Nd Labs, Inc. 9/1/17

Office of Human and Animal Food
Operations East
Division 1

WARNING LETTER
CMS# 510453

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

September 1, 2017

Michael A. Beller
Co-Owner
ND Labs, Inc.
202 Merrick Rd.
Lynbrook, New York 11563

Dear Mr. Beller:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 202 Merrick Rd. Lynbrook, New York on September 20 and 23, 2016. Based on the inspection and review of the product labels you provided during the inspection, we have found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations as described below. You may find the Act and FDA regulations through links on FDA's website at **www.fda.gov (http://www.fda.gov/)**.

Medical Foods

Your LPS Cherry, Liquid Fiber Flow, and Nana Flakes products are misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C § 343(a)(1)] because the product labeling is false and misleading in that the products are labeled and marketed as medical foods but do not meet the definition of a medical food in the Orphan Drug Act [21 U.S.C. § 360ee(b)(3)] or the criteria set forth in Title 21 Code of Federal Regulations section 101.9(j)(8) [21 C.F.R. 101.9(j)(8)].

The Orphan Drug Act defines “medical food” as “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” The regulation in 21 CFR 101.9(j)(8) provides that a food is considered a medical food only if:

i. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding tube;
ii. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
iii. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
iv. It is intended to be used under medical supervision; and
v. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

FDA considers the statutory definition of “medical food” to narrowly constrain the types of products that fit within this category of food. Medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, and must be intended to be used under medical supervision. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms, or reduce the risk of a disease or condition. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who is seriously ill or who requires use of the product as a major component of a disease or condition’s specific dietary management.

Pursuant to 21 CFR 101.9(j)(8)(ii), a medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone. Your LPS Cherry, Liquid Fiber Flow, and Nana Flakes products are promoted as medical foods for use by persons with pressure ulcers, hypoalbuminemia, protein calorie malnutrition, poor appetite, trauma, muscle wasting (cancer/AIDS), immune dysfunction, dialysis, or bariatric surgery (LPS Cherry), chronic constipation, bowel irregularity, irritable bowel syndrome, and diverticulitis (Liquid Fiber Flow), and diarrhea (Nana Flakes).

FDA is not aware of any distinctive nutritional requirements for individuals with pressure ulcers, hypoalbuminemia, protein calorie malnutrition, poor appetite, trauma, muscle wasting (cancer/AIDS), immune dysfunction, dialysis, or bariatric surgery (LPS Cherry), chronic constipation, bowel irregularity, irritable bowel syndrome, and diverticulitis (Liquid Fiber Flow), and diarrhea (Nana Flakes).Therefore, your LPS Cherry, Liquid Fiber Flow, and Nana Flakes products do not meet the definition of a medical food in the Orphan Drug Act [21 U.S.C. § 360ee(b)(3)] or the regulatory criteria for medical foods set forth in 21 CFR 101.9(j)(8)(ii).

Unapproved New Drugs

In addition, we reviewed your website at the Internet address nutritionaldesignsinc.com in August of 2017 and have determined that you take orders there for LPS Cherry, Liquid Fiber Flow, Nana Flakes and CVF (Cereal Vegetable Fruit Fiber) products. The claims on your website and product labels establish that these products are drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the claims that provide evidence that your products are intended for use as drugs include, but are not limited to:

Nana Flakes

Product label:

- "Shorten and Control Diarrhea from the Start…Can be used concurrently when doing a work up for C. difficile. Clinically Proven: Shortens and Controls Diarrhea…"

LPS Liquid Protein – Cherry

Product label:

- "[P]ressure ulcers, hypoalbuminemia…trauma, muscle wasting (cancer/AIDS), immune dysfunction, dialysis, or bariatric surgery…"

Website, nutritionaldesignsinc.com:

- "[A]lso effective for those with pressure ulcers, after bariatric surgery, hypoalbuminemia, muscle wasting and immune dysfunction…"

Liquid Fiber Flow

Product label:

- "Helps to relieve chronic constipation, bowel irregularity, irritable bowel syndrome, and diverticulitis …Helps lower cholesterol levels and stabilize blood sugars…and prevent diarrhea…"

Website, nutritionaldesignsinc.com:

- "[C]hronic constipation…lower blood cholesterol, and helps control blood sugar..."

