IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA, Plaintiff, v. SUNSET NATURAL PRODUCTS, INC., a corporation, and TERESA MARTINEZ (a.k.a. TERESA MARTINEZ-ARROYO) and ELSY CRUZ, individuals, Defendants.	)	Civil No. _____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, and its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the equitable authority of this Court, to permanently enjoin and restrain Sunset Natural Products, Inc., a corporation, and Teresa Martinez and Elsy Cruz, individuals (collectively, "Defendants"), from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

B. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C.

§ 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

PARTIES

4. Plaintiff is the United States of America ("United States")

5. Defendant Sunset Natural Products, Inc. ("Sunset Natural"), is a Florida corporation with its principal place of business at 7345 SW 45th Street, Miami, Florida (the "Facility"), within the jurisdiction of this Court.

6. Defendant Teresa Martinez (aka Teresa Martinez-Arroyo) is Sunset Natural's co-owner and President. Ms. Martinez oversees the firm's day-to-day operations and shares ultimate responsibility for all of the firm's operations with Defendant Cruz. Ms. Martinez performs her duties at the Facility, within the jurisdiction of this Court.

7. Defendant Elsy Cruz is Sunset Natural's co-owner and Vice President. Along with Ms. Martinez, Ms. Cruz oversees the firm's day-to-day operations and shares ultimate responsibility for all of the firm's operations. Ms. Cruz performs her duties at the Facility, within the jurisdiction of this Court.

8. Defendants have been, and are now engaged in, manufacturing, preparing, labeling, packing, repacking, holding, and distributing dietary supplements within the meaning of 21 U.S.C. § 321(ff). Defendants are also contract manufacturers of dietary supplements distributed under other company's names.

9. Defendants manufacture dietary supplements using components that they receive from outside Florida. Defendants also deliver for introduction into interstate commerce finished dietary supplements.

DEFENDANTS' VIOLATIONS OF THE ACT

10. FDA inspected Defendants' facility between September 8-30, 2014. This inspection established that the dietary supplements Defendants manufacture, prepare, pack, label, hold, and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held in a manner that does not comply with the current good manufacturing practice ("cGMP") regulations for dietary supplements set forth at 21 C.F.R. Part 111 ("cGMP regulations").

11. Manufacturing in compliance with cGMP means that the manufacturing process incorporates a set of controls in the design and production processes to ensure a finished product of acceptable, predictable, and reliable quality. Dietary supplements not manufactured, prepared, packed, and held in conformance with the cGMP regulations are deemed adulterated. 21 U.S.C. § 342(g)(1).

12. During the September 2014 inspection, FDA investigators documented numerous significant deviations from the cGMP regulations, including, but not limited to, the following:

A. Failure to establish specifications for any point, step, or stage in the manufacturing process where control is necessary to ensure the dietary supplement's quality, as required by 21 C.F.R. § 111.70(a);

B. Failure to establish identity specifications for components, as required by 21 C.F.R. § 111.70(b);

C. Failed to establish product specifications for identity, purity, strength, and composition of their finished dietary supplements, as required by 21 C.F.R. § 111.70(e);

D. Failure to verify that finished dietary supplements meet product specifications for identity, purity, strength, composition, as required by 21 C.F.R. § 111.75(c);

E. Failure to qualify component suppliers by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations, as required by 21 C.F.R. § 111.75(a)(2)(ii)(A);

F. Failure to conduct at least one appropriate test to verify the identity of a dietary ingredient, as required by 21 C.F.R. § 111.75(a)(1);

G. Failure to establish complete master manufacturing records, as required by 21 C.F.R. §§ 111.205 and 111.210;

H. Failure to establish complete batch production records, including documentation of packaging and labeling operations and adequate documentation that quality control personnel approved and released, or rejected, packaged and labeled dietary supplements, as required by 21 C.F.R. §§ 111.255 and 111.260(k), (l); and

I. Failure to use equipment and utensils of appropriate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained, as required by 21 C.F.R. § 111.27(a).

13. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held under conditions that do not meet the cGMP regulations, 21 C.F.R. Part 111.

14. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS' HISTORY OF VIOLATIONS

15. Many of the dietary supplement cGMP deviations observed during FDA's September 2014 inspection (referenced in Paragraph 11 above) are the same as or similar to those observed by FDA during previous inspections of Defendants' facility in April 2014 and August-September 2012.

16. FDA has warned Defendants about their ongoing dietary supplement cGMP violations. At the conclusion of the September 2014 and 2012 inspections, an FDA investigator issued to Defendant Martinez a List of Inspectional Observations ("Form FDA 483") detailing Defendants' numerous violations of the Act and cGMP regulations, and discussed the observed deviations with her. After both inspections, Defendant Martinez responded to FDA in writing, promising to take corrective actions in response to FDA's observations. Similarly, at the conclusion of the April 2014 inspection, an FDA investigator issued to Defendant Cruz a Form FDA 483 detailing Defendants' numerous violations of the Act and cGMP regulations, and discussed the observed deviations with her. Defendant Cruz responded to FDA in writing, promising to take corrective actions in response to FDA's observations.

17. During a June 2014 meeting between FDA and the firm's general manager, FDA explained the April 2014 Form FDA 483 observations, why the firm's responses to date were inadequate, and that FDA could pursue further enforcement action, including injunction, if

corrections were not made. The firm's general manager stated that she would relay the information to Defendant Martinez who was unable to attend the meeting.

18. On March 19, 2013, FDA issued a Warning Letter to Defendant Martinez, detailing numerous violations of the cGMP regulations observed by FDA during the 2012 inspection. All of the cGMP violations described in the letter were the same as, or similar to, the violations FDA observed during the April 2014 and September 2014 inspections. The Warning Letter stated that it was Defendants' responsibility to ensure compliance with the Act and its implementing regulations and cautioned that failure to take prompt action to correct the deviations, and prevent their recurrence, may result in legal action, including an injunction.

19. Defendant Martinez responded in writing to the Warning Letter with promises to correct the cGMP violations. However, Defendants either did not follow through on their promises to correct and/or failed to fully correct these violations, as shown by FDA investigators' observation and documentation of ongoing, significant cGMP deficiencies during the subsequent 2014 inspections.

20. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, cease manufacturing, preparing, processing, packing, labeling, holding, and distributing dietary supplements at or from the Facility, or at or from any other location(s) at which Defendants manufacture, prepare, process, pack, label, hold, and/or distribute dietary supplements, now or in the future, unless and until Defendants bring

their manufacturing, preparing, processing, packing, labeling, holding, and distributing operations into compliance with the Act and cGMP regulations;

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, be permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

B. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacturing, preparing, processing, packing, labeling, holding, and distribution of all of Defendants' dietary supplements to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated this _____ day of _____, 2015.

Respectfully submitted,

WILFREDO A. FERRER
United States Attorney

By: */s/Franklin G. Monsour, Jr.*
Franklin G. Monsour, Jr.
Assistant United States Attorney
Florida Bar No. A5501761
Franklin.Monsour@usdoj.gov
99 N.E. 4th Street, Third Floor
Miami, Florida 33132-2111
Telephone: (305) 961-9128
Facsimile: (305) 530-7139
Counsel for United States of America

MICHAEL S. BLUME
Director

By: /s/ Melanie Singh
Melanie Singh
Counsel
Consumer Protection Branch
Department of Justice-Civil Division
P.O. Box 386
Washington, D.C. 20044

Of Counsel:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Associate General Counsel
Food and Drug Division

PERHAM GORJI
Deputy Chief Counsel, Litigation

MICHELE SVONKIN
Senior Counsel
United States Department of
Health and Human Services
White Oak Bldg. 32, Rm. 4308
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002