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

VIA EMAIL AND
VIA UNITED PARCEL SERVICE – OVERNIGHT DELIVERY

PREHEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE

March 31, 2018 2:30 PM Eastern, 11:30 AM Pacific

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

C/O Mr. Solomon Abady, Esq.
Abady Law Firm, P.C.
1185 Avenue of the Americas, Fl 3
New York, NY 10036
solomon.abady@customsesq.com
customsesq@gmail.com

Dear Mr. Becker:

Pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act (the 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) has determined that there is a reasonable probability that the following food products manufactured, processed, packed, and/or held by Triangle Pharmanaturals, LLC are adulterated under section 402(a)(1) of the Act [21 U.S.C. 342(a)(1)][1] 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 manufactured, processed, packed, and/or held by Triangle Pharmanaturals, LLC, 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
- "**Raw Form Organics Maeng Da Kratom Ruby Red**" in 300 capsule plastic bottles.

By letter March 30, 2018, FDA notified you of its determination and provided you with the opportunity to voluntarily cease distribution and conduct a recall. The basis for the agency's determination was described in that letter, a copy of which is enclosed. The letter specified a timeframe of 24 hours from receipt of the letter for initiating a voluntary recall. That timeframe has now elapsed and you have not satisfied FDA's requests. Accordingly, pursuant to section 423(b) of the Act, FDA is now **ordering** you to immediately cease distribution of the aforementioned kratom products, and to immediately notify (1) all persons

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

manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling the aforementioned products; and (2) all persons to which the aforementioned products have been distributed, transported, or sold to immediately cease distribution of such products. In providing such notification, you may use any mode of written communication that permits the recipient to confirm receipt of your notification (e.g., postal mail, email, delivery service, personal delivery). We encourage you to provide FDA with a copy of the notification you prepare, before you send it out.

Your notification to these parties shall:

- Identify the products subject to this Order, including any pertinent descriptive information needed to enable accurate and immediate identification of the products.
- Explain concisely the reason for notification and the hazard involved. Specifically, FDA has determined there is a reasonable probability that **all food products containing powdered kratom manufactured, processed, packed, and/or held by Triangle Pharmanaturals, LLC (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 "**Raw Form Organics Maeng Da Kratom Ruby Red**" in 300 capsule plastic bottles) are adulterated under section 402(a)(1) of the Act and that 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 due to contamination with *Salmonella* spp. You may include a copy of this Order and the letter FDA previously sent you with your notification.
- Direct all parties to immediately cease distribution of the affected products and request consignees to extend the cease distribution directive down to the retail level and, if known, to the consumer level.
- Provide a means for the recipient of the notification to confirm receipt of your notification. FDA may subsequently review these records to verify your compliance with this Order.

You are further required to give any warehouse-based third party logistics provider that may be in possession of the aforementioned products sufficient information to identify the article of food covered by this Order.

Opportunity for an Informal Hearing

Pursuant to section 423(c) of the Act, Triangle Pharmanaturals, LLC is being offered an opportunity for an informal hearing on the actions required by this Order and on why the articles that are the subject of this Order should not be recalled. Section 423(c) provides in relevant part that a responsible party subject to a prehearing Order issued under section 423(b) shall be provided with an opportunity for an informal hearing, to be held as soon as possible, but not later than two (2) days after the issuance of the Order (that is, to be held no later than Monday, April 2, 2018). To request an informal hearing, you must submit your request, in writing, to Vinetta Howard King, WO31 RM3524 HFC-1 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002, e-mail: Vinetta.HowardKing@fda.hhs.gov by 3:00 PM Eastern Time (12:00 PM Pacific Time) on Sunday, April 1, 2018.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to this agency's regulations at 21 C.F.R. § 16.26(a), a request for a hearing may be denied, in whole or in part, if the Commissioner or his delegate determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. Accordingly, your request for a hearing should include information that you believe shows that there is a genuine and substantial issue of fact that warrants a hearing. If you wish to request an informal hearing, but do not wish

to request that the hearing be held orally, you should contact the FDA contact person identified in this Order and send a written response containing the basis for your request to the FDA contact person by 3:00 PM Eastern Time (12:00 PM Pacific Time) on Sunday, April 1, 2018. Your submission should state that you waive your opportunity for an oral informal hearing and that you want your request to be based on your written response and other information available to the agency.

If you do not request a hearing in writing as directed above by 3:00 PM Eastern Time (12:00 PM Pacific Time) on Sunday, April 1, 2018, Triangle Pharmanaturals, LLC will be considered to have waived its opportunity for an informal hearing.

If you request an informal hearing, the Presiding Officer (PO) as defined in 21 C.F.R. § 16.42 may deny your request for a hearing if the PO determines that you have not raised a genuine or substantial issue of fact by the material submitted in your hearing request, or if you failed to request the hearing within the timeframe stated in this Order. If the PO determines that a hearing is not justified, written notice of that determination will be provided to you explaining the reasons for denial of the hearing. If the PO grants your request for an informal hearing, at the informal hearing you will have the opportunity to address the actions required by this Order and to explain why the products that are the subject of this Order should not be recalled. The informal hearing will be conducted in accordance with the procedures in 21 C.F.R. Part 16, Regulatory Hearing Before the Food and Drug Administration, to the extent that such procedures are not in conflict with section 423 of the Act. The informal hearing will be closed to protect information not available for public disclosure, as provided by 21 C.F.R. § 16.60. Enclosed are the regulations covering FDA's informal hearing procedures in 21 C.F.R. Part 16. We also refer you to FDA's guideline on electronic media coverage of its administrative proceedings (21 CFR part 10, subpart C).

If you do not submit a timely written request for a hearing, or if your request for a hearing is denied, FDA may, pursuant to section 423(d) of the Act, Order you to recall the affected products within a specified timetable. FDA may also require you to provide periodic reports to the agency describing the progress of the recall; notify consumers about the recall; and take other action as appropriate.

In your submission, you should include your firm's current mailing address, phone number, email, and any other relevant contact information. You should promptly contact the designated contact person, Vinetta Howard King by phone (301-796-8254) or email (Vinetta.HowardKing@fda.hhs.gov) if you have any questions regarding this Order.

Sincerely,

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

Encl: 21 C.F.R. Part 16

cc: Scott R. Cook, Esq. (via email)
Kolesar & Leatham, Attorneys At Law
400 S. Rampart Blvd. Suite 400
Las Vegas NV 89145
scook@klnevada.com