

URGENT: COMPOUNDING PRESCRIPTIONS RECALL
May 25, 2012

Dear Dr., Sir or Madam:

This is to inform you of a product recall involving:

All Sterile Human and Veterinary Compounded Prescriptions Distributed by Franck's Pharmacy from:

November 21, 2011 to May 21, 2012.

This recall is being initiated after the U.S. Food and Drug Administration ("FDA") notified us that environmental sampling of our clean room revealed the presence of microorganisms and fungal growth. In light of the FDA's findings and the resulting possible risk of infection, we have decided that it is imperative that we recall all human and veterinary sterile preparations that have left our control. Accordingly, we are extending the recall to all sterile preparations we have provided to you since November 21, 2011.

If any of these sterile preparations remains under your control, it is essential that you do not use them and that employing appropriate practices, you destroy all such sterile preparations and all remaining portions of such sterile preparations.

This recall should be carried out to the User/Physician level. Your assistance is appreciated and necessary to prevent patient illness. Physicians should be advised to review and evaluate their patient records to determine if any adverse events may have resulted from use of the recalled products. Please report any adverse events to Franck's Compounding Pharmacy and FDA's MedWatch program.

FDA will expect us to be able to account for all of the sterile preparations subject to this recall. As a result, it is critically important that you read, complete, and return the enclosed response form as soon as possible.

We will update you with any relevant details as they become available to us. If you have any questions please call us at 352-690-6773, Monday through Friday from 9AM to 5 PM, EST.

This recall is being made with the knowledge of the Food and Drug Administration.

Paul Franck
President and CEO