

Item #7(6)

**ADDITIONAL MATERIAL
2:00 P.M. PUBLIC HEARING
OCTOBER 28, 2014**

**SUBMITTED AT THE REQUEST OF
COMMISSIONER JACOBS**

Subject:

FW: Fwd: FDA News Release

FDA News Release

U.S. Marshals seize botanical substance kratom from southern California facility

Kratom was marketed with drug claims

For Immediate Release

September 25, 2014

Release

U.S. Marshals at the request of the U.S. Food and Drug Administration today seized more than 25,000 pounds of raw kratom material worth more than \$5 million from Rosefield Management, Inc. in Van Nuys, California.

Mitragyna speciosa, commonly known as kratom, is a botanical substance that grows naturally in Thailand, Malaysia, Indonesia and Papua New Guinea. Kratom is promoted on numerous websites in the United States for its psychoactive and opioid-like analgesic effects and for use in the treatment of morphine and heroin addiction, but it is not approved in the United States for any medical use.

The kratom product, imported by Rosefield Management from C.V. Bali Herbal of Indonesia, contains alkaloids that have pharmacological effects similar to morphine and other opiates. Consumption of kratom can lead to a number of health problems including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, loss of libido, tremors, skin hyperpigmentation, nausea, vomiting, constipation and severe withdrawal signs and symptoms.

"We have identified kratom as a botanical substance that poses a risk to public health and has the potential for abuse," said Melinda Plaisier, the FDA's associate commissioner for regulatory affairs. "This action was taken to safeguard the public from this dangerous product, and FDA will continue to take aggressive enforcement actions against products that are promoted for uses that are unapproved."

In February, the FDA issued an import alert that allows the agency to detain imported kratom without physical examination.

More than 500 cartons of kratom were seized from Rosefield's Van Nuys facility. Rosefield distributed kratom after receiving instruction to do so from Wholesale Shamanic Herbs. Wholesale Shamanic Herbs promoted kratom on its website with claims that the product is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.

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The FDA filed a complaint in the U.S. District Court for the Central District of California alleging that kratom is an unapproved new drug and a misbranded drug under the Federal Food, Drug, and Cosmetic Act.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation and for regulating tobacco products.

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