CVF (Cereal Vegetable Fruit Fiber)

Website, nutritionaldesignsinc.com:

- "Helps against Hemorrhoids, Diverticulitis, IBS, and lowers Cholesterol…"

The LPS Cherry, Liquid Fiber Flow, Nana Flakes, and CVF (Cereal Vegetable Fruit Fiber) products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may

not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR § 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your LPS Cherry, Liquid Fiber Flow, and CVF (Cereal Vegetable Fruit Fiber) products are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, your LPS Cherry, Liquid Fiber Flow, and CVF (Cereal Vegetable Fruit Fiber) products fail to bear adequate directions for their intended uses and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

Misbranded Conventional Food

Even if your LPS Cherry, Liquid Fiber Flow, and Nana Flakes products were not unapproved new drugs, the products would still be misbranded foods under section 403 of the Act [21 U.S.C. § 343] because the products do not comply with the labeling requirements for conventional foods as described below:

1. Your LPS Cherry, Liquid Fiber Flow, and Nana Flakes products are misbranded within the meaning of section 403(q) of the Act [21 U.S.C. § 343(q)] in that the nutrition facts information is not in an appropriate format as defined in 21 CFR 101.9. Specifically:

- The Nana Flakes bears a Supplement Facts panel which is only appropriate for those products which have the statement of identity as a dietary supplement. (21 CFR 101.9)
- The Calories listing for the Liquid Fiber Flow and LPS Cherry are incorrectly calculated at 5 and 100, respectively. (21 CFR 101.9(c)(1)(i)(B)).
- The LPS Cherry and Liquid Fiber Flow labels fail to contain the footnote. (21 CFR 101.9(d)(9)).

2. Your LPS Cherry product is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product label bears a nutrient content claim, but the product does not meet the requirements to make such claim.

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation authorizing the use of such a claim. Characterizing the level of a nutrient on the food labeling of a product without complying with the specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Specifically, the product does not meet the requirements under 21 CFR 101.60(c) for the “Sugar Free” claim on the product label. The product is not a low calorie food per 21 CFR 101.60(b)(2) and fails to bear the statement “not a reduced calorie food,” “Not a low calorie food,” or “not for weight control” immediately adjacent to the claim.

Misbranded Dietary Supplement

In addition to the above violations, your CVF (Cereal Vegetable Fruit Fiber) product is a misbranded dietary supplement under section 403 of the Act [21 U.S.C. § 343] because the product does not comply with the labeling requirements for dietary supplements as described below:

3. Your CVF (Cereal Vegetable Fruit Fiber) product is misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. 343 (q)(5)(F)] in that the presentation of the nutrition information on the labeling of your product does not comply with 21 CFR 101.36. Specifically:

- The Supplement Facts label lists nutrients which are identified as “trace.” Nutrients present in amounts that can be declared as zero in 21 CFR 101.9(c) shall not be declared. [21CFR 101.36(b)(2)]
- The Supplement Facts label lists Fiber which has a Daily Value assigned to it but fails to list the % Daily Value under a heading of “% DV.” [21 CFR 101.36(b)(2)(iii)]
- The Supplement Facts label fails to declare the (b)(2)-dietary ingredient, total carbohydrate. The (b)(2)-dietary ingredients shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with 21 CFR 101.9(c). [21 CFR 101.36(b)(2)]
- Fiber shall be declared as “dietary fiber” and be indented under total carbohydrate. [21 CFR 101.36(b)(2)(i)(B) and 101.9(c)]

4. Your CVF (Cereal Vegetable Fruit Fiber) product is misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] because the label is false and misleading in that the principal display panel of the product label states that it is “made from whole foods,” but the Supplement Facts label and the ingredients statement do not include any whole foods.

5. Your CVF (Cereal Vegetable Fruit Fiber) product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343 (i)(2)] in that the product label fails to declare all the common or usual names of each ingredient used as required by 21 CFR 101.36 and 21 CFR 101.4. Specifically, your ingredient statement includes “vegetable fiber” but fails to list the individual vegetables which comprise the source of the fiber.

6. Your CVF (Cereal Vegetable Fruit Fiber) product is misbranded within the meaning of section 403(q)(1)(A) of the Act [21 U.S.C. § 343(q)(1)(A)] because the serving size declared on the label is incorrect. For example:

- The serving size is expressed in common household measures but fails to be followed by the equivalent metric quantity in accordance with 21 CFR 101.9(b)(7).
- Serving size for a dietary supplement is the maximum amount consumed per eating occasion as recommended on the product label as defined in 21 CFR 101.9(b) and 21 CFR 101.12(b) Table 2. The directions for use state to mix 1 bag of CVF with 2 cups liquid and add to 50 servings of

food, but the serving size is stated as 1 TBS. It is not clear how to consume the equivalent of 1 TBS of the CVF product.

