**Dietary Supplements Containing Live Bacteria or Yeast in Immunocompromised Persons: Warning - Risk of Invasive Fungal Disease**

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**AUDIENCE**: Health Professional, Pediatrics , Internal Medicine, Consumer

**ISSUE**: FDA is warning health professionals of the risks associated with the regarding use of dietary supplements containing live bacteria or yeast in immunocompromised persons. A premature infant administered a dietary supplement, ABC Dophilus Powder (Solgar), as part of in-hospital course of treatment, developed gastrointestinal mucormycosis caused by the mold Rhizopus oryzae and died. Rhizopus oryzae mold was found to be present as a contaminant in an unopened container of the ABC Dophilus Powder, which is formulated to contain three species of live bacteria.

FDA, along with the Centers for Disease Control and Prevention (CDC) and the Connecticut Department of Public Health, are investigating the death of this preterm infant who developed gastrointestinal mucormycosis. In mid-November, Solgar issued a recall for certain lots of ABC Dophilus Powder and public health warnings were issued advising customers and consumers not to use the recalled product.

FDA is informing healthcare providers that dietary supplements, including those that are formulated to contain live bacteria or yeast, are generally not regulated as drugs by the FDA. As such, these products are not subject to FDA’s premarket review or approval requirements for safety and effectiveness, nor to the agency’s rigorous manufacturing and testing standards for drugs, including testing for extraneous organisms.

**BACKGROUND**: FDA is warning health professionals of the potential risks associated with the use of dietary supplements containing live bacteria or yeast in immunocompromised persons. Gastrointestinal mucormycosis primarily occurs in immunocompromised persons, such as prematurely born infants.

**RECOMMENDATION**: FDA advises practitioners to approach the application of these interventions with caution. FDA encourages health care providers who use dietary supplements containing live bacteria or yeast as drugs (e.g., to treat, mitigate, cure, or prevent a disease or condition) to submit an Investigational New Drug Application (IND) for FDA review

Health care providers and consumers are encouraged to report adverse events following use of dietary supplements both to the manufacturer using the address or phone number which is required to be on the product label and to the FDA. Visit [www.safetyreporting.hhs.gov](http://www.safetyreporting.hhs.gov) to submit a report online, or call 1-800-FDA-1088.

[12/09/2014 - [Dear Healthcare Provider Letter](http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/UCM426233.pdf) - FDA]

Previous MedWatch Alert:

[ABC Dophilus Powder by Solgar, Inc: Recall - Risk of Infection](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm423277.htm)