FDA Alert: NxtGen Botanicals Maeng Da Kratom by NGB Corp.: Recall

April 19, 2018

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AUDIENCE: Consumer

ISSUE: NGB Corp. of West Jordan, Utah is voluntarily recalling NxtGen Botanicals Maeng Da Kratom labeled bottles of encapsulated product because it 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.

One illness has been reported to date and the recall was initiated after NGB Corp. was notified of positive Salmonella test results by FDA. NGB Corp. has identified the supplier and source of contaminated product and has ceased the production and distribution of the product.

Distribution of an estimated 1,108 units were sold directly to 22 retailers in Utah, 2 in Massachusetts, and 1 in each of Arizona, Georgia, Minnesota, and California. The lot number can be found on the bottom of each bottle. The possibly affected products bear the lot #171409 and are packaged in plastic sealed bottles sold in 500-miligram capsules.

BACKGROUND: 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.

RECOMMENDATION: Consumers who may be in possession of potentially contaminated products are advised not to consume products labeled NxtGen Botanicals Maeng Da Kratom. All products associated with this recall should be returned to NGB Corp. for a full refund. Customers can return product to the place of purchase for a full refund and retail stores will receive a full refund from NGB Corp. within 14 business days. Customers with questions about this issue should contact NGB Corp. anytime by e-mail at nxtgenbotanicals@gmail.com or via phone at (323) 813-5428 from 8:00 a.m. to 5:00 p.m. MST.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

[04/18/2018 – Recall Notice – FDA]