FDA alerts consumers not to use Kratom NC's products

[6/25/2019] FDA is warning consumers not to use products marketed by Kratom NC, of Wilmington, North Carolina, due to microbial contamination.

FDA laboratory analysis of Kratom NC's raw materials and finished products identified various microorganisms, including *Klebsiella pneumoniae*, *Enterobacter spp.* and *Escherichia sp.* These organisms may cause serious illnesses in vulnerable patient populations.

FDA contacted Kratom NC on June 14 to recommend the company recall all of its products currently on the market. However, the company has not taken any action to recall these potentially dangerous products.

The agency recently issued a warning letter to Kratom NC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kratomnc-576964-05162019) for illegally selling unapproved, misbranded kratom-containing drug products with unproven claims about their ability to treat or cure opioid addiction and withdrawal symptoms. The agency continues to urge consumers not to consume kratom and to seek appropriate medical care from their health care provider.

To date, FDA is not aware of any reports of illness associated with the use of Kratom NC products. The agency asks health care professionals and patients to report unexpected side effects or quality problems associated with these products to FDA's MedWatch Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program):

- Complete and submit the report online at www.fda.gov/medwatch/report.htm (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program); or
- Download and complete the form

(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home), then submit it via fax at 1-800-FDA-0178 (tel:1-800-FDA-0178).

For more information

- Press release: FDA issues warnings to companies selling illegal, unapproved kratom drug products marketed for opioid cessation, pain treatment and other medical uses (/node/388453)