



MAR - 6 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850WARNING LETTERVIA FEDERAL EXPRESS

• Charles Laverty
Chief Executive Officer
Imagyn Medical, Inc.
5 Civic Plaza Suite 100
Newport Beach, California 92660

Dear Mr. Laverty:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed Imagyn Medical, Inc.'s (Imagyn's) Internet website and has determined that the materials on that website have misbranded and adulterated the company's Ovation™ Falloposcopy System (Ovation system). The Ovation system is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The Ovation system was granted marketing clearance pursuant to the agency's clearance of Imagyn's 510(k) premarket notification submission. The clearance letter from FDA advised you that the substantial equivalence determination was "only for a *diagnostic* indication, namely for the secondary workup of proximal tubal occlusion." (Emphases in original.)

The indications for use in your 510(k) are as follows: "The Imagyn Falloposcopy System is indicated for use as a secondary diagnostic tool for the further evaluation of women previously diagnosed with proximal tubal occlusion by hysterosalpingography or selective salpingography." A statement follows: "As stated above, the current indication for use of this product in the United States is for diagnostic, not therapeutic purposes. . ."

In addition, the cleared labeling includes, among others, the following statements:

"This device is only designed to access the proximal portion of the fallopian tube, i.e., the first 2-3 cm. It should only be advanced as far as necessary to achieve a meaningful study. Recognizing that possible adverse effects of more distal advancement, particularly upon normal tubes, have not yet been determined."

"This device is not intended for tubal recanalization, and there is no data available, in particular pregnancy data, showing clinical benefit for this use."

As of today, the section entitled, "Clinicians" on Imagyn's website at <http://www.imagyn.com/products.htm>, includes a statement by the company that, "The

Ovation falloposcopy and tubal recanalization systems enable the physician to access, navigate and view the entire length of the Fallopian tube. The falloposcopy system permits viewing and accurate evaluation of the patency and overall health of the interior of the Fallopian tube. . . . The tubal recanalization system has been shown in clinical trials in Japan to unblock occluded fallopian tubes.”

This language has changed the intended use of your device because, as described above, the labeling clearly states that the device is cleared for use only in the first 2-3 cm. of the tube and not for viewing the entire tube. The labeling also explicitly states that the device is not cleared for tubal recanalization. CDRH's Office of Device Evaluation has informed us that your company was advised that the therapeutic claim of recanalization for your device would require approval pursued through the premarket approval application process and not through the 510(k) premarket notification process.

A company press release, dated February 3, 1997 and announcing your product's marketing clearance, remains on the part of your website entitled, "Investors." That press release makes implied claims that have misbranded and adulterated the product. The press release presents a brief description of hysterosalpingography (HSG) and presents a picture of it as a painful and frequently inaccurate procedure. It also describes chromopertubations, often performed as a followup to HSG. The next paragraph in your press releases states, "Falloscopy, unlike HSG and chromopertubation, enables the physician to directly visualize the interior of the fallopian tube. As a result the physician can further evaluate tubal health and make more informed recommendations on the most appropriate course of therapy. . . ."

This paragraph presents falloposcopy as a substitute for HSG and chromopertubation, rather than as a followup to one of those procedures. This changes the intended use of the product because the cleared intended use states, as described above, "The Imagyn Falloposcopy System is indicated for use as a secondary diagnostic tool for the further evaluation of women previously diagnosed with proximal tubal occlusion by hysterosalpingography or selected salpingography." (Emphasis added.)

The press release also does not include an explicit definition of the limitations included in the use of the device in the proximal fallopian tube, i.e., that it is cleared for use in only the first 2-3 cm. of the fallopian tube.

The press release and other website materials have misbranded and adulterated your company's device within the meanings of section 502(o) and 501(f)(1)(B), respectively, of the Act. FDA's regulations at 21 CFR 801.4 provide that the "intended use" of a product refers to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. The objective intent may be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

FDA's regulations at 21 CFR 807.81(a)(3)(ii) provide that a major change or modification in the intended use of a device currently in commercial distribution requires premarket notification. The device is misbranded because a notice or other information respecting the device was not provided to FDA as required by section 510(k) of the Act. It is adulterated because the device is a class III device under section 513(f) of the Act and does not have an approved application for premarket approval in effect pursuant to section 515(a) of the Act or an approved application for an investigational device exemption under section 520(g) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may also be reflected in other promotional and advertising materials used by your firm. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

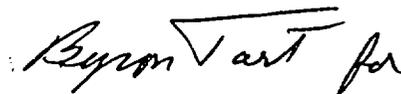
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should also include steps being taken to address any misleading information currently in the marketplace and to prevent similar violations in the future. 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.

Your response should be sent to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the Director, Los Angeles District Office (HFR-PA240), Food and Drug Administration, 19900 Macarthur Blvd., Suite 300, Irvine, California 92612-2445.

Sincerely yours,



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