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John R. Kasich

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 ODA Director  
David T. Daniels

 ODH Director  
Lance D. Himes

DATE: August 14, 2018

TO: Health Commissioners, Directors of Environment Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2018-099a

**World Organix, LLC Issues Voluntary Nationwide Recall of Blissful Remedies Red Maeng Da 100% Mitragyna Speciosa, Blissful Remedies Red Maeng Da Liquid Kratom Mitragyna Speciosa, Blissful Remedies 4 Hour Chill Slow Motion Blend, Due to High Microbial Loads Contamination**

World Organix LLC, is voluntarily recalling lot: 112710 of Blissful Remedies Red Maeng Da 100% Mitragyna Speciosa capsules, Blissful Remedies Red Maeng Da Liquid Kratom Mitragyna Speciosa, Blissful Remedies 4 Hour Chill Slow Motion Blend to the consumer level. These products have been tested by the U.S. Food and Drug Administration ("FDA") and found to be contaminated with High Microbial Loads. Additionally, this serves as a update to a previous press release posted on June 30th 2018, concerning Blissful Remedies Gold Series Ultra Enhanced Indo and Blissful Remedies Kratom+CBD, CBD infused Maeng Da, Red Maeng Da 100% Mitragyna Speciosa, recalled due to Salmonella contamination, where Blissful Remedies was listed as the recalling firm instead of World Organix LLC. To date, World Organix LLC has not received reports of adverse events related to these recalls.

Immunodeficient individuals have a higher probability of developing a disseminated potentially life threatening infection when ingesting or otherwise orally exposed to solutions contaminated by microorganisms. Salmonella, is a microbial 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.

These are unapproved products. The Maeng Da products, containing M. speciose, has psychoactive properties. The 4 Hour Chill Herbal Shot, contains melatonin, which has been reported to treat insomnia. The affected products, lot, best by dates and packaging are as follows:

Product Name	Quantity and Dosage form	Packaging	Lot #
Blissful Remedies Red Maeng Da Liquid Kratom Mitragyna Speciosa	12 ML	White Plastic bottle	112710 Best By Date: 06/2019
Blissful Remedies 4 Hour Chill Slow Motion Blend	1.93 Fluid Oz (57 ml)	White Plastic bottle	112710 Best By Date: 03/2019
Blissful Remedies Red Maeng Da 100% Mitragyna Speciosa	50 capsules	White Foil Pouch	112710 Best By Date: 03/2019

Product Name	Quantity and Dosage form	Packaging	Lot #
Blissful Remedies Gold Series Ultra Enhanced Indo (100% Mitragyna Speciosa)	50 capsules	White Foil Pouch	112710 Best By Date: 03/2019
Blissful Remedies Kratom+CBD, CBD infused Maeng Da	50 capsules	White Foil Pouch	112710 Best By Date: 03/2019

World Organix is notifying its retailers and customers by e-mail and/or telephone and is arranging for return of the recalled products. Customers/retailers that have product that is being recalled should immediately discard them.

Consumers with questions regarding this recall can contact World Organix LLC at [fdarecall@blissfulremedies.com](mailto:fdarecall@blissfulremedies.com) or 1-800-435-8533, 9 am to 6 pm (Central Time Zone), Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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 is an update to a previous press release that was posted on June 30th 2018, where Blissful Remedies product was listed as the recalling firm instead of World Organix.

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

[Original Press Release](#)