



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
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WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

May 19, 2011

W/L 43-11

Mr. Christopher J. Reed, CEO
Reed's Inc.
13000 S. Spring St.
Los Angeles, CA 90061

Dear Mr. Reed:

On October 27, 2010 through November 12, 2010, the U.S. Food and Drug Administration (FDA) inspected your carbonated beverage and human dietary supplement manufacturing facility located at 13000 S. Spring St., Los Angeles, CA 90061. Our investigators identified significant violations of the Current Good Manufacturing Practice (cGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements regulations, Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111).

These violations cause your Reed's Nausea Relief dietary supplement products manufactured in 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 current good manufacturing practice regulations for dietary supplements.

In addition, FDA has reviewed the labeling, Reed's Natural Energy Elixir product, including your website at www.reedsinc.com. Based on our review, we have concluded that this product is in violation of the Act and regulations implementing the food labeling requirements of the Act, which are found in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links in FDA's website at www.fda.gov.

Dietary Supplement CGMP Violations

1) You failed to establish specifications for points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement as required by 21 CFR 111.70, for your Reed's Nausea Relief product. Specifically, you did not establish:

- In-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the dietary supplement and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement [21 CFR 111.70(c)].
- Product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement [21 CFR 111.70(e)].

We received your response to the FDA-483 dated November 18, 2010. In your response, you stated that you will establish product specifications for identity, purity, strength, and composition, start testing the concentrate for amounts of ginger and vitamins prior to shipping to your contract manufacturer, and advise your contract manufacturer to do the same prior to release of the finished product. Your response is inadequate because it does not confirm that you have established in-process and finished product specifications and does not provide documentation of these specifications for our review.

2) You failed to conduct at least one appropriate test or examination to verify the identity of components that are dietary ingredients, as required by 21 CFR 111.75(a)(1). Specifically, you did not conduct identification testing for the dietary ingredients ginger, Vitamin B3, Vitamin B6, and Vitamin B12, prior to using them in the manufacture of Reed's Nausea Relief [21 CFR 111.75(a)(1)(i)]. Instead, your firm uses components that are dietary ingredients based only on certificates of analyses from your supplier. You may rely on a certificate of analysis from a supplier, consistent with the requirements in 21 CFR 111.75(a)(2), to confirm the identity of components that are not dietary ingredients. But, you may not rely on a certificate of analysis from your supplier to confirm the identity of a component that is a dietary ingredient [21 CFR 111.75(a)(1)(i)].

In your November 19, 2010 response, you stated that you will start testing dietary ingredients upon receipt prior to use. Your response is inadequate because you have not provided documentation showing that your firm has started conducting an appropriate test or examination to verify the identity of components that are dietary ingredients prior to use.

3) Your batch production records (BPR) for your Reed's Nausea Relief dietary supplement products do not include the following information, as required by 21 CFR 111.260:

- The batch, lot, or control number of the finished batch of dietary supplement [21 CFR 111.260(a)(1)]. Specifically, your BPR for Reed's Nausea Relief manufactured on 2/11/10, 8/2/10, and 8/3/10 do not have batch, lot or control numbers.
- The identity of the equipment used in producing the batch [21 CFR 111.260(b)]. Specifically, the number of the storage tank used is missing on your BPR for Reed's

Nausea Relief manufactured on 2/10/10 and 8/2/10.

- The date and time of the maintenance, cleaning and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained [21 CFR 111.260(c)]. Specifically, your BPR for Reed's Nausea Relief manufactured on 2/10/10, 8/2/10, and 8/3/10 do not contain this information.
- The unique identifier that you assigned to each component used [21 CFR 111.260(d)]. Specifically, your BPR for Reed's Nausea Relief manufactured on 2/10/10, 8/2/10 and 8/3/10 do not include lot numbers for ginger, vitamin B3, vitamin B6, and vitamin B12.
- The identity and weight or measure of each component used [21 CFR 111.260(e)]. Specifically, your BPR for Reed's Nausea Relief manufactured on 2/10/10, 8/2/10 and 8/3/10 do not list water although it is added in the manufacturing of this product.
- A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing [21 CFR 111.260(f)]. Specifically, your BPR for Reed's Nausea Relief manufactured on 2/10/10, 8/2/10 and 8/3/10 do not contain this information.
- Documentation, at the time of performance, of the manufacture of the batch including the initials of the person weighing or measuring each component used in the batch, the initials of the person responsible for verifying the weight or measure of each component used in the batch, the initials of the person responsible for adding the component to the batch, and the initials of the person responsible for verifying the addition of components to the batch [21 CFR 111.260(j)]. Specifically, BPR for Reed's Nausea Relief manufactured on 2/10/10, 8/2/10 and 8/3/10 do not contain any of this information.

