NATURAL PRODUCTS ASSOCIATION

440 1st St. NW, Ste. 520, Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250
NPAinfo.org

November 29, 2016

Michael J. Lewis,
Diversion Control Division, Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Via Electronic Submission

RE: Docket No. DEA-442W "Withdrawal of Notice of Intent; Solicitation of Comments"

Dear DEA Federal Register Representative,

The Natural Products Association (NPA) is submitting this letter as formal comments to Docket No. DEA-442W "Withdrawal of Notice of Intent; Solicitation of Comments." NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. We are the oldest and largest trade association in the natural products industry representing over 1,400 members accounting for almost 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. Furthermore, NPA is *the* leading trade association for dietary supplements. NPA is a non-profit 501(c) (6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products.

The safety record of the dietary supplement and natural products industry is far superior to prescription drugs or even conventional foods because of a strong federal regulatory regime, significant investment in product safety and quality, consumer demand and self-regulatory programs developed by the men and women of our industry, who want to help people lead healthier lifestyles. Adding an untested and unregulated substance such as kratom to our food supply without the application of longstanding federal rules and guidelines would not only be illegal, it could likely be dangerous, leading to serious unintended consequences as our nation struggles with the crisis of opioid addiction.

NPA strongly supports the prosecution of criminal activity, and has robust internal measures and quality assurance programs to report bad actors to authorities. It is important for the federal government to enforce the laws, designed to protect consumers from potentially dangerous substances introduced into the U.S. diet, which are currently on the books. As former Food and Drug Administration (FDA) officials and regulators of the dietary supplement industry, we can tell you that finished kratom products and raw kratom botanical ingredients have not met the strict standards products and new ingredients must adhere to in order to be marketed to the public and deemed safe for regular use in either our food or our drug supply.

Kratom has been a public health target for almost five years, and its surging growth in use and availability has caught the attention of addiction specialists who believe that it may be contributing to our nation's opiate abuse epidemic. According to Gloria Anderson, supervisor of addiction programming at the Hazelden Betty Ford Clinic, a 12-step facility in New York City, 20 percent of her patients reported using the unapproved drug kratom as "a Band-Aid when they are unable to get ahold of opiates such as painkillers and heroin."[1] Self-medicating with kratom is dangerous without the necessary pre-market approval process set forth by our public health experts at FDA. Even if kratom was delivered as a food, kratom has never been submitted as a new dietary ingredient notification to FDA's Center for Food Safety and Applied Nutrition. The laws governing the sale and distribution of a new dietary ingredient contained in a dietary supplement, a commodity of food in the U.S., are clear and have been in place for 22 years. The statutory rules of the road should be followed.

According to the European Monitoring Centre for Drugs and Drug Addiction, regular use of kratom can cause dependence and have narcotic effects at high doses.[2] It has been banned in countries including Australia, Malaysia, Burma, Denmark, Poland, Lithuania, Sweden, Myanmar, and Vietnam. Six U.S. states have also banned kratom, including Alabama, Arkansas, Indiana, Tennessee, Vermont and Wisconsin. NPA views DEA's consideration to classify kratom a Schedule I drug as a necessary and welcome first step; however, unless it is followed with real enforcement and penalties for those who are

[1] Mauer, J. (2016, February 22). While many kratom users call it a miracle drug, others warn it could be dangerous. Retrieved November 29, 2016, from http://pix11.com/2016/02/22/while-many-kratom-users-call-it-a-miracle-drug-others-warn-it-could-be-dangerous/
[2] Kratom (Mitragyna speciosa) drug profile. Retrieved November 29, 2016, from http://www.emcdda.europa.eu/publications/drug-profiles/kratom

selling it in coffee bars, on the internet, and elsewhere, it will be another unenforced measure on the books. If, on the other hand, those entities who seek to continue to sell kratom wish to do so, they should follow the rules at FDA and the Federal Trade Commission (FTC) regarding the marketing of a new dietary ingredient and the required evidentiary burden to substantiate claims. Firms must submit both safety and efficacy data and research they believe qualifies kratom as a *bona fide* lawful ingredient sold in the U.S. marketplace.

Until the law is followed, however, NPA strongly urges DEA and FDA to take appropriate legal action to ensure that American consumers are protected from an unknown and unregulated botanical ingredient whose use could have widespread and unintended negative consequences for public health and safety.

NPA thanks DEA for the opportunity to comment on this proceeding and this important public health issue.

Sincerely,

Daniel Fabricant, Ph.D.
CEO & Executive Director
Natural Products Association