UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civ. No: 06-3727 RHK/JSM

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

CONSENT DECREE FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by Rachel K. Paulose, United States Attorney for the District of Minnesota, having filed a complaint for permanent injunctive relief against C. R. Canfield Co., Inc. ("Canfield"), a corporation, and Garry R. Persons, an individual (hereinafter, collectively, "Defendants"), and Defendants, solely for the purpose of settlement of this case, and without admitting or denying the allegations in the Complaint, having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. The Complaint alleges that the Defendants have violated the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced for introduction, or delivering or causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, held, or distributed in violation of current good manufacturing practice ("CGMP").

4. The Complaint alleges that the Defendants have violated the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug, as defined by 21 U.S.C. § 321(g)(1), after

shipment of one or more of their components in interstate commerce.

5. The Complaint alleges that the Defendants have violated the Act, 21 U.S.C. § 331(d), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

6. The Complaint alleges that the Defendants have violated the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded under 21 U.S.C. § 352(f)(1), in that they lack adequate directions for use.

7. The Complaint alleges that the Defendants have violated 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 misbranded within the meaning of 21 U.S.C. § 352(f)(1).

8. Upon entry of this Decree, 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 who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any articles of drug, within the meaning of 21 U.S.C. § 321(g)(1), including, but not limited to Defendants' D.S. Dressing, D.S. Mini-Dressing, D.S. Syringe, and D.S. Ointment, at or from Canfield's facilities at 4221 Valley View Road, Edina, Minnesota, or at any additional or alternate facility, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with CGMP. See 21 C.F.R. Parts 210 and 211.

B. Defendants retain, at Defendants' expense, an independent person or persons (the "expert"), to make inspections of their drug manufacturing facilities to

determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. The expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families. Defendants shall notify FDA in writing of the identity of the expert as soon as they retain such expert. The expert shall:

i) Perform a comprehensive inspection of Defendants' facilities and the methods and controls used for manufacturing, processing, packing, labeling, holding, and distributing drugs to determine whether they are in compliance with CGMP;

ii) When appropriate, certify in writing to FDA that Defendants' facilities, methods, and controls are in compliance with CGMP; and

iii) Submit to FDA as part of the certification a full and complete written report prepared by the expert of the results of his or her inspection.

C. Defendants ensure that any new drug, as defined in

21 U.S.C. § 321(p), that they manufacture, processes, pack, label, hold, or distribute is the subject of an approved new drug application under 21 U.S.C. § 355(a) or an investigational new drug application under 21 U.S.C. § 355(i).

D. Defendants ensure that any drug, as defined in 21 U.S.C. § 321(g), that they manufacture, processes, pack, label, hold, or distribute bears adequate directions for use, as defined in 21 C.F.R. § 201.5.

E. Defendants report to FDA in writing the actions they have taken to: (1) correct the CGMP deviations set forth in the Complaint and ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and administered in conformity with CGMP; (2) bring their products into compliance with the drug approval provisions of the Act; and (3) ensure that their products have adequate directions for use.

F. Defendants destroy all finished drug products in their possession, custody, or control that are identified by FDA as adulterated, unapproved, and/or misbranded, in a manner that complies with all applicable environmental laws and any

other applicable federal and state laws. Such destruction shall be conducted under FDA supervision, as FDA deems necessary, and all costs of such destruction shall be borne by Defendants.

G. Defendants reimburse FDA for the costs of any FDA inspections, investigations, supervision, reviews, examinations, and/or analyses that FDA deems necessary to evaluate Defendants' compliance with the terms of this Paragraph.

H. Duly authorized FDA representatives make such inspections, as FDA deems necessary and without prior notice, of Defendants' facilities, including buildings, equipment, finished and unfinished materials, containers, and labeling, and all records relating to the methods used in, and the facilities and controls used for, the manufacturing, processing, packing, labeling, holding, and distribution of drugs, to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are otherwise operating in compliance with CGMP, the Act, and the regulations implementing the Act.

I. FDA notifies Defendants in writing that Defendants

appear to be in compliance with the requirements set forth in Paragraphs 8(A)-(G).

