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

VIA EMAIL AND
VIA UNITED PARCEL SERVICE – OVERNIGHT DELIVERY

AMENDED ORDER – MANDATORY RECALL ORDER

April 2, 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.
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Dear Mr. Becker:

On March 31, 2018, you were ordered: (1) to immediately cease distribution of the below products; and (2) to immediately notify: (i) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such products; and (ii) all persons to which such products have been distributed, transported, or sold to immediately cease distribution:

- **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.

(The "March 31 Order"). Furthermore, you were ordered 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 the March 31 Order.

In the March 31 Order you were provided with an opportunity for an informal hearing. Because you did not request a hearing in the time period specified in the March 31 Order, you waived your opportunity for such a hearing. At this time, FDA has determined that the removal of the aforementioned products from commerce is necessary. Therefore, pursuant to section 423(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 350l(d)], the March 31 Order is hereby amended, and you are ordered to:

1. Immediately cease distribution of the aforementioned products within 24 hours of the issuance of this Order.

2. Issue a recall notification of the aforementioned products within 24 hours of the issuance of this Order to all persons manufacturing, processing, packing, transporting, receiving, holding, or importing and selling such products, and to persons to which such products have been distributed, transported, or sold, which must:

    a) Identify the products subject to this Order, including any pertinent descriptive information needed to enable accurate and immediate identification of the products.

    b) 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 [21 U.S.C. 342(a)(1)] 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 with your notification.

    c) Direct all notified parties to immediately cease distribution, conduct a sub-recall to the retail level, and if known, to the consumer level, and return all the aforementioned products to your facility for destruction.

    d) Provide a means for the recipient of the notification to confirm receipt and that they are following the instructions in your recall notification. Responses must be tracked and non-responding consignees must be re-notified. FDA may subsequently review these records to verify your compliance with this Order.

3. Issue a press release regarding recall of the aforementioned products within 24 hours of the issuance of this Order that provides consumers with any pertinent information needed for them to accurately identify the products subject to this Order, including:

    a) Information to help identify the recalled products including images, any codes (e.g., lot number, expiration date, serial number, packaging information or brand names); and

    b) The geographic areas and dates of distribution of the products; and

    c) A thorough description of the reason for the recall, including the reasonable probability of contamination with *Salmonella*

4. Conduct your recall of the aforementioned products in coordination with the FDA HAFW5 Recall Coordinator [Marjorie Schultz, 1431 Harbor Bay Parkway, Alameda, CA 94502; telephone number (510) 337-6869, fax number (510) 337-6705, and e-mail at orahafwest5recalls@fda.hhs.gov] and in accordance with the time and manner prescribed by this order and 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 prescribed by this order.

5. Provide Ms. Schultz, FDA HAFW5 Recall Coordinator, notification that your recall has been initiated and a copy of your recall notification and press release within 24 hours of the issuance of this Order.

6. Provide to Ms. Schultz the following information within 5 days of the initiation of your recall:

   a) Products Subject to the Recall – product name (include brand name and generic name, where applicable); description of the product including its form (e.g., powder, encapsulated powder, etc.); if the product is perishable, the expected shelf life; the type of packaging (e.g., box, flexible plastic, glass); two complete sets of all labeling including any product labeling, case labeling, package inserts, directions for use and promotional material; any product codes (production identification numbers) – lot/unit numbers; expiration date(s), use by date(s); and any UPC codes.

   b) Recalling Firm – firm name, current address, city, state, and zip code; firm type (e.g., manufacturer, importer, broker, repacker, own-label distributor); and contacts for the recalling firm, including name, title, phone, fax number, and e-mail address.

   c) Manufacturer(s) – firm name, address, city, state, and zip code; and FDA registration number, if applicable.

   d) Volume of product recalled – total quantity produced; date(s) produced; quantity distributed; date(s) distributed; quantity on **hold** by recalling firm and its distribution centers; description of how the product is being quarantined; and estimated amount remaining in marketplace.

   e) Distribution Pattern – number of **direct** accounts (customers to whom you sell directly) by type (e.g., wholesalers/distributors; repackers; manufacturers; retail; consumers (including internet or catalog sales); foreign consignees (specify whether they are wholesale distributors, retailers or users).

   f) Geographic areas of distribution, including any foreign countries.

   g) A consignee list (including name/address/city/state/contact name/phone number for each consignee). Be sure to include any foreign (including Canadian) customers. Indicate what the consignee list represents (e.g., all customers who were shipped recalled product; all customers who were *sold* recalled product.

   h) Method of destruction you propose to use after consignees have returned product to you. Contact Ms. Schultz prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.

7. On a weekly basis, or more often if requested, provide a recall status report to Ms. Schultz that includes:

   a) Dates consignees were notified

   b) Number of consignees notified

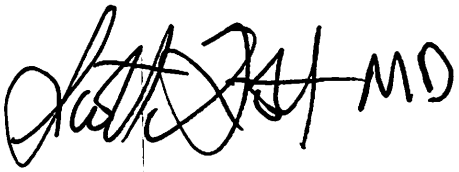
   c) Number of consignees responding

   d) Quantity of recalled product returned or accounted for and

   e) Details of your recall effectiveness checks.

Please note that failure to comply with this order is a prohibited act under section 301(xx) of the FD&C Act. In addition, issuance of this Order does not prohibit FDA from taking other applicable enforcement action, as the agency deems necessary. This order is effective immediately. If you have questions

regarding this order, you may contact Darla Bracy, Program Division Director, at telephone number (510) 337-6773 or via email at Darla.bracy@fda.hhs.gov.



Scott Gottlieb, M.D.
Commissioner, Food and Drug Administration

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