UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, vs. Titan Medical Enterprises, Inc. d.b.a., US Apothecary Laboratories, Crown Labs, and Vista Labs, a corporation, and James L. McDaniel, an individual, Defendants.	Case No. 2:11-cv-10752-ODW(FFMx) STATEMENT OF DECISION GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

This matter comes before the Court on the United States' ("Plaintiff's") Motion for Summary Judgment. The Court has considered Plaintiff's Motion for Summary Judgment and supporting documents, the opposition memorandum submitted by Titan Medical Enterprises, Inc., a corporation, and James L. McDaniel, an individual (collectively, "Defendants"), and the entire record in this case, and hereby grants the motion for summary judgment for the reasons stated herein.

CASE HISTORY

The United States filed its complaint on December 28, 2011, seeking a permanent injunction against Defendants. *See* Dkt. 1 ("Complaint"). Discovery closed on September 17, 2012, and the United States filed its motion for summary judgment on all claims on October 26, 2012.

FINDINGS OF FACT AND LAW

The Court makes the following findings of fact and law:

Drug Adulteration

Defendants manufacture, process, pack, label, hold, and distribute drugs, as defined by 21 U.S.C. § 321(g), for human use. Compl. ¶ 4; Ans. ¶ 4; Joint Stipulation of Facts ("Jt. Stip.") ¶¶ 10, 12; Lee Decl. ¶ 6.

Defendants hold for sale drugs made from components that have been shipped in interstate commerce. Jt. Stip. ¶ 8; *see also* Cruse Decl. ¶ 7, Exhibit 4. Defendants distribute drugs in interstate commerce. Compl. ¶ 6; Ans. ¶ 6; *see also* Joint Stip. ¶ 3.

From 2001 through 2012, Defendants' drug manufacturing operations did not comply with current good manufacturing practice regulations for drugs ("Drug CGMP"), 21 C.F.R. Parts 210-211. Jt. Stip. ¶¶ 62-68, 70; Cruse Decl. ¶¶ 8-9, 12, 15, 16; Deposition of Samuel Hernaez ("Hernaez Dep.") at 14, 19-20; *see generally* Declaration of Nicholas Buhay ("Buhay Decl."). Defendants' drugs are therefore adulterated under 21 U.S.C. § 351(a)(2)(B). S*ee United States v. Radix Labs., Inc.*, 963 F.2d 1034, 1038 n.4 (7th Cir. 1992); *John D. Copanos and Sons, Inc. v. FDA*, 854 F.2d 510, 514 (D.C. Cir. 1988); *United States v. Barr Labs., Inc.*, 812 F. Supp. 458, 465 (D.N.J. 1993); *United States v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 544 (8th Cir. 1981).

Dietary Supplement Adulteration

Defendants manufacture, process, pack, label, hold, and distribute dietary supplements, as defined by 21 U.S.C. § 321(ff), for human use. Compl. ¶ 4; Ans. ¶ 4; Jt. Stip. ¶¶ 51-53; Declaration of Carl C. Reynolds ("Reynolds Decl.") ¶ 24.

Defendants hold for sale dietary supplements made from components that have been shipped in interstate commerce. Jt. Stip. ¶ 7; *see also* Jt. Stip. ¶¶ 4-5. Defendants distribute dietary supplements in interstate commerce. Cruse Decl. ¶ 7, Exhibit 7 at 4; *see also* Joint Stip. ¶ 6.

From 2010 through 2012, Defendants' dietary supplement manufacturing operations did not comply with current good manufacturing practice regulations for dietary supplements ("Dietary Supplement CGMP"), 21 C.F.R. Part 111. Jt. Stip. ¶¶ 69, 71; Cruse Decl. ¶¶ 8, 10, 13, 17; *see generally* Reynolds Decl.; Hernaez Dep. at 19-20. Defendants' dietary supplements are therefore adulterated under 21 U.S.C. § 342(g).

Distribution of Unapproved New Drugs

Defendants have sold enteric coated tablets containing 600 milligrams of guaifenesin. Ans. ¶ 20.

Defendants' tablets containing 600 milligrams of guaifenesin are new drugs within the meaning of 21 U.S.C. § 321(p)(1). Joint Stip. ¶¶ 59-61; *see* Declaration of Charles E. Lee ("Lee Decl.") ¶ 27.

FDA has not approved a new drug application, abbreviated new drug application, or investigational new drug application for Defendants' enteric coated tablets, Guaifenesin 600 mg Entero Release Tablets. Joint Stip. ¶ 58; *see also* Lee Decl. ¶ 25.

DISCUSSION

Pursuant to the Court's findings of fact above, Plaintiff, the United States of America, is entitled to judgment as a matter of law because the Defendants' stipulations, Defendants' depositions, and the undisputed evidence show that Defendants have repeatedly violated 21 U.S.C. §§ 331(a) and (k), by distributing adulterated drugs and dietary supplements in interstate commerce and causing drugs and dietary supplements to become adulterated while holding them for sale after shipment of one or more of their components in interstate commerce. *See John D. Copanos and Sons*, 854 F.2d at 514; *United States v. Bel Mar Labs., Inc.*, 284 F. Supp. 875, 881 (E.D.N.Y. 1968); *United States v. Western Serum Co.*, 498 F. Supp. 863, 867 (D. Ariz. 1980); *United States v. Undetermined Quantities . . . Proplast II*, 800 F. Supp. 499, 502 (S.D. Tex. 1992). The undisputed evidence further shows that Defendants have violated 21 U.S.C. § 331(d), by distributing unapproved new drugs in interstate commerce. The Court further finds that Defendants, unless restrained by order of this Court, will continue to violate the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 331(a), (d), and (k). *See United States v. Laerdal Mfg. Corp.*, 73 F.3d 852, 857 (9th Cir. 1995) (citing *S.E.C. v. Koracorp Indus., Inc.*,575 F.2d 692, 298 (9th Cir. 1978)); *United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 176 (9th Cir. 1987); *United States v. Organic Pastures Dairy Company*, 708 F. Supp. 2d 1005, 1012 (E.D. Cal. 2010).

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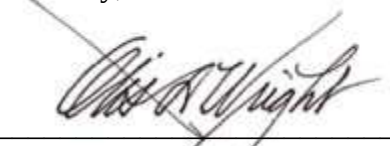
Accordingly, this Court enters summary judgment in favor of the United States and enters the United States' proposed order of permanent injunction.

SO ORDERED

DATED this 4th day of February, 2013.



The Honorable Otis D. Wright
United States District Judge