TO:
Food and Drug Administration
Center for Devices and Radiology Health
Regulations Staff (HFZ-215)
1350 Piccard Dr.
Rockville, Maryland 20857
(original and 2 copies provided - total 3 copies)

March 15, 2001

TO:
Food and Drug Administration
Center for Devices and Radiology Health
Document mail Center (HFZ-470)
9200 Corporate Boulevard
Rockville, Maryland 20850
(original and 2 copies provided - total 3 copies)

ATTN: Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal Devices Branch
Division of Reproductive, Abdominal,
Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
FOR: Kathy Olvey

REFERENCE: Petition To Reclassify Colonic Irrigation Devices for Manufacturers Listed

Dear Sirs:

Purpose: To petition the FDA to change the classification of the colonic irrigation systems (including speculums & rectal nozzles) from Class II to Class III for the following colonic irrigation systems [actual classification should be Class I - see below] (in alphabetical order by manufacturer):

a. Clearwater Colon Hydrotherapy, Inc. - Clinical Model PPC-101 & The Traveler PPC-101)
b. Colon Therapeutics Research, Inc. - model Jimmy John III
c. Dotolo Research Corp. - The Toxygen Model BSC-UV
d. Specialty Health Products, Inc. - model Hydro San Plus
e. Tiller MIND BODY, Inc. - model LIBBE

... and no other colonic devices from other manufacturers

Background: For approximately the past 100 years there have been colonic irrigation devices in use in the US and around the world. This equipment is a simple extension of the enema and is simply a more complete and detailed enema-like procedure. Control and regulation of these devices started in 1938 with the Federal Food, Drug, and Cosmetic Act, which was modified and strengthened in 1976, then amended in 1990 and 1992.

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Although there is currently a requirement for manufacturers of colonic irrigation equipment to register with the FDA and receive a PMA prior to marketing the equipment. The reality is that there are many devices being marketed without FDA registration. In 1988, the American Colon Therapy Association (ACTA) was formed, and in 1992 the name was changed to the International Association for Colon Hydrotherapy (I-ACT). Since the inception of this organization, there has been a concerted effort and vocal advocacy for the use of FDA registered Colon Hydrotherapy equipment. I-ACT has been instrumental in establishing training standards, providing certification, and working to strengthen the professionalism of the industry around the world. In addition they provide a referral service for trained colon hydrotherapists around the world.

Approximately a year ago, I-ACT joined with the above listed manufacturers to form an alliance to ensure the highest level of safety for the public and increase the professionalism of the colon hydrotherapy industry. With this alliance in place, one of the first steps is to work with the FDA to align the classification of colonic irrigation equipment from Class II with restricted use for "colon cleansing when medically indicated, such as before radiologic or endoscopic examinations" {CFR876.5220 (b)(1)} to Class III "when the device is intended for other uses, including colon cleansing routinely for general well being." {CFR876.5220(b)(2)} You will see below that we believe the requirement to have a Class III classification for "colon cleansing for general well being" is not accurate and the classification should be a Class I classification... however, the CFR as written requires a Class III designation for "general well being". {CFR876.5220(b)(2)}

When attempting to get a reclassification from Class II to Class III, we understand that we must prove that colonic irrigation (using the FDA registered equipment listed above) is safe; and that the colonic irrigation (using the FDA registered equipment listed above) is effective in colon cleansing routinely for general well being..

Facts: Since these manufacturers listed above have been registered with the FDA, using disposable speculums/rectal nozzles, there have been over 5 million colonics administered. Additionally, in this time, there has not been one verified or validated case, or any litigation alleging injury or death as a result of the use of the colon hydrotherapy equipment from the manufacturers listed above.

Challenges: The classification for Colonic Irrigation systems from Class II (with restricted use for "colon cleansing when medically indicated, such as before radiologic or endoscopic examinations" {CFR876.5220 (b)(1)} to Class III "when the device is intended for other uses, including colon cleansing routinely for general well being." {CFR876.5220(b)(2)} appears to be inconsistent with the definitions found in CFR 860.3 "Definitions" in that Class I devices are subject to only general controls... Class II is for devices "that purport or represent to be for use in supporting or sustaining human life", while a Class III device is "life sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury." Class III equipment has "critical components" that if they fail, the death of an individual may be the result. None of the colonic irrigation equipment listed above have any "critical components". If any of those components fail, the colonic irrigation procedure simply comes to a stop without injury or harm.

