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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-04-08

October 23, 2003

Helen Wood, President
Wood Hygienic Institute, Inc.
2220 E. Irlo Bronson Highway
Kissimmee, Florida 32744

Dear Ms. Wood:

During the Food and Drug Administration's (FDA) inspection of Wood Hygienic Institute, Inc., located in Kissimmee, Florida, on June 20, 2003, we determined that your establishment manufactures and distributes colonic irrigation systems in the United States. Your colonic irrigation systems include a five gallon tank, tubing, and a rectal instrument. The systems are placed in boxes and sold to students trained at your institute. The systems are used by the students for the purpose of treating individuals for "general well-being," as well as for other claimed benefits, including relief from headaches, skin problems, chronic diarrhea, and preventing many serious diseases. These colonic irrigation systems are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act), because they are intended for use in the cure, mitigation, treatment, or prevention of disease, and they do not achieve their primary purposes through chemical action within or on the body and are not dependent upon being metabolized for the achievement of their primary intended purposes. Colonic irrigation devices are classified in Title 21, Code of Federal Regulations (CFR), Section 876.5220

The above-stated inspection revealed that your colonic irrigation systems are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices, which are set forth in the Quality System (QS) regulation, Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Your firm failed to establish and conduct quality audits to verify that your quality system is effective and in compliance with an established quality system, as required by 21 CFR 820.22 (FDA 483, Item #5).
2. Your firm failed to establish and maintain procedures addressing corrective and preventive action (CAPA), as required by 21 CFR 820.100 (FDA 483, Item #7).
3. Your firm failed to establish and maintain a design history file, as required by 21 CFR 820.30(j) (FDA 483, Item #1).
4. Your firm failed to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30 (FDA 483, Item #2).
5. Your firm failed to establish and maintain procedures to assure that all purchased product and services conform to specified requirements, as required by 21 CFR 820.50 (FDA 483, Item #3).
6. Your firm's device master record fails to include or refer to the location of quality assurance procedures and specifications, as required by 21 CFR 820.181 (FDA 483, Item #4).
7. Your firm failed to establish procedures to ensure that device history records for each batch, lot or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality System Regulation as required by 21 CFR 820.184 (FDA 483, Item #6).

Your colonic irrigation systems are also adulterated under section 501(f)(1)(A), in that they are Class III devices which are required by a regulation promulgated under section 515(b) of the Act (21 CFR 876.5520(b) to have in effect an approved premarket approval application, and for which no approval or investigational device exemption is in effect.

Your colonic irrigation systems are misbranded under section 502(o) of the Act, in that they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, were not included in a list required by section 510(j), and a notice or other information respecting them was not provided as required by section 510(k).

Your colonic irrigation systems are also misbranded within the meaning of section 502(t)(2) in that your firm failed or refused to furnish material or information required by or under section 519 respecting the device. Specifically,

your firm failed to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17, and to establish and maintain MDR event files as required by 21 CFR 803.18. Written MDR procedures include the following requirements:

- (a) Internal systems that provide for:
 - (1) Timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements;
 - (2) A standardized review process/procedure for determining when an event meets the criteria for reporting under this part; and
 - (3) Timely transmission of complete medical device reports to FDA and/or manufacturers;

- (b) Documentation and record-keeping requirements for:
 - (1) Information that was evaluated to determine if an event was reportable;
 - (2) All medical device reports and information submitted to FDA and manufacturers;
 - (3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and
 - (4) Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

The inspection revealed that your firm may use latex tubing in the manufacture of the colonic irrigation systems. Devices containing natural rubber must bear appropriate labeling as described in 21 CFR 801.437. The required statements must appear on all device labels, and other labeling, and must appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper. Failure to include required cautionary statements would misbrand the device under section 502(f)(2) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying

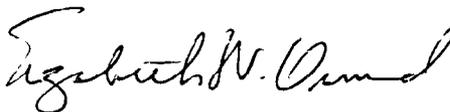
problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA.

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 award of contracts. Additionally, no premarket approval applications for Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments 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 money penalties.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. 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 completed. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely yours,


for Emma Singleton
Director, Florida District