Biotek, Inc. 3/13/18

6th Ave & Kipling St, DFC Bldg 20
PO Box 25087
Denver, CO 8022-0087

March 13, 2018

WARNING LETTER

Via UPS Overnight
SIGNATURE REQUIRED

Norman J. Larsen, President
Biotek Inc.
334 Marshall Way N, Suite F
Layton, UT 84041

Ref: # HAF4W (DEN)-18-04-WL

Dear Mr. Larsen:

On August 14-24, 2017, the U.S. Food and Drug Administration (FDA or we) inspected your facility located at 334 Marshall Way N, Suite F, Layton, UT. During the inspection, we collected labeling for your products. Based on our inspection and subsequent review of your firm's labeling, we found serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations. You can find copies of the Act and FDA's regulations through links on FDA's homepage at **www.fda.gov (http://www.fda.gov/)**.

Unapproved New Drugs/ Misbranded Drugs

FDA reviewed your website at the Internet address https://bio35.com/ in March 2018 and have determined that you take orders there for the products Bio-35 (including Gluten-Free Q Iron-Free), Lipotropic Formula, and ProCal. The claims on your website 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 a drug include:

Bio-35 (incl. Gluten-Free Q Iron-Free)

- “Immune system is improved helping to combat stress and disease”
- “Stress…the cause of all degenerative diseases.” ~ Stress of Life, Hans Selye, M.D.
- “They also protect against toxic reaction and heavy metal poisoning.”

Lipotropic Formula

- “Improves Triglyceride Level in Blood”
- “Lipase enzymatically converts triglycerides, which have a tendency to clog veins and arteries…”
- “Increases Resistance to Disease”
- “Lipotropics, in general, help reinforce the thymus gland to increase resistance to disease by: • Increased antibody production • Increased production and action of phagocytes, which surrounds and reduces invading viruses and microbes.*”
- “Lecithin and sphingomyelin help to keep cholesterol more soluble, deterring buildup of plaque or cholesterol deposits in the blood vessels.

ProCal

- “To help with Restless Leg Syndrome or Muscle Cramps take one capsule in the morning and two capsules two to three hours before sleep.”

The products listed above 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 USC § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 USC §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate 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 C.F.R. § 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 Pro-Cal product is intended for prevention or 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 product safely for its intended purpose. Accordingly, Pro-Cal fails to bear adequate directions for its intended use and, therefore, the product is 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 this misbranded drug violates section 301(a) of the Act [21 U.S.C. § 331(a)].

Adulterated Dietary Supplements

Our investigators observed the following significant violations of FDA's Current Good Manufacturing Practice (CGMP) requirements for dietary supplements, Title 21, Code of Federal Regulations (CFR), Part 111 (21 CFR Part 111), which render your dietary supplement products adulterated under section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)]. Additionally, even if your Bio-35 (including Gluten-Free Q Iron-Free), Lipotropic Formula, and ProCal products did not have therapeutic claims which make them unapproved new drugs, Bio-35 (including Gluten-Free Q Iron-Free), Lipotropic Formula, and ProCal would be adulterated within the meaning of section 402(g)(1) of the Act [21 U.S.C. §342(g)(1)] for the reasons described below.

We understand that you contract with other manufacturers to perform certain operations relating to products that are distributed into interstate commerce under your firm's name. Furthermore, we understand that your firm is responsible for the labels for your products and that you perform certain operations such as packaging and repackaging, labeling, and holding operations for products distributed into interstate commerce under your firm's name.

To the extent that you contract with other firms to manufacture, package, and/or label product on your behalf that your firm releases for distribution under your firm's name, your firm has an obligation to know what and how manufacturing, packaging, and/or labeling activities are performed so that you can make decisions related to whether your dietary supplement products conform to established specifications and whether to approve and release the products for distribution [72 Fed. Reg. 34752, 34790 (Jun. 25, 2007)]. Although a firm may contract out certain dietary supplement manufacturing, packaging, and/or labeling operations, it cannot contract out its ultimate responsibility to ensure that the dietary supplement it places into commerce (or causes to be placed into commerce) is not adulterated for failure to comply with dietary supplement CGMP requirements (see United States v. Dotterweich, 320 U.S. 277, 284 (1943) (explaining that an offense can be committed under the Act by anyone who has "a responsible share in the furtherance of the transaction which the statute outlaws"); United States v. Park, 421 U.S. 658, 672 (1975) (holding that criminal liability under the Act does not turn on awareness of wrongdoing, and that "agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act" can be held accountable for violations of the Act). In particular, the Act prohibits a person from introducing or delivering for introduction, or causing the delivery or introduction, into interstate commerce a dietary supplement that is adulterated under section 402(g) for failure to comply with dietary supplement CGMP requirements (see 21 U.S.C. 342(g) and 331(a)). Thus, a firm that contracts out some or all of its operations must establish a system of production and process controls to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record (21 CFR 111.55). The quality control personnel must ensure that the manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record (21 CFR 111.105). Further, you must have documentation of the quality control personnel review and approval for release of any packaged and labeled dietary supplement (21 CFR 111.127(h) and 111.140(b)(2)).

