

EXHIBIT 19

Import Alert 54-15

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(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 54-15

Published Date: 02/21/2025

Type: DWPE

Import Alert Name:

DETENTION WITHOUT PHYSICAL EXAMINATION OF DIETARY SUPPLEMENTS AND BULK DIETARY INGREDIENTS THAT ARE OR CONTAIN MITRAGYNA SPECIOSA OR KRATOM

Reason for Alert:

FDA has seen an increase in the number of shipments of dietary supplements and bulk dietary ingredients that are, or contain kratom, also known as Mitragyna speciosa, mitragynine extract, biak-biak, cratom, gratom, ithang, kakuam, katawn, kedemba, ketum, krathom, krton, mambog, madat, Maeng da leaf, nauclea, Nauclea speciosa, or thang. These shipments of kratom have come in a variety of forms, including capsules, whole leaves, processed leaves, leaf resins, leaf extracts, powdered leaves, and bulk liquids made of leaf extracts. Importers' websites have sometimes contained information about how their products are used.

Kratom is a botanical that qualifies as a dietary ingredient under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(ff)(1)]. When marketed as a dietary ingredient, FDA also considers kratom to be a new dietary ingredient under section 413(d) of the Act [21 U.S.C. 350b(d)] because, to the best of the agency's knowledge, there is no information demonstrating that this substance was marketed as a dietary ingredient in the United States before October 15, 1994.

Furthermore, based on FDA's review of the publicly available information regarding kratom, there does not appear to be a history of use or other evidence of safety establishing that kratom will reasonably be expected to be safe as a dietary ingredient. In fact, the scientific literature disclosed serious concerns regarding the toxicity of kratom in multiple organ systems. Consumption of kratom can lead to a number of health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms. In the absence of a history of use or other evidence of safety establishing that kratom will reasonably be expected to be safe as a dietary ingredient, kratom and kratom-containing dietary supplements and bulk dietary ingredients are

adulterated under section 402(f)(1)(B) of the Act [21 U.S.C. 342(f)(1)(B)], because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

Guidance:

Districts may detain, without physical examination, the specified products from the firms identified in the RED LIST of this alert. The specified dietary supplements and bulk dietary ingredients from the firms listed on the RED LIST of this Import Alert have been found to contain kratom.

When detained products appear to be dietary supplements or bulk dietary ingredients as discussed in this alert and are not currently listed on the RED LIST of this alert, Districts should forward appropriate evidence/documentation as a "Center Review Detention" case via CMS to CFSAN/OC/DE/LDSCT team. Based on the Center's evaluation, a CMS case for addition to the RED LIST of this alert may be forwarded to DIO/IOMB team by the District's Compliance Branch.

Districts should be on alert to the possibility that the labeling, marketing, and/or promotion of kratom and kratom-containing products may indicate that such products appear to be unapproved and/or misbranded drugs. For such products, Import Alert 66-41 may be applicable.

Questions or issues involving import operations should be addressed to OII Division of Import Operations (DIO) at (301) 796-0356 or Imports@fda.hhs.gov.

Questions or issues involving science policy, analysis, preparation, or analytical methodology, should be addressed to FDAPRIVATELABIMPORTALERTS@fda.hhs.gov

Questions or issues with regard to human food on policy, sample collection recommendations, or any additional questions not directly related to a detained entry, should be addressed to the Human Foods Program Imports Enforcement Branch at HFP-OCE-Imports@fda.hhs.gov

Product Description:

Kratom (aka Mitragyna speciosa, mitragynine extract, biak-biak, cratom, gratom, ithang, kakuam, katawn, kedemba, ketum, krathom, krton, mambog, madat, Maeng da leaf, nauclea, Nauclea speciosa, or thang)

Charge:

"The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be a dietary supplement or contains a dietary ingredient that is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. [Adulteration, Section 402(f)(1)(B)]."

OASIS Charge Code: UNSFDIETSP