



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 31 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Norm Cooper
President
Garaventa (Canada) Ltd.
P.O. Box 1769
Blaine, Washington 98231-1769

Dear Mr. Cooper:

This letter is a follow-up to telephone conversations and one letter, dating back to October 1997, between you and Mr. William F. Defibaugh of my staff.

During the October 1997, telephone conversations, you stated that your firm manufactures the GSL-1, GSL-2, GSL-3 Stair-Lifts, which your firm distributed to various dealers in the United States. Two examples of these dealers that you provided to Mr. Defibaugh during the February 18, 1998, telephone conversation are [REDACTED]

In addition, you stated that your firm also distributes to these various dealers, the following three products which your firm imports from a [REDACTED] firm: Stair-Trac, Stair-Porter, and Evacu-Trac. You stated that your firm is the exclusive dealer in the United States for the referenced [REDACTED] products. On March 6, 1998, Ms. Pat Forsyth of your firm informed Mr. Defibaugh that the [REDACTED] firm is [REDACTED].

Your October 22, 1997, letter provided promotional brochures for all of the above-named products. Additional information you provided during the October 1997 telephone conversations revealed a serious regulatory problem involving all of these products.

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Page 2 - Mr. Norm Cooper
Garaventa (Canada) Ltd.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), all of the above-named products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance by way of a Premarket Notification Submission (510(k)) for their products from the Food and Drug Administration (FDA) before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that your firm obtained marketing clearance before it began offering any of the above-named products. You confirmed this during the October 1997 and February 14, 1998, telephone conversations. The kind of information that your firm needs to submit in order to obtain this clearance was provided to you by our Division of Small Manufacturers Assistance, to whom Mr. Defibaugh referred you during the October 1997 telephone conversations. The FDA will evaluate this information and decide whether these products may be legally marketed.

Because your firm does not have marketing clearance from FDA, marketing these products is a violation of the law. In legal terms, the products are adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. The products are adulterated under the Act because your firm did not obtain premarket approval based on information developed by your firm that shows that your devices are safe and effective. Your products are misbranded under the Act because your firm did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

The above-named products are also misbranded and in violation of the law under Section 502(o) of the Act because they are being distributed by dealers in the United States (initial distributors) who are not duly registered under Section 510 of the Act, and because the devices are not included in a

Page 3 - Mr. Norm Cooper
Garaventa (Canada) Ltd.

list required by Section 510(j) of the Act. The referenced listing requirement is the responsibility of the manufacturers (Garaventa Ltd. and [REDACTED]). The above is based on a review of our records, your confirmation during the October 1997 telephone conversations that your firm has not listed the products it manufactures, and recent telephone conversations between Mr. Defibaugh and representatives of the two referenced dealers. Information concerning these requirements was also provided to you by our Division of Small Manufacturers Assistance.

Mr. Defibaugh explained all of the above requirements to you during the October 1997 telephone conversations. At that time, you stated that your firm would come into full compliance with these requirements. During the recent February 18, 1998, telephone conversation, however, you stated that your firm had not yet complied with any of these requirements because [REDACTED]

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include detaining the above-named devices without physical examination upon their entry into the United States (U.S.), pending correction of the violations. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

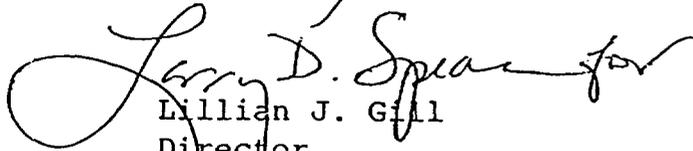
It is necessary for you to take action on these matters now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Mr. William F. Defibaugh, Compliance Officer, Orthopedic, Physical Medicine, and Anesthesiology Devices Branch, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Md 20850.

Page 4 - Mr. Norm Cooper
Garaventa (Canada) Ltd.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance, registration, and listing for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at <http://www.fda.gov/cdrh/>

If you have more specific questions about how FDA marketing requirements affect your particular devices, or about the content of this letter, please feel free to contact Mr. Defibaugh at (301) 594-4660, ext. #121.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill". The signature is written in dark ink and is positioned above the typed name and title.

Lillian J. Gill
Director

Office of Compliance
Center for Devices and
Radiological Health