UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civ. No: ____-____

UNITED STATES OF AMERICA,	)
	)
Plaintiff,	)
	)
v.	)
	)
C. R. CANFIELD CO., INC., and GARRY R. PERSONS, an individual,	)
	)
Defendants.	)

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by Rachel K. Paulose, United States Attorney for the District of Minnesota, respectfully represents to this Honorable Court as follows:

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 court's inherent authority in equity, to enjoin C. R. Canfield, Co., Inc. ("Canfield"), a corporation, and Garry R. Persons, an individual, (hereafter, collectively "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are

adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (b) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (c) violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p), that are not approved pursuant to 21 U.S.C. § 355(a), or exempt from approval pursuant to 21 U.S.C. § 355(i); (d) violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and (e) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

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

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

4. Defendant Canfield is a business incorporated under the laws of the state of Minnesota. Canfield manufactures products, including human drug products, at 4221 Valley View Road, Edina, Minnesota, within the jurisdiction of this Court.

5. Defendant Persons, an individual, is the president and owner of Canfield. He has overall responsibility for, and authority over, all operations of the corporation, including the manufacture of human drug products in the basement of Defendant Persons' home at 4221 Valley View Road, Edina, Minnesota, within the jurisdiction of this Court.

6. Defendants receive drug ingredients, namely Eugenol and White Petrolatum, in interstate commerce from outside of the state of Minnesota and introduce their finished human drug products into interstate commerce for shipment outside of the state of Minnesota.

7. Defendants have been and are now engaged at the facility located at 4221 Valley View Road, Edina, Minnesota, in manufacturing, processing, packing, labeling, holding,

and distributing in interstate commerce, products that are regulated as drugs within the meaning of 21 U.S.C. § 321(g) because they contain the drug Eugenol and are intended for dental use in the treatment of dry socket syndrome, a dental condition associated with severe pain that may occur following a tooth extraction when either a blood clot has failed to form in the socket, or a blood clot that did form becomes dislodged.

8. Defendant's drugs, which are marketed to dentists, include Canfield's Mini-D.S. Dressing® (radiopaque gauze impregnated with 20% Eugenol in a white petrolatum base), Canfield's D.S. Dressing® (radiopaque gauze impregnated with 20% Eugenol in a white petrolatum base), Canfield's D.S. Syringe® (a syringe filled with 20% Eugenol in a white petrolatum base), and D.S. Ointment (20% Eugenol in a white petrolatum base). These products are regulated as drugs within the meaning of 21 U.S.C. § 321(g) because they contain the drug Eugenol and are intended for dental use in the treatment of dry socket syndrome.

Adulteration

9. The United States Food and Drug Administration ("FDA") conducted an inspection of the Defendants' facility

between February 14 and 15, 2006 (the "February 2006 inspection").

10. During the February 2006 inspection, the FDA investigators observed that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, labeling, holding, or distribution of Canfield's Mini-D.S. Dressing, Canfield's D.S. Dressing, Canfield's D.S. Syringe, and D.S. Ointment do not conform to or are not operated or administered in conformity with current good manufacturing practice (CGMP). See 21 C.F.R. Parts 210 and 211.

11. The failure to manufacture, process, pack, or hold drugs in conformity with CGMP causes those drugs to be adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

12. CGMP includes procedures and practices that are intended to ensure that drugs have the quality, purity, and other attributes necessary for their safe and effective use. FDA has promulgated regulations establishing minimum CGMP requirements applicable to drugs. See 21 C.F.R. Parts 210 and 211. These regulations require manufacturers to control all aspects of the processes and procedures by which drugs are manufactured, processed, packed, or held to prevent

production of unsafe and ineffective products. Drugs that are not manufactured in conformance with CGMP are deemed to be adulterated as a matter of law. See 21 U.S.C. § 351(a)(2)(B).

13. As a result of the CGMP violations, the drugs manufactured, processed, packed, or held by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B). These CGMP violations include, but are not limited to:

A. Failure to establish procedures designed to prevent microbiological contamination of drug products not required to be sterile, as is required by 21 C.F.R. § 211.113(a).

B. Failure to test each component of a drug product to verify the identity of the component, as required by 21 C.F.R. § 211.84(d)(1).

C. Failure to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release, as is required by 21 C.F.R. § 211.165(a).

D. Failure to develop a written testing program

designed to assess the stability characteristics of drug products, which shall be used to determine appropriate storage conditions and expiration dates, as required by 21 C.F.R. § 211.166(a).

E. Failure to sanitize at appropriate intervals, equipment and utensils to prevent contamination that would alter the safety, identity, strength, quality, or purity of drug products, as required by 211 C.F.R. § 211.67(a).

