FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA ELECTRONIC MAIL

Notification of Opportunity to Initiate a Voluntary Recall

March 30, 2018

Mr. Chris Becker, Owner
Triangle Pharmanaturals, LLC
5320 Cameron Street, Suite #7
Las Vegas, NV 89118

Dear Mr. Becker:

Pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 350l], as amended by the FDA Food Safety Modernization Act (Pub. L. 111-353 (Jan. 4, 2011)), the U.S. Food and Drug Administration (FDA) is providing your firm, Triangle Pharmanaturals, LLC, with an opportunity to voluntarily cease distribution and conduct a recall of the below referenced products manufactured and distributed by your firm. Section 423(a) of the FD&C Act provides in relevant part that if FDA "determines...that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402 [21 U.S.C. § 342] or misbranded under section 403(w) [21 U.S.C. § 343(w)] and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals," before taking further action under section 423 of the FD&C Act, FDA must offer the responsible party the opportunity to voluntarily cease distribution and recall such articles .[1]

As discussed further below, FDA has determined that there is a reasonable probability that the following food products are adulterated under section 402(a)(1) of the FD&C Act[2] and there is a reasonable probability that the use of or exposure to these products will cause serious adverse health consequences or death to humans or animals:

All food products containing powdered kratom, including:

- **"Raw Form Organics Maeng Da Kratom Emerald Green"** in 300 capsule plastic bottles;
- "**Raw Form Organics Maeng Da Kratom Ivory White**" in 300 capsule plastic bottles; and

[1] The term "responsible party" is defined in section 417(a)(1) of the FD&C Act [21 U.S.C. § 350f(a)(1)] and refers to the person who submits the registration for a food facility that is required to register under section 415(a) of the FD&C Act [21 U.S.C. 350d], at which the food at issue is manufactured, processed, packed or held. As such, the owner, operator, or agent in charge of the facility who is responsible for submitting the registration (whether or not such registration has been submitted) is also responsible for implementing and assuring the recall is performed, if so ordered under Section 423 of the FD&C Act.

[2] Under section 402(a)(1) of the FD&C Act, a food shall be deemed adulterated if "it bears or contains any poisonous or deleterious substance which may render it injurious to health."

U.S. Food and Drug Administration
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- "**Raw Form Organics Maeng Da Kratom Ruby Red**" in 300 capsule plastic bottles.

If you do not voluntarily cease distribution and conduct a recall within the time and manner prescribed below, FDA may, by order, require you to immediately cease distribution of the affected products and to immediately give notice to other parties.

FDA's Determination

The basis for FDA's determination that there is a reasonable probability that the products identified above are adulterated under section 402(a)(1) of the FD&C Act and that there is a reasonable probability that the consumption of the those products will cause serious adverse health consequences or death to humans or animals is as follows:

- Two finished product samples, collected by the Oregon Health Authority/ Oregon Division of Public Health on February 22, 2018, were found positive for *Salmonella*.
  - One sample of **Raw Form Organics Maeng Da Kratom Emerald Green**(300 capsule jar) collected from (b) (4) as Sample ID Number KRA0005. This sample tested positive for *Salmonella* . Documentation regarding this sample and its analysis is attached as Exhibit 1.
  - One sample of **Raw Form Organics Maeng Da Kratom Ivory White**(300 capsule jar) collected from (b) (4) as Sample ID Number KRA0006. This sample tested positive for *Salmonella* . Documentation regarding this sample and its analysis is attached as Exhibit 2.

- A third finished product sample, purchased by FDA on March 12, 2018, was found positive for *Salmonella*.

  One sample of **Raw Form Organics Maeng Da Kratom Ruby Red** (300 capsule jar) purchased over the internet from (b) (4) (FDA sample #1038482). This sample tested positive for *Salmonella* . Documentation regarding this sample and its analysis is attached as Exhibit 3.

- A fourth finished product sample, collected by FDA on March 14, 2018, was found positive for *Salmonella*.
  - One bottle of Molecule Precision Labs Kratom Super Green Malay collected at Triangle (FDA sample # 1044001) was found positive by FDA for Salmonella. Documentation regarding this sample and its analysis is attached as Exhibit 4.

- A fifth product sample, collected by FDA on March 14, 2018, was found positive for *Salmonella*.
  - 9 of 30 subsamples analyzed from a sample of 90 unlabeled black plastic bottles (approximately 45 g each) of unidentified-brand kratom powder collected at Triangle by FDA (FDA sample # 1044000) were found positive by FDA for *Salmonella*. Documentation regarding this sample and its analysis is attached as Exhibit 5.

- A sixth sample, of in process product collected by FDA on March 15, 2018, was found positive for *Salmonella*.
  - 15 of 15 tested samples of kratom powder found in the mixer at Triangle (FDA sample # 1044002) were found positive by FDA for *Salmonella*. Documentation regarding this sample and its analysis is attached as Exhibit 6.

- A person in Utah who became ill with *Salmonellosis* in an ongoing outbreak of foodborne illness

identified this specific brand of kratom ("Raw Form Organics") in capsule form, in response to questions about foods and drinks that the person consumed before becoming ill.