The significant violations documented during the inspection include, but are not limited to the following:

1. You failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by, 21 CFR 111.103. Specifically, you did not establish and follow any quality control written procedures pertaining to your operations as a repacker, labeler, holder, and distributor of dietary supplements.

We have reviewed your undated letter, received September 6, 2017, and the update letter dated February 21, 2018; however, we are unable to evaluate the sufficiency of your corrective actions. You stated this observation would be

corrected in 3 months, you did not specify how the observation would be corrected and to date you provided no documentation that it has been done.

2. Your firm failed to implement a system of production and process controls that covers all stages of packaging, labeling, and holding of dietary supplements to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.55. Specifically, you do not have a system of production and process controls to ensure the quality of your dietary supplements that you receive from your contract manufacturers and that your dietary supplement products are labeled as specified in the master manufacturing record. For example:

- The label on your Bio-35 Softgel capsule bottle does not state your product contains soy. However, contract manufacturer batch records for your Bio- 35 Softgel capsules, manufacturer lot # S17D055, manufacture date of 6/28/17, indicate this product contains soy lecithin.
- The ingredients Magnesium Trisilicate and Titanium Dioxide were listed as ingredients on the Certificate of Analysis for the bulk finished Lipotropic Formula, but were not present on your finished product label for your Lipotropic Formula received from a contract manufacturer in bulk for packaging, labeling, and distribution by your firm, manufacturing lot # 0727601, with manufacture date of 09/2016.
- Our review of your Pro-Cal tablets, received from a contract manufacturer in bulk for packaging, labeling, and distribution by your firm, manufacturing lot # 04173532, with manufacture date of 05-10-17, revealed the following:
  - Ingredients listed in the Pro-Cal Tablets formulation sheet provided by the contract manufacturer for lot # 04173532 fail to match the finished product label.
  - Upon our investigator's request on 8/14/17, your contract manufacturer provided a master manufacturing record for our review. Because there was no batch production record received for this lot, there was no indication this lot met specifications and was approved for release, apart from contract manufacturer Quality Assurance signatures on the bulk finished product Certificate of Analysis.

We have reviewed your undated letter, received September 6, 2017, and the update dated February 21, 2018. Your response stated this observation would be corrected in 3 months. However, we are unable to evaluate the adequacy of your corrective action because you did not specify how the observation would be corrected or provide documentation to show it had been corrected.

3. You failed to establish specifications to provide sufficient assurance that the product you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) is adequately identified and is consistent with your purchase order, as required by 21 CFR 111.70(f). Specifically, your firm does not have in place any specification(s) to identify that the products you receive are consistent with your purchase order. Once you have established specifications, you must determine whether the specifications established under § 111.70(f) are met, as required by 21 CFR 111.75(e).

We have reviewed your undated letter, received September 6, 2017 and the update dated February 21, 2018; however, we are unable to evaluate the sufficiency of your corrective actions. You stated this observation would be corrected in 3 months, but you did not specify how the observation would be corrected and have not provided documentation of corrective action.

4. You failed to establish specifications for dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements (packaging specifications), as required by 21 CFR 111.70(d). Packaging that may come into contact with dietary supplements must be safe and suitable for its intended use and must not be reactive or absorptive or otherwise affect the safety or quality of the dietary supplement. Specifically, you have not established any label and packaging specifications for dietary supplements

you receive in bulk from contract manufacturers for repackaging and labeling. Once you have established these specifications, you must verify that such specifications are met, in accordance with 21 CFR 111.75(f).

5. You failed to establish specifications for the packaging and labeling of the finished packaged and labeled dietary supplements, including specifications that ensure that you used the specified packaging and that you applied the specified label, as required by 21 CFR 111.70(g). Specifically, during the inspection, it was noted that you did not establish such specifications. Once you have established such specifications, you must, at a minimum, as required by 21 CFR 111.75(g), conduct a visual examination of the packaging and labeling of the finished packaged and labeled dietary supplements to determine whether you used the specified packaging and applied the specified label.

