, including the well-known strains *Bifidobacterium lactis* BB-12 (Bb-12™) and *Lactobacillus rhamnosus* GG (LGG™). *Bifidobacterium* and *Lactobacillus* species are present in the microflora of healthy children and infants and reside primarily in the large intestine. They support good health in these populations by helping to maintain a healthy balance within the intestine's microbial ecology.*

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure, treat, or prevent any disease.

Carefully Manufactured by:
Solgar, Inc., 300 Willow Tree Road
Leonia, NJ 07605 U.S.A.

For more information, call toll-free
1-877-661-6644, or visit www.solgar.com
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ENHANCED SERIES

ABC DOPHILUS® POWDER

FOR INFANTS AND CHILDREN

100% DAIRY, LACTOSE & MILK FREE
SUITABLE FOR VEGETARIANS

NET WT 1.75 oz (50 g)

DIETARY SUPPLEMENT

Supplement Facts
Serving Size: 1 Teaspoon (1.5 g)
Servings Per Container: About 33

Amount Per Serving	%DV for Infants and children under 4 years of age
Calories 0	
Total Carbohydrate	0 g
ABC Dophilus®	1.5 g
Powder Complex: Supplying 1 billion viable microorganisms: B. lactis, BB-12®	
410 million viable microorganisms S. thermophilus, TH-4®	
410 million viable microorganisms L. rhamnosus, LGG®	
160 million viable microorganisms	

*Daily Value (DV) not established
Other Ingredients: Maltodextrin

SUGGESTED USE: As a dietary supplement for infants and children, baby one half (1/2) teaspoon (1.5 g) daily, or as directed by a healthcare practitioner. Mix with infant formula, milk, juice or water or may be sprinkled on foods.

FREE OF: Gluten, Wheat, Dairy, Soy, Yeast, Sugar, Salt, Artificial Flavors, Sweeteners, Preservatives and Color.

If you are pregnant, nursing, taking any medication, or have any medical condition, please consult your healthcare practitioner before taking any dietary supplement. This product contains milk ingredients that may not be tolerated by children. This product may contain small amounts of lactose. Contains 160 million viable microorganisms.

REFRIGERATE AFTER OPENING. Do not use after date and remove all clumps.

KEEP OUT OF REACH OF CHILDREN.

36 Fl. Oz. (1.01 L) net. See the legal disclaimer of the Home.

©2012 © registered trademark of Solgar, Inc. The product is sold by weight net by volume. Amounts may vary slightly.



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