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April 23, 2018

By Federal Express

Dr. Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
White Oak Building 1, Room 2217
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Gottlieb:

On behalf of our client, the American Kratom Association (AKA), we are writing to express the AKA's concern the U.S. Food and Drug Administration's (FDA's) may use the reports of *Salmonella* in certain kratom products as a basis to order a mandatory recall of all kratom products on the market. For the reasons explained below, such an FDA position would exceed the statutory authority for mandatory recalls under the language carefully crafted by Congress when enacting the FDA Food Safety Modernization Act (FSMA) in 2010. Such an FDA position also would unfairly penalize those companies who adhere to rigorous food safety requirements and whose products are not implicated in the disease outbreak.

Established in 2014, the AKA is committed to restoring full consumer access to kratom and to preserving and protecting the freedom of consumers in the United States to make their own choices for their well-being and maintaining a healthy lifestyle. Kratom (*Mitragyna speciosa*) is a natural analgesic that has been used for hundreds of years to safely alleviate pain, combat fatigue, and help with general well being. Unfortunately, the spread of misinformation, both scientific and anecdotal, about kratom has created a challenging regulatory environment. The AKA was formed to organize and represent a community of responsible consumers, provide the general public with clarification surrounding matters of health and wellness where kratom could play an important role, educate lawmakers and regulators, and support scientific research efforts.

We do want to make clear that AKA is fully supportive of the need to recall any product that has the potential to contain *Salmonella*. A recall is appropriate in instances when the data demonstrate a manufacturer's specific product has the potential to contain *Salmonella*. We urge FDA to apply the same rigorous and investigative standards when investigating the links between *Salmonella* and certain kratom products that the agency has utilized when investigating other food safety outbreaks.

AKA also urges FDA to honor the language found in the Federal Food, Drug, and Cosmetic Act (FFDCA) and recognize kratom supplements can be marketed lawfully on the basis of their common use in foods. The agency's creative interpretation of the FFDCA and position that kratom products cannot lawfully be marketed—despite the extensive history of use for hundreds of years—is driving many of the companies to operate in gray markets outside of the agency's oversight. AKA believes the American population would be better served if the agency would focus its time and efforts making certain kratom supplements are manufactured under the dietary supplement good manufacturing practices (GMPs) where contamination with *Salmonella* would have been avoided.

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Background

On February 12, 2018, FDA and the Centers for Disease Control and Prevention (CDC) began investigating a multi-state outbreak of salmonellosis from multiple serotypes of *Salmonella*. 1/ According to CDC, epidemiologic evidence collected to date indicates that kratom or kratom-containing products are a likely source of this outbreak. 2/ As of April 19, 33 of 66 FDA samples analyzed from distributors and retail locations of interest have been found positive for one or more strains of *Salmonella*. 3/ FDA and CDC currently are collaborating with local health officials to identify specific brand names and suppliers of products to learn more about the possible source and route of *Salmonella* contamination. 4/

To date, there have been multiple voluntary recalls associated with the outbreak. 5/ In addition, on April 2, 2018, FDA exercised its mandatory recall authority under FSMA to order the recall of all food products containing powdered kratom manufactured, processed, packed, or held by Triangle Pharmanaturals LLC. 6/ FDA issued the order after several Triangle Pharmanaturals products were found to contain *Salmonella*. 7/ AKA supports the recall from the market of any product—whether a kratom supplement or a food product—that contains *Salmonella*. AKA is concerned, however, that FDA may try to use this food safety outbreak investigation to issue a mandatory recall for all kratom products in the marketplace, regardless of processor, packer, or supplier.

FDA Does Not Have the Legal Authority to Require a Recall of All Kratom Products

The statutory language states that FDA's mandatory recall authority is product specific and requires data demonstrating a particular product presents a risk of serious adverse health consequences or death. Under FSMA, FDA has the authority to mandate a recall "If the Secretary determines, based on information gathered through the reportable food registry under section 350f of this title or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 342 of this title or misbranded under section 343(w) of this title and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals." 8/

There are several important factors that make up this authority.