- *Salmonella* bacteria are a common cause of human illness. Approximately one million *Salmonella* illnesses (known as salmonellosis) occur in the US each year. Most occur due to consumption of contaminated food products. Approximately 27% of ill individuals require hospitalization, and several hundred deaths occur each year.[1]

  There are approximately 2500 different *Salmonella* serotypes. *Salmonella typhi* and *Salmonella paratyphi* cause enteric fever (e.g. typhoid fever), a severe illness in which the bacteria spread from the intestine to other organs causing fever, abdominal pain, and other serious symptoms. These serotypes are uncommon in the US. All other *Salmonella* serotypes are non-typhoidal *Salmonella* ("NTS").[2] Infection with NTS most often results in a self-limited acute gastroenteritis, with nausea, vomiting and diarrhea.[3,4] Occasionally, patients require hospitalization for dehydration and complications, which include bloody diarrhea or extra-intestinal illnesses, such as bacteremia, meningitis, osteomyelitis or urinary tract infections.[1,3] High-risk populations for these potentially life-threatening complications are infants, the elderly, the immunocompromised and individuals with medical conditions, including sickle cell anemia.[3] Extra-intestinal infections occur in about 8 percent of persons with laboratory-confirmed *Salmonella* infection.[5] Some individuals develop chronic carriage of NTS: they are asymptomatic, but shed the bacteria in their stool for more than 12 months after acute infection.[3] Reactive arthritis, believed to be an immune-mediated reaction against host antigens located in the joints, has been shown to occur in approximately 6% of persons who experience *Salmonella enteritidis* in outbreak settings; the interval range between onset of diarrhea and onset of arthritis in one outbreak was 1 day to 4 months.[6] The infectious dose for salmonellosis to occur can be as low as 100 bacteria.[2] It is possible that some consumers might become ill after exposure to even lower doses if they have severe pre-existing disease(s) or conditions that increases their susceptibility. Medications that decrease stomach acid can increase the risk of salmonellosis.[5] A *Salmonella* outbreak linked to a food supplement formulated into capsules was reported in Germany in 2010.[7]

References:

1. Scallan E, Hoekstra RM, Angulo FJ, et al. Foodborne illness acquired in the United States--major pathogens. *Emerg Infect Dis* 2011; 17(1): 7-15.
2. American Public Health Association. Control of Communicable Diseases Manual 19th edition, An Official Report of the American Public Health Association. 19th edition. 2008.
3. Pegues DA, Miller SI. *Salmonella* Species. In: Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas and Bennett's Principles and Practice of Infectious Diseases. Philadelphia, PA: Elsevier Saunders; 2015: 2559-68.
4. Committee on Infectious Diseases AAoP. *Salmonella* Infections. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. Red Book: 2015 Report of the Committee on Infectious Diseases 30th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2015: 695-702.
5. CDC. Salmonella. Information for healthcare professionals and laboratories (https://www.cdc.gov/salmonella/general/technical.html; accessed on March 28, 2018).
6. Thomson GT, DeRubeis DA, Hodge MA, Rajanayagam C, Inman RD. Post-Salmonella reactive arthritis: late clinical sequelae in a point source cohort. *Am J Med* 1995;98:13-21.
7. Stoker P, Rosner B, Werber D et al. Outbreak of *Salmonella Montevideo* associated with a dietary food supplement flagged in the Rapid Alert System for Food and Feed (RASFF) in Germany, 2010. *Euro surveill* 2011;16(50):20040.

Opportunity to Initiate a Voluntary Recall

As discussed above, in accordance with section 423(a) of the FD&C Act, we are providing you with an opportunity to voluntarily cease distribution and conduct a recall of the products identified in this letter. If you elect to voluntarily cease distribution and conduct a recall of these products, you should do so in the following time and manner:

- Within 24 hours of your receipt of this letter, cease distribution and initiate a recall of all products identified in this letter.
- Notify all direct consignees and request that those who further distributed these products conduct a sub-recall to the retail level and, if known, to the consumer level.
- Issue a press release for your firm's recall.
- Conduct your recall(s) of these products in coordination with the FDA HAFW5 Recall Coordinator [Marjorie Schultz, 1431 Harbor Bay Parkway, Alameda, CA 94502; telephone number (510) 337-6898, fax number (510) 337-6705, and e-mail at orahafwest5recalls@fda.hhs.gov], and in accordance with the manner prescribed by FDA.
- Follow the procedures for recalls found in FDA's regulations at 21 C.F.R. Part 7 to the extent that such procedures do not conflict with the time and manner prescriptions in this letter. A copy of the Part 7 regulations is enclosed.

If you do not voluntarily cease distribution and conduct a recall in the time and manner described in this section, FDA may, by order, require you to immediately cease distribution of the identified products. Additionally, FDA may, by order, require you to immediately notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such products to immediately cease distribution of such products; and to immediately notify all persons to which such products have been distributed, transported, or sold, to immediately cease distribution of such products.

Please respond to this letter by contacting Darla Bracy, Program Division Director, at telephone number (510) 337-6773 or via email at darla.bracy@fda.hhs.gov as soon as possible. If a response is not received from you within 24 hours of your receipt of this letter, FDA may, by order, require you to immediately cease distribution and notify applicable parties, as explained above.

Sincerely,

Stephen M. Ostroff, M.D.
Deputy Commissioner for Foods and Veterinary Medicine

cc (via e-mail):
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