6. You failed to prepare and follow a written master manufacturing record (MMR) to ensure that the dietary supplements are packaged and labeled as specified in the MMR at your firm, as required by 21 CFR 111.205(b)(1). Specifically, during the inspection, you informed our investigator that you did not prepare and follow written master manufacturing records for dietary supplements packaged and labeled at your firm. We note that your master manufacturing records must include the requirements set forth in 21 CFR 111.210. In addition, as required by 21 CFR 111.255, we note you must prepare a batch production record every time you package and/or label a batch of a dietary supplement and your batch production record must include complete information relating to the production and control of each batch for those dietary supplements that are packaged and labeled at Biotek [see also 21 CFR 111.260].

7. Your firm failed to collect and hold reserve samples of each lot of packaged and labeled dietary supplement that you distribute, as required by 21 CFR 111.83(a). Specifically, you did not collect and hold reserve samples for each lot of packaged and labeled dietary supplement that you distribute.

8. Your firm failed to establish and follow written procedures for cleaning the physical plant and grounds and for pest control, as required by 21 CFR 111.16. In addition, your firm failed to make and keep records of these written procedures, as required by 21 CFR 111.23(b).

9. Your firm failed to establish and follow written procedures for packaging and labeling operations, as required by 21 CFR 111.403. During the inspection, you acknowledged to our investigator that you do not have written procedures for packaging and labeling of dietary supplements.

10. Your firm failed to establish and follow written procedures for holding and distributing operations, as required by 21 CFR 111.453. Specifically, you have no written procedures for the holding and distribution of your dietary supplement products. Once you establish written procedures for your holding and distributing operations, we note you must make and keep records of such written procedures, as required by 21 CFR 111.475(b)(1).

11. Your firm failed to establish and follow written procedures to fulfill the requirements related to returned dietary supplements, as required by 21 CFR 111.503. Specifically, you did not have any written procedures for when a returned dietary supplement is returned, including procedures for identifying, holding, evaluating, and disposing of returned products. Once you have established such procedures, you must keep records for returned dietary supplements, as required by 21 CFR 111.535(b)(1).

12. Your firm failed to establish and follow written procedures for calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and for maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to package, label, or hold components or dietary supplements, as required by 21 CFR 111.25(b) and (c). Additionally, when you establish and follow such written procedures, you must make and keep these records, in accordance with 21 CFR 111.35(b)(1). Specifically, you told our investigator that you did not have any procedures in place for your employees to follow.

Misbranded Dietary Supplements

Based on labeling collected during the inspection of your firm, we note that several of your products are misbranded under section 403 of the Act and FDA's labeling regulations, *Title 21, Code of Federal Regulations,* Part 101 (21 CFR 101), as follows:

1. Your Bio 35, Pro-Cal, Glucosamine HCL and Glucosamine Chondroitin products are misbranded within the meaning of section 403(w) of the Act [21 U.S.C. § 343(w)] in that the labels fail to declare the presence of major food allergens present in the products, namely soy, as required by section 403(w)(1) of the Act. Specifically, your product contains the ingredient, lecithin, which you identified to our investigator as being of "soy" origin. Glucosamine HCL and Glucosamine Chondroitin declare "warning: do not consume if allergic to shellfish" but do not specify the species of Crustacean shellfish as required by the Food Allergen Labeling and Consumer Protection Act.

Section 201(qq) of the Act [21 U.S.C. § 321(qq)] defines as "major food allergens" milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains, an ingredient that bears or contains a major food allergen, unless either:

- The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients, section 403(w)(1)(A) of the Act [21 U.S.C. § 343(w)(1)(A)], or
- The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived (e.g., "flour (wheat)"), except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen), section 403(w)(1)(B) of the Act [21 U.S.C. § 343(w)(1)(B)].

2. Your Bio 35, Pro-Cal, Lipotropic Formula, Flaxseed Oil, Glucosamine HCL, Glucosamine Chondroitin Blend, Glucosamine Sulfate, **(b)(4)**, Vitamin C with rose hips, and MSM are misbranded within the meaning of section 403(s)(2)(B) of the Act [21 U.S.C. § 343(s)(2)(B)] because the product labels fail to identify the products by using the term "dietary supplement" in accordance with 21 CFR 101.3(g), which requires that a dietary supplement be identified by the term "dietary supplement" as part of the product's statement of identity, except the word "dietary" may be deleted and replaced by the name of the dietary ingredient in the product or an appropriate descriptive term.

