DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administra
2098 Gaither Road
Rockville MD 20850

AUG 23 2005

Ms. Mary Ruth Baker
President/CEO
Clearwater Colon Hydrotherapy, Inc.
3145 S.W. 74th Terrace
Ocala, Florida 34474

Dear Ms. Baker:

This is in reply to your letter dated March 22, 2004, in which you requested responses to the following questions regarding our policy on the regulation of colonic irrigation devices and their prescription requirements. We apologize for the delay in our response. The following represents our interpretation of your question followed by our answer.

1. Are the manufacturers of all Class II colonic irrigation systems required to sell their devices to prescription holders only, or can they sell to individuals who do not hold a prescription?

Because these devices can have potentially harmful effects, according to 21 CFR 801.109, they can be sold by prescription only. In most states that is by or on the order of a physician. The only exceptions are in states which allow other types of practitioners to prescribe these devices.

2. Are the manufacturers of all Class II disposable rectal speculums required to sell their devices to prescription holders only, or can they sell to individuals who do not hold a prescription?

Because rectal speculums are also Class II devices, they can have potentially harmful effects, and according to 21 CFR 801.109, they can be sold by prescription only, that is by or on the order of a physician.

3. The disposable rectal speculum manufactured by Clearwater Colon Hydrotherapy, Inc. is a Class I device. If the speculum is intended to be used with a Class I colonic irrigation system, can the firm sell this device to an individual who does not hold a prescription? What if the speculum were intended to be used with a Class II colonic irrigation system? In this case, would Clearwater need to request a prescription from the purchasers of the speculum?

First of all, let us clarify that there are no Class I colonic irrigation devices, and there are no Class I speculums. The only Class I device in this product area is an enema kit which is exempt from premarket notification. The Clearwater device is therefore a Class II device and thus, a prescription would be required from the purchasers of such speculum.

4. Does the patient need to hold a medical or naturopathic prescription in order for a therapist/practitioner to perform a colonic irrigation procedure?

The person eligible to prescribe the use of the device is regulated by each state and may be different in each case.

5. In your letter, you stated the following: "Does the physician of the clinic be of the same state and supervise as a medical director?"

We do not have a definite answer for this question as it may depend on state law.

6. In your letter, you stated the following: "On my original 510(k) Kathy Olvey explained on the prescription statement on the Physician to be used in the blank space and nothing else? Please confirm."

According to 21 CFR 801.109, the prescription statement reads "Caution: Federal law restricts this device to sale by or on the order of a _____." The blank is to be filled in by the appropriate specialty, e.g., physician, dentist, veterinarian, etc. Ordinarily, for colonic irrigation devices, the appropriate prescribing person would be a physician; however, it may depend on state law, as described in the answer to number four (4).

7. In your letter, you stated the following: "Does the actual therapy require that the client/patient have a prescription from a physician for a (therapist) to give a colon irrigation?"

We believe this is the same question as number four (4).

8. In your letter, you stated the following: "Can a Class I device be used on the public in a commercial environment as a colonic irrigation?"

As noted in the answer to number three (3), a class I device is an enema kit. Enema kits are regulated per 21 CFR 876.5210, and are intended to promote evacuation of the contents of the lower colon, only.

9. In general, does a patient need to hold a prescription in order to purchase a Class I device?

As previously mentioned, there are no Class I colonic irrigation devices only Class I enema kits, which do not require a prescription.

10. In general, does a patient need to hold a prescription in order to purchase a Class I disposable rectal speculum?

If the disposable rectal speculum is intended to be used with an enema kit, a prescription is not needed since enemas are not prescription devices. Any speculum used with a colonic irrigation device is a Class II device and thus, a prescription would be required from the purchasers of such speculum.

11. What are the regulatory requirements needed to be fulfilled by the manufacturers of colonic irrigation systems and disposable rectal speculums?

These devices are regulated under 21 CFR 876.5220 either as Class II devices requiring a premarket notification (510(k)) or as Class III devices requiring a premarket approval application (PMA). Per 21 CFR 876.5220(b), if the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations, then it would be considered a Class II colonic irrigation device. However, if the device is intended for other uses, including colon cleansing routinely for general well being, then it would be considered a Class III colonic irrigation device. Therefore, depending on the indication for use, the manufacturers of these devices must meet the requirements for submission of either a 510(k) or PMA. The kind of information manufacturers need to submit in order to obtain this approval or clearance is available through the Internet at www.fda.gov/cdrh/devadvice/3122.html.

Additionally, manufacturers of medical devices (subject to premarket review or notification) are required to follow the current good manufacturing practices set forth in the Quality System regulation (21 CFR Part 820). They are also required to follow the medical device reporting requirements set forth in the Medical Device Reporting regulation (21 CFR Part 803).

Furthermore, if you wish to obtain additional information about all of the Food & Drug Administration's (FDA) requirements for manufacturers of medical devices you may contact our Division of Small Manufacturers, International, and Consumer Assistance at (800) 638-2041 or visit the above mentioned Internet website.

12. What are the penalties for not complying with the FDA's regulatory requirements?

Some of the regulatory actions initiated by FDA include but are not limited to warning letters, seizures, injunctions, and/or civil money penalties.

13. What are the requirements needed to be fulfilled by colonic irrigation practitioners?

In most states, colonic irrigation devices (including the speculums used with these devices) can only be sold by or on the order of a physician.

14. In your letter, you stated the following, "Can a manufacturer have one physician write a prescription for all the equipment and speculums to there clients in different states? (1) If they can, would the client still need to have a prescription for therapy also?"

    Unfortunately, we do not have an answer for this question. We believe that it is dependent on the state and each case may be different.

We hope we have answered most of your questions. If you have any more specific questions about how FDA's requirements affect colonic irrigation devices or concerning the contents of this letter, please do not hesitate to contact me at the letterhead address or at (240) 276-0115.

Sincerely yours,

Paul F. Tilton
Chief
OB/GYN, Gastroenterology, and
Urology Devices Branch
Division of Enforcement A
Office of Compliance
Center for Devices and Radiological
Health