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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751VIA FEDERAL EXPRESSWARNING LETTER

FLA-99-78

July 21, 1999

Mr. Raymond Dotolo
Chief Executive Officer
Dotolo Research Corporation
2875 MCI Drive
Pinellas Park, Florida 33782

Dear Mr. Dotolo:

We are writing to you because on February 23 & 26, 1999, FDA Investigator Michael W. Roosevelt, collected information that revealed serious regulatory problems involving colonic irrigation systems (Class II), which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The Colon Hydrotherapy Instrument model 1085 is adulterated within the meaning of 501(f)(1)(B) of the Act, in that it is a class III device under section 513(f) and does not have an approved application for premarket approval in effect pursuant to section 515(a) or an application for an investigational device exemption under section 520(g).

The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

1. Failure to maintain a complete device master record (DMR) for the colon hydrotherapy system, e.g., the DMR does not include or refer to the location of required information, such as manufacturing procedures, and the document is not signed by an

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approving official. This observation was also made during the previous inspection dated May 15, 1997. [21 CFR 820.181, FDA 483, Item #1]

2. Failure to establish, maintain and implement written procedures for: corrective and preventive action, [21 CFR 820.100]; review, control of, and disposition of non-conforming product, [21 CFR 820.90]; and change control procedures. [21 CFR 820.30(i), FDA Item #2]
3. Failure to assure that finished devices meet all specifications, e.g., your finished test procedure specifies an acceptable tolerance for the pressure gauge reading of + or - 0.01 PSI, however, two of five finished device forms reviewed (#1630 and #1634), revealed the test gauge readings differed by 0.02 PSI. These devices were also distributed without further explanation in the test record. [21 CFR 820.80(d), FDA 483, Item #3]
4. Failure to test the oxygen flowmeter either as an incoming component or as part of the finished device. No certifications are received from the supplier. [21 CFR 820.80(b) & (d), FDA 483, Item #4]
5. Failure to have written procedures for incoming component acceptance that includes a signature and date of an approving official, e.g., your procedures state that 5% of the Temperature and Pressure gauges received are to be tested and, in another area the procedure states that 100% testing is to be completed prior to installation in the colon hydrotherapy system. [21 CFR 820.40(a), FDA 483, Item #5]

The Colon Hydrotherapy Instrument model 1085 is also misbranded within the meaning of section 502(o), in that a notice or other information respecting the device was not provided to the FDA as required by section 510(k) and 21 CFR 807.81(a)(3)(ii). The device has a major modification of the intended use, i.e., colon cleansing routinely for general well being.

Until your firm receives notice from the Center for Devices and Radiological Health clearing the device for commercial distribution, the Toxygen BSC-UV colonic irrigation system with an oxygenated external water filtration system is adulterated within the meaning of section 501(f)(1)(B) of the Act, in that it is a class III device under section 513(f) and does not have an approved application for premarket approval in effect pursuant to section 515(a) or an application for an investigational device exemption under section 520(g).

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Under 21 CFR 876.5220 Colonic Irrigation systems are class II when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations; however, they are class III when the device is intended for other uses, including colon cleansing routinely for general well being.

The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

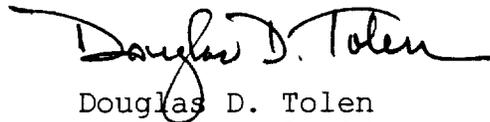
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

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Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407)475-4728.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Douglas D. Tolen
Director, Florida District