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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

September 24, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 – 37

Garry R. Parsons
President
C.R. Canfield Co., Inc.
4221 Valley View Road
Edina, Minnesota 55424

Dear Mr. Parsons:

This letter is in reference to your firm's manufacturing, marketing, and distribution of Canfield's Mini-D.S. Dressing® 20% Eugenol, USP, Canfield's D.S. Dressing® 20% Eugenol, USP, and Canfield's D.S. Syringe 20% Eugenol, USP. The dressing products consist of 20% eugenol in white petrolatum impregnated on a radiopaque gauze strip while the syringe product consists of a pre-filled syringe containing 20% eugenol in white petrolatum. All three products are intended for the treatment of dry socket syndrome and are labeled for over-the-counter (OTC) sale.

Based on the labeled indications for the treatment of dry socket syndrome, the products are drugs as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). We are not aware of any similarly formulated and labeled products ever being marketed as OTC drugs, nor are we aware of any evidence that these products as formulated and labeled are generally recognized as safe and effective for OTC use. Therefore, these products are also "new drugs" [Section 201(p) of the Act]. Under Section 505 of the Act, a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Since these products are not the subject of approved NDAs, they may not be marketed in the United States and their continued marketing violates Section 505 of the Act. The three products are also misbranded [Section 502(f)(1)] of the Act for failure to bear adequate directions for use.

Inspection of your firm's operations were conducted on October 7 and 10, 2002, and on May 24 and 26, 2004. During these inspections, information was obtained which revealed deficiencies in your firm's application of the Good Manufacturing Practices (GMPs). These GMPs are defined in Title 21, Code of

Federal Regulations, Part 211 (21 CFR 211) and may be found at our website, *www.fda.gov*. The deficiencies are as follows:

[21 CFR 211.113(b)] Failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile.

For example, there are no written procedures designed to prevent the products, labeled as sterile, from microbiological contamination.

[21 CFR 211.167(a)] Failure to have, for each batch of drug product purporting to be sterile, appropriate laboratory testing to determine conformance to such requirements.

For example, the last sterility test for any batch of drug product was conducted in 1996.

[21 CFR 211.84(a) and (d)] Failure to withhold from use each lot of components, drug product, containers, and closures until the lot has been sampled, tested, examined, and released by the quality control unit.

For example, the reliability of the Certificates of Analysis for the Eugenol component has not been determined. There was no Certificate of Analysis for the Petrolatum. Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

[21 CFR 211.165(a)] Failure to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, prior to release.

For example, finished products are never tested for identity and strength prior to release.

[21 CFR 211.166(a)] Failure to implement a testing program designed to assess the stability characteristics of drug products.

For example, there is no written testing program designed to assess the stability characteristics of drug products.

[21 CFR 211.137(a)] Failure to bear an expiration date determined by appropriate stability testing described in 21 CFR 211.166.

For example, there is a lack of data to support the firm's three year expiration date for drug products.

[21 CFR 211.22(a) and (d)] Failure to have a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products. The responsibilities and procedures applicable to the quality control unit shall be in writing and shall be followed.

For example, the [redacted] employee, [redacted], does not perform the responsibilities required by a quality control unit.

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market, and it is not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the stated violations. You should also include an explanation of each step you have taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Compliance Office Tyra S. Wisecup at the address in the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

WCB/ccl