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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, Maryland 20850

July 12, 2002

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Gregory R. Angle, Senior Vice President/CEO
Corondelet St. Mary's Hospital
1601 W. St. Mary's Road
Tucson, Arizona 85745

Dear Mr. Angle:

An inspection of your establishment in Tucson, Arizona, conducted February 26-28, by the U.S. Food and Drug Administration (FDA) Investigator Paul R. Whitby, included coverage for reprocessing of respiratory therapy medical devices. The inspection included a collection of information related to reprocessing of single-use devices (SUDs) such as the Airlife Dual Spray MiniSpacer Metered Dose Inhaler Dispenser with 22 mm O.D. x 22 mm I.D. Connectors and the Airlife One-Way Valve.

These products are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). Under this United States Federal law, these 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 for their products from 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. Your establishment qualifies as a manufacturer in that SUDs were being reprocessed in your facility at the time of inspection.

Our records do not show that you obtained marketing clearance before you began reprocessing these SUDs. The kind of information you need to submit in order to obtain this clearance can be found at FDA's web site at: <http://www.fda.gov/cdrh/devadvice/3122.html>. Once submitted, the FDA will evaluate this information and decide whether your product may be commercially distributed.

Because you do not have marketing clearance from FDA, the reprocessing of these SUDs is in 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. They are adulterated under Section 501(f)(1)(B) because your firm did not obtain premarket approval based on information developed by you that shows your devices are safe and effective. They are misbranded under Section 502(o) because your manufacturing establishment is not registered under Section 510, the devices were not included in a list required by Section 510(j), and a notice or other information regarding the devices was not provided to the FDA as required by Section 510(k).

You should take prompt action to correct these violations at your facility. Failure to achieve prompt corrective action may result in regulatory action without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further processing of these products, or assessing civil money penalties.

It is necessary for you to take action on this matter now. We acknowledge receipt of your March 4, 2002, response in which you stated that Corondelet St. Mary's Hospital ceased reprocessing of these medical devices and will no longer reprocess single-use devices. If this is still correct, please confirm this to us in writing within fifteen (15) days of your receipt of this letter.

This inspection found numerous objectionable conditions at your facility, as cited on the Form FDA-483. We would like to advise you that if you plan to reprocess single-use devices after August 14, 2002, Corondelet St. Mary's Hospital will be responsible for ensuring that the devices comply with all applicable requirements for manufacturing medical devices, as found in Title 21 Code of Federal Regulations, Part 820. Your facility will also be responsible for all applicable requirements for labeling the medical devices appropriately, as found in Title 21 Code of Federal Regulations, Part 801, and reporting adverse events as a manufacturer, as found in Title 21 Code of Federal Regulations, Part 803.

We would also like to advise you that the Cidex 2% glutaraldehyde solution used for reprocessing the Ventolin Actuators was not used according to the manufacturer's, Olympic Medical, instructions and, consequently, may not achieve an acceptable level of disinfection. Specifically, Cidex was cleared by FDA as a high-level disinfectant when used for 45 minutes at 25° C, while your facility policy states use for 20 minutes. The Ventolin Actuators reprocessed at your facility are products regulated by the Center for Drug Evaluation and Research and are subject to their regulations.

Your response should be directed to my attention at the above address. If you have further questions, you may contact Brenda Hayden by telephone at (301) 594-4659, Ext. 150.

Sincerely yours,



for

Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health