Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Volara System

ISSUE: Baxter International Inc. issued an Urgent Medical Device Correction for the Volara System (home care) to reinforce important safety information regarding a possible risk of decrease in oxygen levels (oxygen desaturation) or injury that may result in lung tissue damage due to over-expansion (barotrauma) in the home care environment. These potential events may occur while using the Volara device in line with a ventilator with the required Volara ventilator adaptor or Volara patient circuit kit oscillation and lung expansion (OLE) therapy.

Baxter received one report of a patient experiencing oxygen desaturation while using the Volara device in line with a ventilator in a home care environment.

For more information about this alert, click on the red button **"Read Alert"** below.

BACKGROUND: This urgent medical device correction applies to the Volara System with in-line ventilator adaptor the Volara Patient Circuit Kit.

RECOMMENDATIONS:

- Current patients should continue to use their **Volara** therapy as prescribed by their physician.
- Caregivers and/or patients should monitor for signs of respiratory distress (increased breathing rate, wheezing, bluish color around the mouth, inside the lips or in the fingernails, changes in alertness or drop in oxygen level) during **Volara** therapy when used in line with a ventilator.

If patients do not see improvement after stopping the Volara therapy, they should seek medical attention.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.

Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.