

United States Food and Drug Administration

Cincinnati District Office

Notice of FDA Action

Entry Number: [REDACTED]

Notice Number: 1
June 24, 2015

Importer:
[REDACTED]
[REDACTED]
[REDACTED]

> <

Port of Entry: 4197, DHL at Cincinnati, Cincinnati, OH
Carrier: POLAR AIR CARGO, INC.;
Date Received: June 9, 2015
Arrival Date: June 2, 2015
Filer of Record: DHL Express USA Inc, Erlanger, KY 41018-1272
Consignee: [REDACTED]

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
* 001/001	Kratom	20 KG	Detained 06-24-2015

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/FDA	Product Description	Respond By
001/001	Kratom	July 15, 2015

FD&CA Section 402(f)(1)(B), 801(a)(3) Adulteration
The article appears to be a dietary supplement or 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. It appears that [REDACTED] is importing kratom for human consumption. Kratom has not been the subject of a New Dietary Ingredient application.

Please direct your response to:

[REDACTED]
U.S. Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097

[REDACTED]
[REDACTED]