7. Your CVF (Cereal Vegetable Fruit Fiber) product is misbranded within the meaning of section 403(s)(2)(A)(ii)(I) of the Act [21 U.S.C. § 343 (s)(2)(A)(ii)(I)] in that it fails to include the quantitative amount by weight per serving size of all the dietary ingredients as required by 21 CFR 101.36 and 101.9. A statement of the number of grams of soluble and insoluble dietary fiber in a serving shall be required when a claim is made on the label or in labeling about soluble or insoluble fiber. [21 CFR 101.9(c)(6)(i)(A) and (B)]

We offer the following comments regarding your CVF (Cereal Vegetable Fruit Fiber) product:

- The serving size on your CVF product is incorrectly identified as “TBS.” If this is intended to reflect a tablespoon, the correct abbreviation is “tbsp.” [21 CFR 101.9(b)(7)(iv)]
- Your information panel includes ingredient information intermingled with information that is considered intervening material. An example of intervening material is the statement of “An all natural blend of” and “OU Kosher & Pareve.” All information appearing on the information panel of the product label should appear in one place without other intervening material. [21 CFR 101.2(e)]
- Maltodextrin and inulin cannot contribute to the dietary fiber amount per serving declared in the Supplement Facts.[21 CFR 101.9(c)(6)(i)]

We also offer the following comments regarding your LPS Cherry, Liquid Fiber Flow and Nana Flakes products to the extent you intended to market these products as conventional foods:

- The LPS Cherry and Liquid Fiber Flow products appear to be products that require further preparation. 21 CFR 101.12(c)(1) states that the reference amount for the unprepared product shall be the amount of the unprepared product required to make the reference amount for the prepared product. We are unable to determine what these products are intended to be and therefore are unable to identify the appropriate serving size.
- Your LPS Cherry, Liquid Fiber Flow, and Nana Flakes product labels include the disclaimer statement “These statements have not been evaluated by the FDA…” This disclaimer applies to the label or labeling of dietary supplements that bear a claim under section 403(r)(6) of the Act [21 U.S.C. § 343(r)(6) and 21 CFR 101.93(b). As your products are not dietary supplements, such statement should not be used on the label or labeling of conventional foods.
- Your LPS Cherry product is manufactured with Whey Hydrolysate which is made from the allergen, milk. To declare this allergenic ingredient you may either list it parenthetically immediately after the ingredient or in a “Contains” statement immediately following the ingredient statement. Your use of an asterisk linking to a separate statement is not provided for in section 403(w) of the Act.
- The Business name and address are not in the format required by 21 CFR 101.5(c) in that it is missing the street address. The street address may be omitted if it is shown in a current city directory or telephone directory. On Your LPS Cherry and Liquid Fiber Flow products, there also appears to be intervening material separating the business name and address. 21 CFR 101.5 does not allow for the phone number and website address to be included as part of the business address.

- Your ingredient statement for the LPS Cherry product states “Natural and Artificial Colors and Flavors.” This is not an appropriate declaration of added color and flavor ingredients per 21 CFR 101.22.
- As you may already know, FDA finalized new requirements for nutrition labeling on May 27, 2016. The new Nutrition Facts label includes updates to the required nutrient declarations and formatting requirements. Although, FDA intends to extend the initial compliance date of July 26, 2018 or July 26, 2019 (depending on the size of the manufacturer), manufacturers may begin revising labels now to meet the new requirements. For more information on the new requirements, please see **http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm)**.

This letter is not intended to be an all-inclusive list of violations at your facility or in connection with your products. You are responsible for ensuring that your facility operates in compliance with the Act and other applicable laws. You should take prompt action to correct the violations noted in this letter. Failure to do so may result in regulatory action by FDA without further notice, including, without limitation, seizure and injunction.

Section 743 of the Act [21 U.S.C. § 379j-31] authorizes FDA to assess and collect fees to cover FDA’s costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determining whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses incurred in connection with FDA’s arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the re-inspection fees [21 U.S.C. § 379j-31(a)(2)(B)]. For a domestic facility, FDA will assess and collect fees for reinspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. In your response, you should include documentation, including photographs or other useful information that would assist us in evaluating your corrections. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Please send your reply to the Food and Drug Administration, Attention: Scott R. Izyk, Compliance Officer, One Winners Circle, Suite 110, Albany, NY 12205. If you have questions regarding any issues in this letter, please contactScott R. Izykat 518-453-2314 x1012 or **scott.izyk@fda.hhs.gov (mailto:scott.izyk@fda.hhs.gov)**.

Sincerely,
/S/
Ronald Pace

Program Division Director
Office of Human and Animal Food Operations East – Division 1

Close Out Letter

- **ND Labs, Inc. - Close Out Letter 12/4/18 (/ICECI/EnforcementActions/WarningLetters/2017/ucm628079.htm)**

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