In your November 18, 2010 response, you stated that your BPR has been modified and you included a blank BPR form. Your response is inadequate because, although you have revised the form used to produce your BPR, you have not provided documentation that this form is being used and completed by your employees. The form that you provided was not completed and therefore did not include all of the information required to be included in your BPR under 21 CFR 111.260.

4) You did not quarantine components before you use them in the manufacture of your Reed's Nausea Relief dietary supplement, as required by 21 CFR 111.155(c). You must quarantine such components until: (1) you collect representative samples of each unique lot of components (and, for components that you receive, of each unique shipment, of each unique lot within each shipment); (2) quality control personnel review and approve the results of any tests or examinations conducted on components; and (3) quality control personnel approve the components for use in the manufacture of a dietary supplement, including approval of any treatment (including in-process adjustment) of components to make them suitable for use in the manufacture of a dietary supplement, and releases them from quarantine [21 CFR 111.155(c)]. However, you did not quarantine the components used in the manufacture of your Reed's Nausea Relief before using them, as required by 21 CFR 111.155(c). Further, your quality control personnel did not approve and release from quarantine the components prior to their use in the manufacture of Reed's Nausea Relief, as required by 21 CFR 111.155(c)(3).

In your November 18, 2010 response, you stated that you have designated a quarantine area in Warehouse (b)(4) which will be used in future. Your response is inadequate because you did not

provide any documentation showing that your firm quarantines components before using them in manufacturing your dietary supplement products. Further, you did not address how your quality control personnel will be involved in the quarantine process.

5) You failed to calibrate instruments you use in manufacturing or testing a component or dietary supplement, as required by 21 CFR 111.27(b). Specifically, your firm did not calibrate the production room scale used to measure the weight of components to be added to your dietary supplements.

In your November 18, 2010 response, you stated that calibration weights have been ordered and upon receipt, the scale will be calibrated. Your response is inadequate because you have not indicated or provided documentation that the weights have been ordered and that your firm has calibrated the instruments used in manufacturing and testing component and dietary supplements consistent with the requirements in 21 CFR 111.27(b).

Unapproved and Misbranded New Drugs

6) Your Reed's Natural Energy Elixir product label and your website, www.reedsinc.com, on the webpage entitled "New Product! REED'S Natural Energy Elixir," promote your beverage product for conditions that cause the product to be a drug under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your product label and website establish that the product is a drug because it is intended for use in the cure, mitigation, treatment or prevention of disease. Examples of some of the claims found on your product label and website include:

- "GREEN TEA [ingredient] . . . lowers bad cholesterol."
- "GOJI [ingredient] . . . increases resistance to disease."
- "CAMU CAMU [ingredient] . . . antidepressant."

Your product is not generally recognized as safe and effective for the above referenced uses and therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 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.

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

Misbranded Food

7) Your Reed's Natural Energy Elixir 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 nutrient

content claims that are not authorized by regulation or fail to meet the terms of authorizing regulations. Under section 403(r)(2)(A)(i) 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 promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient of the type required to be in the labeling misbrands the food under section 403(r)(1)(A) of the Act.

