Department of Health and Human Services

Public Health Service
Food and Drug Administration
Denver District Office
Building 20-Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

June 17, 2015

**WARNING LETTER**

**VIA UPS Overnight**

Mr. Jason A. Brooks, Co-Owner
Desert Stream, Inc.
55 W 200 N
Nephi, UT 84648-1426

**Reference #: DEN-15-13-WL**

Dear Mr. Brooks,

The U.S. Food and Drug Administration (FDA) conducted an inspection of your dietary supplement manufacturing facility located at 55 W 200 N, Nephi, Utah, on September 15-17, 2014. During the inspection, we evaluated the manufacturing of your **(b)(4)** dietary supplement products at your facility. The inspection revealed serious violations of the Current Good Manufacturing Practice (CGMP) regulation in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111). These violations cause your **(b)(4)** dietary supplement products manufactured at your facility to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)], in that the dietary supplements have been prepared, packed, or held under conditions that do not meet CGMP regulations. You can find the Act and its implementing regulations through links on FDA's home page at http://www.fda.gov.

In addition, FDA collected samples of labeling for several of your products during our inspection. Our review of your product labeling revealed the following significant violations:

**Unapproved New Drugs**

Based on our review of your product labels, we have determined that the product names of your dietary supplements, **(b)(4)** for Arthritis Discomforts, promote your products for conditions that

cause them to be drugs within the meaning of section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your labels establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease.

These products are not generally recognized as safe and effective; therefore, each of these products is a "new drug" under section 201(p) of the Act (21 U.S.C. § 321(p)(1)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in section 505(a) of the Act [21 U.S.C. § 355a)]; see also section 301(d) of the Act [21 U.S.C. § 331(d)]. 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.

Furthermore, your **(b)(4)** is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions cannot be written so that a layperson can use this drug safely for its intended purpose. Thus, this drug is misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], in that its labeling fails to bear adequate directions for use. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

**Adulterated Dietary Supplements**

Your significant CGMP violations are as follows:

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 disposition decisions, and for approving or rejecting any reprocessing, as required by 21 CFR 111.103. Specifically, during our inspection, you informed our investigator that you do not have written procedures for your quality control operations.

You also failed to implement quality control operations in your manufacturing, packaging, labeling, and holding operations for producing the dietary supplements to ensure the quality of the dietary supplements and that the dietary supplements are packaged and labeled as specified in the master manufacturing records, as required by 21 CFR 111.65. Specifically, no implementation of quality control procedures was observed during the inspection.

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014. We cannot evaluate the adequacy of your response because you did not provide sufficient documentation. Your response letter states you intend to implement a **(b)(4)** procedure covering **(b)(4)** of raw product. However, no information or supporting documentation was provided regarding your establishment of written procedures for quality control operations.

2. Your batch production record (BPR) failed to accurately follow the appropriate master manufacturing record (MMR), as required by 21 CFR 111.255(c). Our investigators reviewed your BPRs and found that several of your BPRs list the use of components that are not listed in your "manufacturing batch record" (which appears to be your MMR), or components are listed in your MMR, but are not added during manufacture of the product as indicated on your BPR. Specifically:

a. **(b)(4)**:
i. **(b)(4)** is listed as a component on your MMR for this product, but your BPR does not appear to include **(b)(4)** as a component in the production of this lot, as indicated by a line crossing out this component.
ii. **(b)(4)** was added at a greater quantity than indicated in your MMR.
iii. **(b)(4)** is not listed as a component on your MMR, but is listed in your BPR as a component that was added during production of this lot.

b. **(b)(4)**:
i. **(b)(4)** is listed on your MMR; however, your BPR does not appear to include **(b)(4)** as a component in production of this lot, as indicated by a line crossing out this component.
ii. Your BPR documenting the production of this lot showed the addition of the excipients **(b)(4)** (identified as **(b)(4)**) and **(b)(4)**; however, they are not listed as components on your MMR.

c. **(b)(4)**:
i. The weight quantities for three components listed on your MMR were altered on your BPR and replaced with different quantities. Specifically, **(b)(4)** of the component **(b)(4)** was supposed to be added according to your MMR; however, **(b)(4)** was crossed out and **(b)(4)** was written in on your BPR; **(b)(4)** was changed from **(b)(4)** on your MMR to **(b)(4)** on your BPR; and **(b)(4)** was increased from **(b)(4)** on your MMR to **(b)(4)** on your BPR. These changes would also impact the order of ingredients listed on the label.

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014. We cannot evaluate the adequacy of your response because you did not provide documentation demonstrating how you will ensure that your BPRs accurately follow the appropriate MMR as required by 21 CFR 111.255(c).