Unapproved New Drugs

14. During the February 2006 inspection, the FDA investigators observed that Defendants cause the introduction into interstate commerce of unapproved new drugs.

15. Canfield's products, including Mini-D.S. Dressing, D.S. Dressing, and D.S. Syringe are regulated as drugs within the meaning of 21 U.S.C. § 321(g) because they contain the drug Eugenol and are intended for dental use in the treatment of dry socket syndrome.

16. The labeling on Canfield's D.S. Dressing and Mini-D.S. Dressing note that the products contains 20% Eugenol and are intended for the "treatment of Dry Socket Syndrome." The labeling also states that the products are for dental

use only. The labeling on Canfield's D.S. Syringe states that the product contains 20% Eugenol and is a "[d]ry socket treatment in a syringe for use by patients." The directions describe that the product is to be applied inside a tooth socket to control pain.

17. Canfield's Mini-D.S. Dressing, Canfield's D.S. Dressing, and Canfield's D.S. Syringe are new drugs within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

18. Canfield's Mini-D.S. Dressing, Canfield's D.S. Dressing, and Canfield's D.S. Syringe are unapproved new drugs within the meaning of 21 U.S.C. § 355(a) because they lack approved new drug applications ("NDAs") or abbreviated new drug applications ("ANDAs"), and are not the subject of effective investigational new drug applications ("INDs") under 21 U.S.C. § 355(i).

19. The introduction into interstate commerce of drugs,

such as Canfield's Mini-D.S. Dressing, Canfield's D.S. Dressing, and Canfield's D.S. Syringe, that are not the subjects of approved NDAs, ANDAs, or effective INDs, is a violation of 21 U.S.C. § 331(d).

Misbranding

20. During the February 2006 inspection, FDA investigators observed that Defendants' D.S. Ointment failed to bear any instructions for its use.

21. Canfield's D.S. Ointment is misbranded within the meaning of 21 U.S.C. § 352(f)(1) because it fails to bear adequate directions for use, and is not exempt from that requirement. See 21 C.F.R. § 201.5.

History of Violations

22. Defendants have a history of continuing violations. The CGMP deficiencies the FDA investigators observed during the February 2006 inspection are the same as, or similar to, prior deficiencies observed by FDA investigators during inspections conducted on June 1 and 6, 2005; May 24 to 26, 2004; and October 7 to 10, 2002.

23. Defendants' noncompliance has continued in the face of repeated warnings from FDA regarding their violations. At the close of each of the FDA inspections of

Canfield in 2006, 2005, 2004, and 2002, FDA investigators issued to Defendants a detailed List of Inspectional Observations ("Form FDA-483"), which notified Defendants of the investigators' observations. FDA investigators discussed the deficiencies listed in the Forms FDA-483 with Defendants.

24. Defendants also received a Warning Letter from FDA, dated September 24, 2004, that emphasized the nature of Defendants continuing CGMP violations and informed Defendants that they were marketing drugs without approved applications and without adequate directions for use as required by the Act.

25. FDA warnings have been unsuccessful in promoting the necessary corrections. Despite Defendants' promised corrections, the violations have continued. Based on Defendants' repeated course of conduct, Plaintiff is informed and believes that, unless restrained by order of this Court, Defendants will continue to manufacture and distribute human drugs in violation of 21 U.S.C. §§ 331(a), 331(d), and 331(k).

Violations of the Act

26. Defendants violate the Act, 21 U.S.C. § 331(a), by

causing the introduction into interstate commerce of drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

27. Defendants also violate the Act, 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

28. Defendants violate the Act, 21 U.S.C. § 331(d), by causing the introduction into interstate commerce of unapproved new drugs that are not the subjects of FDA approvals pursuant to 21 U.S.C. § 355(a), or exempt from approvals pursuant to 21 U.S.C. § 355(i).

29. Defendants violate the Act, 21 U.S.C. § 331(a) by causing the introduction into interstate commerce of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

30. Defendants also violate 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

WHEREFORE Plaintiff respectfully prays:

I. That Defendants and each and all of their directors, officers, agents, representatives, employees, successors or assigns, attorneys, and any and all persons 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 the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p), that are not

approved pursuant to 21 U.S.C. § 355(a), or exempt from approval pursuant to 21 U.S.C. § 355(i);

D. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

II. That FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the published rates prevailing at the time the inspections are accomplished; and

III. That the Court award Plaintiff costs and other such relief as the Court deems just and proper.

DATED this 15 day of September, 2006.

Respectfully submitted,

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