9. After Defendants receive written notice from FDA pursuant to Paragraph 8(I) that they appear to be in compliance with Paragraphs 8(A)-(G) of this Decree, 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 who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any act that:

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

B. Violates 21 U.S.C. § 331(k) by causing articles of drug 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); or

C. Violates 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i); or

D. Violates 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of drug that are misbranded under 21 U.S.C. § 352(f)(1), in that they lack adequate directions for use; or

E. Violates 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).

10. After Defendants receive written notice from FDA pursuant to Paragraph 8(I) that they appear to be in compliance with Paragraphs 8(A)-(G), Defendants shall retain an independent person or persons (the “auditor”) to conduct audit inspections of their drug manufacturing operations not less than once every six (6) months for a period of three (3)

years and, for the following two (2) year period, at least once every twelve (12) months. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families. If Defendants choose, the auditor may be the same person or persons retained as the expert in Paragraph 8(B).

A. At the conclusion of each audit inspection, the auditor shall prepare a written audit report (the "audit report") analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspections are completed. In addition, Defendants shall maintain the audit

reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any audit report observations, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, propose a schedule for completing corrections ("correction schedule"). That correction schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor

shall report in writing to FDA whether each of the audit report observations has been corrected.

11. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample or samples, or other information, that Defendants have failed to comply with any provision of this Decree, have violated FDA regulations or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, FDA regulations, or the Act, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, or distributing any or all drug(s);

B. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

C. Submit additional reports or information to FDA;

D. Recall specified drug products released or

distributed by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers; or

E. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, FDA regulations, and the Act, including, but not limited to, requiring that Defendants re-institute or re-implement any of the requirements in Paragraph 8 of this Decree. Upon receipt of such notification, Defendants shall immediately and fully comply with the terms of the notice. In the event that Defendants disagree with the terms of the notice, Defendants may appeal to this Court and shall continue to immediately and fully comply with the terms of the notice unless and until the Court modifies or overturns the notice. Defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in Paragraph 15 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

12. Any order issued pursuant to paragraph 11 shall specify the deficiencies or violations giving rise to the order.

13. Any cessation of operations pursuant to paragraph 11 shall continue until FDA notifies Defendants in writing that Defendants appear to be in compliance with this Decree, FDA regulations, and the Act, and that Defendants may, therefore, resume operations.

14. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and without prior notice to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs; to take samples of Defendants' finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all drug products, including

components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

15. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $76.10 per hour and fraction thereof per representative for inspection work; $91.18 per hour or fraction thereof per representative for analytical or review work; $0.445 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the

standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

16. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to 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, and post a copy of this Decree in the employee common areas at their manufacturing facilities. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Decree.

17. Defendants shall notify FDA at least fifteen (15) calendar days before any change in ownership or character of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change

in the corporate structure of C. R. Canfield, Co., Inc., or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least thirty (30) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph within fifteen (15) calendar days of such service on a prospective successor or assign.

18. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, FDA Minneapolis District Office, 212 Third Avenue South, Minneapolis, Minnesota 55401. In the event this address changes, FDA shall inform Defendants of this change, and all notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be sent by Defendants to the new address without further order of the Court.

19. Should the United States bring, and prevail in, a

contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

20. Defendants shall abide by the decisions of FDA, which decisions shall be final. FDA decisions under this Decree, to the extent that they are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard, 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

21. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

22. No sooner than sixty (60) months after Defendants receive written notification from FDA pursuant to Paragraph 8(I) of this Decree, Defendants may petition FDA for leave to

ask this Court to dissolve this Decree. If during such sixty (60) month period, FDA has not notified defendants in writing of any significant violations with this Decree, the Act, and all applicable regulations, FDA will grant such petition and Defendants may request that this Decree be dissolved.

Dated this 18th day of September, 2006.

IT IS SO ORDERED:

s/Richard H. Kyle
UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR Defendants

s/Garry R. Persons
GARRY R. PERSONS
in his individual capacity

s/Garry R. Persons
GARRY R. PERSONS
on behalf of
C. R. CANFIELD Co., Inc.

s/James Nelson
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