We believe the CFR 876.5220 does not accurately reflect the documented safety and effectiveness of the current colonic irrigation systems, and should be rewritten to either include in the Class II classification a Colonic Irrigation device for " improving general health", or create a Class I Colonic Irrigation device for " improving general health". We believe that the current CFR 876.5220 is incorrect requiring a Class III classification of colonic devices for "colon cleansing routinely for general well being."

We understand this classification was established in November 1983 and was reported in the Federal Register Volume 48, No. 227. page 53619 (attached - Section 1). The Federal register indicates that there was only one comment received that agreed with the proposed regulation changes. It went on to state that comment described "several risks and hazards concerning the use of the colonic irrigation system." At that time, the FDA agreed with the comment. We intend to show that colonic irrigation using FDA registered equipment is absolutely safe and without any hazards as the last 18 years of use have documented with no injury or death in over 4.5 million procedures.

However, even if the FDA approves the reclassification and changes the regulation allowing a Class I classification, it is the desire of each manufacturer and the International Association for Colon Hydrotherapy that the FDA continue to monitor the colonic irrigation manufacturing facilities for Good Manufacturing Procedures to assist in ensuring the continuing high quality equipment and practices now evident in the practices of the Colonic Irrigation manufacturers listed above. We are committed to working with the FDA to ensure the highest level of safety for the public, and to ensure the largest numbers of individuals may avail themselves of this modality should they choose to do so for their own health and hygiene.

Structure of the Package:

Section 2 of this package has the Reclassification Petition as required by the FDA CFR860.123 (a) with its ten (10) parts as required.

Section 3 is comprised of five parts - a part for each manufacturer to identify the number of Speculums or Rectal Nozzles they have manufactured or sold (which is used to determine the number of colonic irrigation procedures that have been completed). Each manufacturer also provides letters supporting the use of their equipment, documenting the effectiveness and safety.

Section 4 is a copy of an article from the Townsend Letter for Doctors and Patients - August / September 2000 validating the effectiveness of colonic irrigation by medical professionals.

Section 5 has a copy of a March 25, 1997 Letter from the State of Florida Department of Business and Professional Regulation. Florida presently is the only state in the US that registers/ licenses colon hydrotherapists. After checking their records, they had "no complaints for the preceding five years involving injury or the spread of infection to a consumer following this type (sic. colon hydrotherapy) of procedure."

Section 6 is an April 22, 1997 letter from the Center for Disease Control and Prevention (CDC) wherein they state the CDC, " ... have not investigated outbreaks of infection related to colonic irrigation." Had there been any reports of infection due to colonic irrigation they would have, of course, investigated the reports.

Section 7 of this package are copies of three documents that show support for colonic irrigation for general health.

First is a copy of an article from the Nutrition & Dietary Consultant - May 1986 by Donale J. Mantell, M.D. In this article he indicates why he believes colonic irrigation is so valuable, and concludes on page 7 of the article; ".. colonhydrotherapy is the safe, gentle infusion of purified warm water into the colon under conditions that offer safety, using no chemicals or drugs. It is the natural solution to conditions which interfere with the normal function of the colon". He continues his conclusion; "Why is colon hydrotherapy a valuable treatment modality? A healthy colon is essential to a healthy body."

Second is a reprint of a 1993 published (Exp Clin Gastroenterol Vol 3, No2, 1993, pgs 108 - 113) study of colonic hydrotherapy from the Department of Physiology, University of Kuopio, Kuopio Finland; scientifically documenting the value of colon hydrotherapy. The findings of this study ; "showed colon hydrotherapy decreased the activity of several fecal enzymes releasing toxic compounds and diminished the chemical loading. It also appeared to normalize the gut function and promote softness of the stools."

Third is a reprint of a letter from Stephen L Reisman, M.D. indicating his support for colon hydrotherapy for, as he describes it "janitorial services".

Section 8 is a copy of New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff.

Section 9 of this package are copies of petitions signed by individuals from around the world identifying their desire to have colonic irrigation available to them for maintaining their health.