- **FDA's Mandatory Recall Authority is Product Specific:** The language of the statute is specific to "an article of food" for which there is a reasonable probability that "exposure to such article" would cause serious adverse health consequences or death to humans or animals (i.e., present a SAHCODHA hazard). FDA's mandatory recall authority thus is

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1/ FDA Investigates Multistate Outbreak of Salmonella Infections Linked to Products Reported to Contain Kratom (last visited Apr. 20, 2018), available at https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm597265.htm.
2/ *Id.*
3/ *Id.*
4/ *Id.*
5/ *Id.*
6/ Amended Order – Mandatory Recall Order (Apr. 2, 2018), available at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM603489.pdf.
7/ *See* Notification of Opportunity to Initiate a Voluntary Recall (Mar. 30, 2018), available at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm603487.pdf.
8/ Federal Food Drug and Cosmetic Act § 423(a); 21 U.S.C. § 350l(a).

specific to particular products, and does not extend to all manufacturers within a particular product industry. In other words, FDA potentially has the authority to mandate a recall by a specific manufacturer or manufacturers, but cannot order a blanket, industry-wide recall.

- **FDA Must Have Supporting Data Specific to Particular Product to Exercise Its Authority:** The statute also requires that before FDA may exercise its authority, it must have "information gathered through the reportable food registry…or through any other means" demonstrating that a specific article of food presents a SAHCODHA hazard. Notably, in the case of Triangle Pharmaceuticals, FDA explained that it based its determination to require a recall on two samples of Triangle Pharmaceuticals' finished product collected by the Oregon Health Authority, which were found positive for *Salmonella*; four finished product samples purchased or collected by FDA, which tested positive for *Salmonella*; and an individual in Utah who became ill with *Salmonellosis* and reported consuming a Triangle Pharmaceuticals product prior to becoming ill. 9/ In Draft Guidance, FDA identifies "epidemiological data" and "consumer and trade complaints," which are data associated with foodborne outbreaks, as examples of the type of data that would support a decision to invoke mandatory recall authority.10/ Without direct evidence of product contamination and human illness specific to each industry member's products, FDA does not have the authority to require all manufacturers within a product category to issue a recall.

- **Evidence Must Show Reasonable Probability the Product Presents a SAHCODHA Hazard:** The standard of proof necessary to support a determination by FDA to require a recall is a "reasonable probability" that exposure to or use of an article of food presents a SAHCODHA hazard. This is not a suspicion or even a "reasonable belief," but rather a "reasonable probability." Further, the law requires evidence to show that the product poses a risk of "serious adverse health consequences or death." Without product testing results, epidemiological data, or reports of consumer illness tied to specific products, this standard is not met.

- **The Burden of Proof Is on FDA:** The statute places the burden of proof on FDA by stating that a recall may only be issued if "The Secretary determines" there is a reasonable probability that exposure to an article of food will cause harm. Thus, it is incumbent upon FDA to demonstrate that a particular article of food presents a SAHCODHA hazard.

- **This Authority Cannot Be Delegated Beyond the FDA Commissioner:** Congress recognized the significance of the mandatory recall authority and the effect that it could have on regulated industry. Therefore, the statute specifically states that this authority cannot be delegated by the Secretary of Health and Human Services beyond the FDA Commissioner. Decisions like this must be made at the highest level.

Because FDA cannot satisfy these factors, AKA would oppose any FDA attempts to use its mandatory recall authority to require an industry-wide recall of kratom or kratom-containing products. As an analogy, FDA would not have the authority to issue a recall of all spinach or spinach-containing products on the market based on an *E. coli* outbreak that is linked to a few spinach farmers; instead, FDA's authority would be limited to mandating a recall by those spinach producers

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9/ *Supra* note 7.

10/ Draft Guidance for Industry, Questions and Answers on Regarding Mandatory Food Recalls (May 2015), available at https://www.fda.gov/RegulatoryInformation/Guidances/ucm445428.htm.

for which there is evidence that exposure to their products would present a SAHCODHA hazard. The same is true of kratom products: FDA does not have authority to issue an industry-wide recall of all kratom or kratom-containing products on the market based on the *Salmonella* outbreak which has been linked to specific kratom products.

In sum, the authority granted to FDA to mandate recalls is narrow. It applies only to particular products, rather than product categories, and places the burden on FDA to identify information demonstrating that exposure to the product could result in a SAHCODHA hazard.

Again, the AKA position that dietary supplements should be free of pathogens such as *Salmonella* is unwavering. AKA also supports the need to recall from the market of any food, including kratom products, when the underlying data demonstrate the potential of the product to be contaminated with *Salmonella*. Many of the AKA member companies are producing kratom products under rigorous food safety plans and appropriate GMPs that assure their products are free from contamination. The companies that adhere to rigorous food safety requirements should not get pulled into an industry-wide mandatory recall, particularly given the lack of such authority under the FFDCA.

We thank you for your consideration of the information in this letter.

Sincerely,

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