



DATE: June 7, 2012

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: *ASG*
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Botanical Laboratories Recall

SUGGESTED

ACTION: Unclassified Recall; 38 bottles of 33.8 oz "Digestive 3 in 1 Health " liquid dietary supplement and 275 bottles of 16 oz. "Digestive Health 3 in 1" liquid dietary supplement, because a supplier of one of the ingredients has indicated the ingredient has the potential to be contaminated with Salmonella; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. Both 33.8 oz. and 16 oz "Digestive 3 in 1 Health" were distributed nationwide through retail stores, and online retailers. The product was distributed after 05/01/2012. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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.

Botanical Laboratories Inc. Recalls Wellesse Digestive 3 in 1 Health® Because of Possible Health Risk

Contact

Botanical Laboratories Inc.
800-232-4005

FOR IMMEDIATE RELEASE - June 4, 2012 - Botanical Laboratories of Ferndale, WA is recalling 38 bottles of 33.8 oz "Digestive 3 in 1 Health " liquid dietary supplement and 275 bottles of 16 oz. "Digestive Health 3 in 1" liquid dietary supplement, because a supplier of one of the ingredients has indicated the ingredient has the potential to be contaminated with Salmonella, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with Salmonella often experience : fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with Salmonella can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis.

No illnesses have been reported to date.

On 05/29/12 Botanical Laboratories was informed by raw ingredient supplier Corn Product Int. that retain samples of a lot (#117369) of a raw material Purimune (Galacto Oligosaccharide), which was one of the ingredients used to make "Digestive 3 in 1 Health" had tested positive for salmonella. To date, raw material received and tested by Botanical Laboratories have tested negative for salmonella. To date, no lots of "Digestive 3 in 1 Health" final product have tested positive for salmonella.

In an abundance of caution, Botanical Laboratories is voluntarily recalling the following: 16 oz. size has "LOT 34441C (followed by a four digit time code)A EXP 03/2014" jet coded on the bottom of the bottle. The 33.8 oz. size has "LOT 34552C (followed by a four digit time code)A EXP 03/2014" jet coded on the bottom of the bottle. Both "Digestive 3 in 1 Health" 16 oz. and 33.8 oz. products are packaged in white HDPE plastic bottles with a full body shrink sleeve label. The label is predominantly orange with green trim and print. The brand Wellesse appears across a white band at the top of the bottle in blue print. The product name "Digestive 3 in 1 Health" is printed on the front of the label in white with green trimmed print.

Both 33.8 oz. and 16 oz "Digestive 3 in 1 Health" were distributed nationwide through retail stores, and online retailers. The product was distributed after 05/01/2012.

Consumers who have purchased Wellesse "Digestive 3 in 1 Health" with one of the above referenced lot numbers are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-232-4005.

Product images attached separately for reference.

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[RSS Feed for FDA Recalls Information](#)¹ [[what's this?](#)²]

[Photo: Product Labels](#)³