



4/30/97  
EJL

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

June 20, 1997

Ref: 97-DAL-WL-27

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

Mr. Rocky Bruno, Owner  
Colon Hygiene Services  
1910 Justin Lane  
Austin, Texas 78757-2411

Dear Mr. Bruno:

During an April 28, 1997, inspection of your Austin, Texas facility, a Texas Department of Health investigator, under contract to the Food and Drug Administration, determined that you manufacture and use a colonic irrigation system. Colonic irrigation systems are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Title 21 of the Code of Federal Regulations (21 CFR), Part 876.5220 classifies colonic irrigation systems as Class III devices, which may not be commercially distributed without an approved application for premarket approval (PMA), if the device is marketed for any indication other than medically indicated colon cleansing (e.g., prior to a radiological or endoscopic examination). Marketing colonic irrigation systems for routine colon cleansing to promote the general well being of a patient requires an approved PMA, while marketing a colonic irrigation system for medically indicated colon cleansing requires the submission of a Section 510(k) notification as prescribed in the Premarket Notification Procedures regulations described in 21 CFR Part 807, Subpart E.

Your colonic irrigation device 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 it does not have an approved application for premarket approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption under Section 520(g).

Page - 2 Mr. Rocky Bruno, Owner  
June 20, 1997

Colon Hygiene Services

Additionally, your device is misbranded within the meaning of Section 502(o), in that it was manufactured in an establishment not duly registered under Section 510, it was not included in a list required by Section 510(j), and a notice or other information respecting the device was not provided to the FDA as required by Section 510(k). The forms and instructions to register your facility and list your device are enclosed with this letter. Section 510(k) and PMA submission guidance documents may be obtained from our Small Business Assistance Program at the following address: FDA Southwest Regional Office, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982, (214) 655-8100.

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. 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. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA 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 the receipt of this letter, of the specific steps you have taken to correct these violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the correction will be completed.

Your response to this letter should be addressed to James Austin Templer, Compliance Officer, at the above letterhead address.

Sincerely yours,



Joseph R. Baca  
District Director

Enclosures