



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FACSIMILE
VIA FEDERAL EXPRESS

APR 28 1999

Mr. Bob Coradini
President and Chief Executive Officer
Cordis Corporation
40 Technology Drive
Warren, New Jersey 07059

Dear Mr. Coradini:

The Promotion and Advertising Policy Staff of the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) has reviewed an advertisement placed for Cordis' S.M.A.R.T. stent. The stent is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act. The advertisement has misbranded and adulterated the device, as described below, within the meaning of several sections of the Act.

FDA cleared the stent on December 18, 1998, following its review of the company's premarket notification submission, k980823. The clearance letter advised Cordis Corporation that the device had been cleared for marketing and it imposed several limitations and requirements on the labeling and marketing of the stent. The stent was cleared for use with the following indication: "The Cordis Nitinol Stent and Delivery System is intended for palliation of malignant neoplasms in the biliary tree."

The clearance letter advised you that CDRH's Office of Device Evaluation (ODE) had determined that there was a reasonable likelihood that this device would be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with section 513(i)(1)(E) of the Act, ODE directed the company to include the following limitation in the Warnings section of the stent labeling.

"The safety and effectiveness of this device for use in the vascular system have not been established."

Furthermore, the letter instructed you, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

These statements made you aware of how important it is to make it explicit to your audience that the device has a narrow cleared indication and that the safety and effectiveness of the device for use in the vascular system have not been established.

An ad that appears in the February, 1999 issue of Endovascular Surgery, called also on its cover "an Interdisciplinary Journal for Vascular Specialists," advertises Cordis' S.M.A.R.T. stent and refers to it as being from Cordis Endovascular. The ad makes an implied claim for vascular use for the stent because it appears in a journal intended for vascular specialists.

The agency's regulations at 21 CFR 801.4 provide that "intended use" 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. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

The device is, therefore, misbranded and adulterated. It is misbranded within the meaning of section 502(o) because the company did not submit to FDA a notice or other information respecting the device as required by section 510(k) of the Act. It is adulterated within the meaning of section 501(f)(1)(B) of the Act because it is a class III device for which there is not in effect an approved premarket approval application, as required by section 515 of the Act.

9 - line paragraph redacted

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.

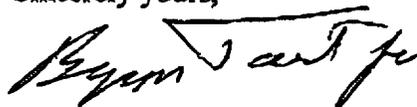
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in FDA's initiating regulatory action without further notice. Such actions include, but are not limited to, seizure, injunction and/or civil money penalties.

Please notify this office in writing, within 15 working days of receiving 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 New Jersey District Office. Please send a copy of your response to the Director, New Jersey District Office, (HFR-MA340), Waterview Corporate Center, 10 Waterview Boulevard, 3rd floor, Parsippany, New Jersey 07054.

Sincerely yours,



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