- Your product label bears the nutrient content claim “Rich in epigallocatechin gallate (EGCG) a powerful antioxidant.” Nutrient content claims using the term “antioxidant” must comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a reference daily intake (RDI) must have been established for each of the nutrients that are the subject of the claim [21 CFR 101.54(g)(1)], and these nutrients must have recognized antioxidant activity [21 CFR 101.54(g)(2)]. The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) [21 CFR 101.54(g)(3)]. For example, to bear the claim “high in antioxidant vitamin C,” the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term “antioxidant” or “antioxidants” may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity [21 CFR 101.54(g)(4)]. This claim does not comply with 21 CFR 101.54(g)(1) because no RDI has been established for EGCG.
- Your product label bears the claim “Camu Camu- a . . . fruit with the highest concentration of vitamin C of any plant.” This is a nutrient content claim subject to section 403(r)(1)(A) of the Act because it characterizes the level of a nutrient of a type required to be in the labeling of food (vitamin C) by using the term “highest concentration.” Under section 403(r)(2)(A) of the Act, a nutrient content claim may be made only if the characterization of the level made in the claim uses terms which are defined by regulation. However, FDA has not defined the characterization “highest concentration” by regulation. Therefore, this term may not be used in nutrient content claims.

8) Your Reed’s Natural Energy Elixir product is misbranded within the meaning of 403(q) of the Act [21 U.S.C. 343(q)] in that the product fails to provide nutrition information in accordance with 21 CFR 101.9. For example:

- Nutrition information on your product label is presented in the simplified format for nutrition labeling provided for in 21 CFR 101.9(f). However, your product label fails to bear the statement “Not a significant source of ___” (with the blank filled in with the name(s) of any nutrient(s) identified in 101.9(f) and calories from fat that are present in insignificant amounts) at the bottom of the nutrition label, as required by 21 CFR 101.9(f)(4).
- The serving size in the nutrition facts panel is not declared in an appropriate household unit. Under 21 CFR 101.9(5)(iv), individually packaged products within multi-serving

containers and single serving containers, must use a description of the individual container or package (e.g., can, box, package) as a serving size. Your product is a single serving container; however, your serving size is declared as 10.5 fl. oz. (315 ml).

9) Your Reed's Natural Ginger Nausea Relief product is misbranded within the meaning of section 403(s)(2)(B) of the Act [21 U.S.C. 343(s)(2)(B)] because the label fails to identify the product as a dietary supplement [21 CFR 101.3(g)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility, and in connection with your products. It is your responsibility to ensure that your firm and all of your products comply with the Act and FDA regulations.

You should take prompt action to correct the violations described in this letter. Failure to do so may result in regulatory action without further notice. Such action may include, but is not limited to, seizure or injunction.

We offer the following comments about your Reed's Natural Energy Elixir product:

- In accordance with 21 CFR 101.4(a) and (b), ingredients required to be declared on the label of a food must be listed by common or usual name in descending order of predominance by weight and the name of an ingredient shall be a specific name and not a collective (generic) name. However, your ingredients statement bears the collective declaration of sweeteners (sweetened by a blend of sugar cane and pineapple juice concentrate, and honey)".
- In addition, your ingredient statement lists "fresh ginger root," as an ingredient. Ingredients required to be declared on the label of food must be listed by their common or usual names and without intervening material [21 CFR 102.(e) and 101.(4)(a)(1). Extraneous modifiers such as "fresh" are not part of the common or usual name of the ingredient to which they refer; rather, they are considered intervening material and therefore should be included in the ingredient statement.
- Further, your ingredient statement lists "B6, B3, B12" as ingredients; however the ingredient statement does not list the sources of these vitamins. For example, niacin (21 CFR 184.1530) and niacinamide (21 CFR 184.1534) are food ingredients that provide vitamin B3. Further, vitamin B6 can be provided by pyridoxine hydrochloride (21 CFR 184.1676). Vitamin B12 is a food ingredient that can be described as vitamin B12 (21 CFR 184.1945).

Please notify this office in writing within fifteen working days from your receipt of this letter of the specific steps that you have taken to correct the violations noted above and to prevent the recurrence of similar violations. Your response should include any documentation necessary to show that the correction has been achieved, such as copies of new labels for your products. If you cannot complete all corrective actions within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your response should be sent to:

Mr. Blake Bevill
Director, Compliance Branch
Food and Drug Administration
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612

If you have any questions about the content of this letter, please contact Dr. Raymond W. Brullo, Compliance Officer, at 949-608-2918.

Sincerely yours,

/s/

Alonza E. Cruse
District Director