3. Your batch production records failed to include complete information relating to the production and control of each batch as required by 21 CFR 111.255(b) and 21 CFR 111.260. Specifically, your batch production records do not include the following information required by 21 CFR 111.260:

a. The identity of equipment used in producing the batch, as required by 21 CFR 111.260(b);
b. The date and time of maintenance, cleaning, and sanitizing of equipment and processing lines used in producing the batch, or cross-reference to records, as required by 21 CFR 111.260(c);
c. The unique identifier assigned to each component, as required by 21 CFR 111.260(d).
d. Statements of actual yield and percentage of theoretical yields at appropriate phases of processing, as required by 21 CFR 111.260(f);
e. The results of any testing or examination performed during the batch production, or a cross-reference to such results, as required by 21 CFR 111.260(h);
f. The initials of the person responsible for verifying the weight or measure of each component used in a batch and the initials of the person responsible for verifying the addition of components to the batch, as required by 21 CFR 111.260(j)(2)(ii) and 21 CFR 111.260(j)(2)(iv);

g. An actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the master manufacturing record, as required by 21 CFR 111.260(k)(2); and
h. Documentation at the time of performance that quality personnel approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaging or relabeled dietary supplement, as required by 21 CFR 111.260(l)(4).

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014. In your response you stated that "batch work will not be left blank." You also stated that you implemented a "procedure and changed our **(b)(4)**" and that "cleaning documentation will be kept on the machine for **(b)(4)**." You further stated that equipment IDs will be added to the Master Batch Record, along with a cleaning log being added to each room and specific equipment, which will be "cleared by QA." Finally, you stated that **(b)(4)** have been added to the **(b)(4)** which now has a **(b)(4)**. We cannot evaluate the adequacy of your response because you failed to provide documentation showing that you have addressed the violations present in your batch production records. No copies of completed batch production records have been provided.

4. You failed to conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient prior to its use, as required by 21 CFR 111.75(a)(1)(i). Specifically, during our inspection, you informed our investigator that you do not conduct testing to verify the identity of your dietary ingredients. For example, you did not conduct identity testing for the following dietary ingredients you use in the manufacture of your dietary supplement products:

a. **(b)(4)** ingredients before using in production of the dietary supplement **(b)(4)**;
b. **(b)(4)** ingredients before use in production of the dietary supplement **(b)(4)**;
c. **(b)(4)** ingredients before use in production of the dietary supplement **(b)(4)**; and
d. **(b)(4)** ingredients before use in production of the dietary supplement **(b)(4)**.

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014, in which you state that you commit to conducting **(b)(4)** as an **(b)(4)**. We cannot evaluate the adequacy of your proposed corrective action because you did not provide us with any documentation of your testing. You must establish an identity specification, as required by 21 CFR 111.70(b)(1), and you must ensure that **(b)(4)** is an appropriate, scientifically valid method, as required by 21 CFR 111.75(h)(1). Each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person's assigned functions, as required by 21 CFR 111.12(c).

5. You failed to establish and follow written procedures for fulfilling the requirements for components of dietary supplements as required by 21 CFR 111.153. Specifically, during the inspection, you were unable to provide, and verbally indicated you had not established, written procedures related to component examination, as required by 21 CFR 111.155, and label controls, as required by 21 CFR 111.160.

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014. We are unable to evaluate the adequacy of your response. In your response you stated that you have created a full book of Standard Operating Procedures (SOPs) and training has been provided to employees; however, no documentation was provided to allow us to verify the creation of the SOPs, their adequacy, or the training of employees on the SOPs.

6. You failed to establish and follow written procedures for manufacturing operations, as required by 21 CFR 111.353, and you failed to make and keep records of these written procedures, as required by 21 CFR 111.375(b). The requirements for manufacturing operations are specified in 21 CFR 111.355, 111.360, 111.365, and 111.370. Specifically, during the inspection, you were unable to provide any documentation that you have established written procedures for manufacturing operations and you informed our investigator that you do not have written procedures.

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014. We are unable to evaluate the adequacy of your response. In your response you stated that you have created a full book of Standard Operating Procedures (SOPs) and training has been provided to employees; however, no documentation was provided to allow us to verify the creation of the SOPs, their adequacy, or the training of employees in the SOPs.

7. You failed to establish and follow written procedures for your packaging and labeling operations, as required by 21 CFR 111.403, and you failed to make and keep records of the written procedures for packaging and labeling operations, as required by 21 CFR 111.430(b). During the inspection, you were unable to provide any documentation that you had established, followed, and maintained written procedures for your packaging and labeling operations, and you informed our investigator that you do not have written procedures.

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014. We are unable to evaluate the adequacy of your response. In your response you stated that you have created a full book of Standard Operating Procedures (SOPs) and training has been provided to employees; however, no documentation was provided to allow us to verify the creation of the SOPs, their adequacy, or the training of employees in the SOPs.

8. You failed to establish and follow written procedures to fulfill the requirements related to product complaints, as required by 21 CFR 111.553. Further, you did not make and keep records of the written procedures for fulfilling the requirements related to product complaints, as required by 21 CFR 111.570(b)(1). During the inspection, you were unable to provide any documentation that you have established written procedures to fulfill the requirements related to product complaints, and you informed our investigator that you do not have written procedures.

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014. We are unable to evaluate the adequacy of your response. In your response you stated that you have created a full book of Standard Operating Procedures (SOPs) and training has been provided to employees; however, no documentation was provided to allow us to verify the creation of the SOPs, their adequacy, or the training of employees in the SOPs.

