



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1163B

FEB 5 1997

Food and Drug Administration
Rockville MD 20857

Warning Letter

Mr. Augustine Lien
Vice President, Operations
Gynecare, Inc.
235 Constitution Drive
Menlo Park, California 94025

Dear Mr. Lien:

The U.S. Food and Drug Administration (FDA) has reviewed Gynecare, Inc.'s promotional materials regarding the Uterine Balloon Therapy™ system. This product is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). This device is part of an investigational clinical trial and does not yet have approved marketing clearance.

The Uterine Balloon Therapy system is being promoted on Gynecare Inc.'s Internet home page @<http://www.gynecare.com>. These promotions represent the product as safe and effective for the treatment of menorrhagia, i.e., excessive menstrual bleeding. The promotional materials, copies of which are enclosed, include press releases and information distributed via the Internet. Some of the claims made about the unapproved device include, but are not limited to, the following:

- o In your home page section entitled "About Gynecare," you state that "Uterine Balloon Therapy offers patients significant medical, cost and lifestyle advantages over current treatments, including the risks and costs of hysterectomies" and that "more than 300 patients have been treated without any major complications, and as of June 1996, clinicians reported a 90+% success in 195 patients who have had at least six months follow-up."
- o Your September 26, 1996, press release entitled, "Promising New Findings in Studies of Office-Based Alternatives to Hysterectomy," states that "these studies validate the use of innovative office-based procedures as viable, cost-effective alternatives to hysterectomy and other traditional surgical techniques for the treatment of uterine disorders." The press release also states that two studies "demonstrate that the system appears to be a safe and effective treatment for women with excessive uterine bleeding" and "87% success rate in treating more 100 patients with excessive bleeding *** all were well-tolerated and no complications were reported."
- o Your January 23, 1996, press release entitled, "Gynecare Begins U.S. Clinical Trials of Non-Surgical Alternative to

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Hysterectomy," states, "The Uterine Balloon Therapy system is a new therapy which allows women who suffer from menorrhagia to lead a normal life. Our international (clinical investigators have reported that this device *** has a 95% success rate." The article concludes by identifying a contact for further information.

These above-referenced materials establish that your firm is promoting the Uterine Balloon Therapy system for the treatment of menorrhagia despite the fact that the product has not received marketing clearance. Such promotion renders your Uterine Balloon Therapy system adulterated within section 501(i) of the Federal Food, Drug, and Cosmetic Act. Furthermore, Title 21 of the Code of Federal Regulations (21 CFR), section 812.7, prohibits the promotion and commercialization of an investigational device.

A sponsor or investigator, or any person acting for or on their behalf, is prohibited from promoting or test marketing an investigational device until after the FDA has approved the device for commercial distribution. Furthermore, no claims can be made, either explicitly or implicitly, that the device is either safe or effective for the purposes for which it is being investigated or that the device is in any way superior to, or more cost-effective than any other device. Press releases and Internet Web sites may not be used as promotional tools or as an attempt to commercialize a product prior to approval or clearance.

Advertising for recruitment into an investigational device study should not use terms such as "new treatment," "new medication," or "new therapy" without explaining that the test article is investigational. Phrases such as "The Uterine Balloon Therapy system is a new therapy which allows women who suffer from menorrhagia to lead a normal life" and "our international clinical investigators have reported that this device *** has a 95% success rate" as seen in the January 23, 1996, press release, implies that all study subjects will be receiving newly marketed products of proven worth.

Although the FDA does encourage the full exchange of scientific information concerning investigational devices, including the dissemination of scientific findings through scientific/medical publications or conferences, safety and efficacy conclusions and statements of a promotional nature are inappropriate.

This letter is not intended to be an all-inclusive list of deficiencies associated with the promotion of the Uterine Balloon Therapy system. It is your responsibility to ensure that materials distributed within the United States are in conformance with each requirement of the Act and other applicable Federal regulations.

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Within fifteen (15) working days of receipt of this letter, please notify this office, in writing, of the specific actions you plan to take to correct the cited violations. You should include all steps being taken to address violative information currently in the marketplace and actions to prevent similar violations in the future.

Your response should be directed to the U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I, 2098 Gaither Road, Rockville, Maryland 20850, Attention: Kevin M. Hopson. A copy of this letter has been sent to the U.S. Food and Drug Administration's San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502. We request that a copy of your response also be sent to that office.

Please direct all questions concerning this matter to Mr. Hopson at (301) 594-4720, ext. 128.

Sincerely yours,



for Lillian J. Gill
Director
Office of Compliance
Center for Devices
and Radiological Health

Enclosures