3. Your Bio 35 gluten free product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. §343(i)(2)] in that the 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,

- The Bio 35 gluten free product label lists "C. Sodium Copper" as an ingredient, but this is not the common or usual name of the ingredient. In addition, the label on your Bio-35 Softgel capsule bottle does not state your product contains soy. However, contract manufacturer batch records for your Bio- 35 Softgel capsules, manufacturer lot # S17D055, manufacture date of 6/28/17, indicate this product contains soy lecithin;
- The ingredients Magnesium Trisilicate and Titanium Dioxide were listed as ingredients on the Certificate of Analysis for the bulk finished Lipotropic Formula, but were not present on your finished product label for your Lipotropic Formula received from a contract manufacturer in bulk for packaging, labeling, and distribution by your firm, manufacturing lot # 0727601, with manufacture date of 09/2016;

- The ingredients listed in the Pro-Cal Tablets formulation sheet provided by the contract manufacturer for lot # 04173532 fail to match the finished product label.

4. Your Vitamin C with rose hips 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. The 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. For example, your Vitamin C with rose hips product label recommended use suggests the consumer takes “two to three capsules daily”, but the serving size lists 1 capsule.

5. Your Bio 35, Bio 35 Iron Free, Bio 35 Gluten Free, Lipotropic Formula, Pro-Cal 120 Capsules, Pro-Cal 240 Tablets, Pro-80 90 Tablets and **(b)(4)** product labels are 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 products does not comply with 21 CFR 101.36. Specifically, the product labels fail to include the “Servings Per Container” per 21 CFR 101.36(b)(1)(ii).

6. Your Bio 35, Bio 35 Iron Free, Bio 35 Gluten Free, Pro-Cal 180 Capsules, Pro-Cal 240 Tablets, Pro-80 90 Tablets and **(b)(4)** products are misbranded within the meaning of section 403(q)(5)(F) in that the labels fail to list the % symbol on % Daily Value column adjacent to the numerical. Likewise, in your Bio 35 Iron Free product label declares amounts per 2 capsules but the serving size is 3 capsules (21 CFR 101.36(b)(1)(ii)).

7. Your Bio 35 Iron Free product is misbranded within the meaning of section 403(k) of the Act [21 U.S.C. § 343(k)] because the product label bears or contains an artificial coloring, flavoring, or a chemical preservative, but does not bear labeling stating that fact. For example, your product contains the ingredient “Caramel,” but the label does not specify its function as a color. The label of a food to which any coloring has been added must declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of 21 CFR 101.22(k).

This letter is not intended to be an all-inclusive list of the violations that may exist at your facility or about your products. It also does not indicate that FDA has conducted an all-inclusive review of all the products you manufacture and/or distribute. It is your responsibility to ensure the products you manufacture and/or distribute are following all applicable statutes and regulations, including the Act and applicable FDA regulations. You should take prompt action to correct all the violations noted in this letter and establish and implement procedures that will prevent the recurrence of these violations and the occurrence of other violations. Failure to correct and prevent these violations, or similar ones, may result in FDA taking regulatory action, including, without limitation, seizure or injunction.

In addition, we note the following deviations:

- Your Flaxseed Oil product label lists “which typically contains” within the Supplement Facts label. This is considered intervening material per 21 CFR 101.2(e). In addition, the terms “Recommended use” listed between the Supplement Facts box and Other Ingredients is considered intervening material on the labels of the following products: Bio 35, Bio 25 Gluten Free, Bio 35 Iron Free, Pro-Cal 120 Capsules / 240 Tables, Lipotropic Formula Pro-80, Glucosamine HCl and **(b)(4)**.
- Your Bio 35, Pro-Cal, and Lipotropic Formula products do not bear the required dietary supplement disclaimer accurately as listed in accordance with 21 CFR 101.93(b).
- Your Bio 35 100 and 300 Capsules declare St. John’s Bread as a color on the label, which is not a recognized FDA color. In addition, the Pro-Cal soft gel product label states the product contains the color “Orange 3” as an ingredient, which is not recognized as an FDA approved color.

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 after an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Reinspection-related costs mean 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 reinspection 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 respond to this office in writing within fifteen (15) working days from your receipt of this letter. In your response, identify the steps you have taken or will take to correct the above-noted violations and prevent similar ones. In your response, please include the timeframe in which the corrections will be completed and provide any documentation that will effectively assist us in evaluating whether the corrective actions have been made and the adequacy of such corrective actions. If you are unable to complete the corrective actions within fifteen (15) working days, identify the reason for the delay and the time within which you will complete the corrections.

Your reply should be addressed to the U.S. Food and Drug Administration; Attn: Nancy G. Schmidt, Compliance Officer; P.O. Box 25087, Denver, Colorado, 80225-0087. You may reach Ms. Schmidt at (303) 236-3046 if you have any questions about this matter.

Sincerely,
/S/
LaTonya M. Mitchell
Program Division Director
Office of Human and Animal Food Operations –
Division IV West

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