Discussion:
In as much as there are no predicate devices for colon irrigation equipment for use in "general well being", and since the CFR directs an automatic Class III designation {CFR876.5220(b)(2)}, we believe that our request for reclassification falls under New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff Section 207 (FDAMA); Section 513 (f) (2) of the FDCA; 21 USC 360c(f)(2). This document is intended to apply to low risk products that have been classified as Class III..." (section 8)

We believe this document is applicable because colon hydrotherapy is, by experience, a safe (low risk) procedure and by CFR is "automatically placed in Class III" for "colon cleansing for general well being" .

To validate the low risk, we asked each manufacturer to identify the numbers of Speculums / Rectal Nozzles (the part inserted into the rectum allowing water to flow into the rectum and disposed of after each client) that they had manufactured. This would indicate the approximate numbers of colon hydrotherapy sessions that have been performed since the manufacturers have been required to maintain records. The manufacturers reported that they had sold 5,135,099 Speculum/Rectal Nozzles. This does not include the colonics administered with the stainless steel speculums, the numbers of these procedures is unknown.

Knowing there have been over 5,000,000 colon hydrotherapy session provides us a baseline for discussion. Since the FDA has been registering colon hydrotherapy equipment (mid '70s), we also know that there has not been one verified or validated case, or any litigation alleging injury or death as a result of the use of the colon hydrotherapy equipment from the manufacturers listed above. The State of Florida (section 5) who monitors colon hydrotherapy sessions (since colon hydrotherapists are state registered/licensed) reports they have no reports of injury and no complaints; and, the Center for Disease Control (section 6) has no reports of infection etc. as a result of colon hydrotherapy.

We also understand that Section B of the "Request for Evaluation of Automatic Class III Designation" third paragraph provides us the opportunity to use "any available data from human experience with the device... as well as deductive reasoning as to why the FDA should classify the product into Class I or Class II."

The reasoning is as follows: Colon Hydrotherapy equipment has been registered with the FDA since about 1976 and since that time has been safe. Cleansing of the colon for "general well being" should be in the same classification as the enema kit (Class I) BUT should still have the requirement for Good Manufacturing Procedures, Record Keeping, and Complaint Files.

In the past couple of years, thousands of individuals, from around the world, have signed petitions supporting colon hydrotherapy to maintain their health. (section 9)

Another argument for a classification to Class I vice Class III is that the definition of a Class III device is one that "is life-sustaining, or for a use preventing impairment of human health, or if the device presents a potential unreasonable risk of illness of injury". Colon Hydrotherapy devices are not life sustaining and their use does not present a potential for unreasonable risk of illness or injury. Colon hydrotherapy equipment for colon cleansing routinely for general well being; therefore, should be classified in Class I.

Summary:

In as much as we believe the CFR needs modification for a Class I designation for colonic irrigation systems, we are submitting this package to have colonic irrigation equipment for the manufacturers listed above reclassified to Class III for general well being since a Class I designation is not available at this time. Should there become a Class I designation for colonic irrigation equipment then this request for reclassification should be deemed a request to reclassify colonic irrigation equipment for "general wellbeing" into Class I.

Should you have any questions please feel free to contact me at any time at 210-366-2888 or by fax at 210-366-2999.

Sincerely,

A. R. Hoenninger, III
Managing Director C3SG

atch (s):

1. Federal Register
   Volume 48, No. 227. page 53619
2. Reclassification Petition - parts 1-10
3. Manufacture Specific Breakdowns
   a. Clearwater Colon Hydrotherapy, Inc.
   b. Colon Therapeutics, Inc.
   c. Dotolo Research Corp.
   d. Specialty Health Products, Inc
   e. Tiller MIND BODY, Inc.
4. Townsend Letter Article
5. Letter from State of Florida
6. Letter from CDC
7. Three supporting documents
   1) article from the Nutrition & Dietary Consultant - May 1986
   2) reprint of a 1993 published (Exp Clin Gastroenterol Vol 3, No2, 1993, pgs 108 - 113) study of colonic hydrotherapy from the Department of Physiology, University of Kuopio, Kuopio Finland
   3) reprint of a letter from Stephen L Reisman, M.D.
8. New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff Section 207 (FDAMA)
9. Petitions with Signatures

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