9. You failed to establish and follow written procedures to fulfill the requirements related to returned dietary supplements, as required by 21 CFR 111.503. During the inspection, you were unable to provide any documentation that you have established written produces to fulfill the requirements related to returned dietary supplements, and you informed our investigator that you do not have written procedures.

We received your undated response to the Form FDA 483, Inspectional Observations, on October 8, 2014. We are unable to evaluate the adequacy of your response. In your response you stated that you have created a full book of Standard Operating Procedures (SOPs) and training has been provided to employees; however, no documentation was provided to allow us to verify the creation of the SOPs, their adequacy, or the training of employees in the SOPs.

10. You failed to take all the necessary precautions during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements, as required by 21 CFR 111.365. Specifically, during the inspection, while observing manufacturing operations, our investigator noted the following instances of potential cross-contamination:

a. An employee in the blending area was observed placing bags of raw materials directly on the floor of the production room and then placing the bags inside the blender, a food contact surface;
b. Employees in the blending and encapsulation rooms moved between various production areas, through plastic drapes, using their hands to move the plastic curtains for entry and exit, and then returned to food contact tasks without washing hands or changing gloves.

You also did not use effective measures to protect against the inclusion of metal or other foreign material in components or dietary supplements, such as filters or strainers; traps; magnets, or electronic metal detectors, as required by 21 CFR 111.365(i). During the inspection, our investigator observed, and you verbally confirmed, that your production operation did not have measures in place to protect against the inclusion of metal in your dietary supplements.

We received your undated response letter on October 8, 2014. We are unable to evaluate the adequacy of your response because you did not include any documentation with your response. In your response you stated that you have purchased a table to hold bags of material off the floor. You also stated that you will have employees walk through drapes parting them by forearm or back when moving from area to area. You further stated that you have implemented screens that will be used over the **(b)(4)** product is stored for packaging, and that each product barrel will have a **(b)(4)** for inspection. Your response, however, provides no documentation that adequate training was provided. No documentation has been provided to indicate you have established employee procedures to protect against cross-contamination. Further, no documentation was provided to allow us to verify the installation of the table near the mixer to prevent material being placed on the floor. With regard to the screening procedure you have implemented, your response did not include documentation or photographs to help us verify your proposed corrective actions. In addition, if the screens themselves are metal, your corrective action may not be adequate to effectively protect against the inclusion of metal in components or dietary supplements. We are therefore unable to evaluate the adequacy of your proposed corrective actions.

11. Your MMR failed to include written instructions, as required by 21 CFR 111.205(h). Specifically, your MMRs do not include specific actions necessary to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure that the dietary supplement is packaged and labeled as specified in the MMR, as required by 21 CFR 111.205(h)(3).

**Misbranded Dietary Supplements**

Your **(b)(4)** dietary supplement products are misbranded within the meaning of section 403(i)(2) of the Act in that the product labels fail to declare all the common or usual names of each ingredient used as required by 21 CFR 101.36. Specifically:

- **(b)(4)**, is misbranded because the batch record indicates the ingredients **(b)(4)** are part of the product; however, these ingredients are not declared on the product label.
- **(b)(4)**, is misbranded because the batch production record lists the ingredients **(b)(4)** (identified as **(b)(4)**) and **(b)(4)** were added to the dietary supplement; however, these ingredients are not declared on the product label.
- **(b)(4)**, is misbranded because the batch record indicates the ingredient **(b)(4)** is part of the product; however, this ingredient is not on the product label.

Your **(b)(4)** dietary supplement products are misbranded within the meaning of section 403(s)(2)(B) of the Act because the labels fail to identity the product using the term "dietary supplement" as required by 21 CFR 101.3(g).

Your **(b)(4)** products are misbranded within the meaning of section 403(q)(1)(A) because the serving sizes declared on the labels are incorrect. 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, the recommendation on the **(b)(4)** product label suggests the consumer take 2 capsules morning and evening 1 hour after meal, but the serving size lists 1 capsule. The serving size listed should be 2 capsules.

The violations described above are not meant to be an all-inclusive list of violations at your facility or that exist in connection with your products or their labeling. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with the Act and applicable FDA regulations. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in enforcement action without further notice, including, without limitation, seizure and injunction under section 302 and 304 of the Act [21 U.S.C. §§ 332 and 334].

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 re-inspection-related costs. A re-inspection 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 determine whether compliance has

been achieved. Re-inspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the re-inspection and domestic facility and assessing and collecting the re-inspection fees (21 U.S.C. 379j-31(a)(2)(B)). FDA will assess and collect fees for re-inspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified non-compliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any re-inspection-related costs.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the violations cited in this letter. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of the related documentation that would assist us in evaluating your corrections. If you cannot complete corrective action within fifteen (15) working days, state the reason for the delay and the time within which you will complete the correction.

Your written response should be directed to the U.S. Food and Drug Administration, Attention: Nancy G. Schmidt, Compliance Officer, Denver Federal Center, 6th Avenue and Kipling Street, Building 20, Denver, CO 80225. If you have questions about this letter, please contact Ms. Schmidt at (303) 236-3046.

Sincerely,
/S/
LaTonya M. Mitchell
Denver District Director