DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

June 7, 2004

FACSIMILE AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David L. Sparks, R.Ph., President/CEO
Professional Compounding Centers of America
9901 South Wilcrest Drive
Houston, TX 77099

Dear Mr. Sparks:

This letter supplements our January 9, 2004, letter to your firm. We are in receipt of your February 5, 2004, response to that letter.

In your February 5th letter, you state that "[d]epriving patients of access to medication containing domperidone when prescribed by their physician would not be in their best interests...." and "[w]e believe that at least for domperidone, which is a well-established drug that provides a critical alternative for patients who could not otherwise obtain relief, it is appropriate for pharmacists to continue to compound that drug, and for PCCA to supply it to them." We disagree with these conclusions, for reasons including possible health risks related to the use of domperidone.

Health Risks Associated with Domperidone

FDA is concerned with the public health risks associated with the compounding of domperidone. There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest and sudden death in patients receiving an intravenous form of domperidone that has been withdrawn from marketing in several countries. Among other uses, FDA has become aware of the use of domperidone by lactating women to increase breast milk production because of its effect on prolactin levels. While domperidone is approved in several other countries for the treatment of gastric stasis and gastroparesis, domperidone is not approved in any country for enhancing breast milk production in lactating women. In several countries where the oral form of domperidone continues to be marketed, labels for the product note that domperidone is excreted in the breast milk of lactating women and recommend that women taking domperidone avoid breast-feeding. Because of this, FDA recommends that breast-feeding women not use domperidone to increase milk production.

New Drug and Misbranding Violations

The domperidone that you repack and distribute violates section 502(f)(1) of the Act because its labeling does not contain adequate directions for use and it is not otherwise exempt from this requirement under the Act. We have reviewed your arguments supporting the distribution of bulk domperidone for use in pharmacy compounding and we are unpersuaded. The current use of domperidone in the United States and elsewhere is beside the point. The fact remains that domperidone is not an active

ingredient contained in any FDA-approved drug product. As we have stated before, FDA's enforcement discretion does not extend to the use of active ingredients that are not part of an approved product. Thus, FDA does not sanction domperidone's use in pharmacy compounding and will not exercise its enforcement discretion with regard to violations caused by compounded products containing domperidone. We also will not exercise our enforcement discretion with regard to violations caused by the bulk drug substance.

Please notify this office in writing within 15 working days of receipt of this letter of the steps that you will take to correct your firm's violations, including an explanation of the steps taken to prevent their recurrence. You should address your reply to the U.S. Food and Drug Administration, Attention: Jim Lahar, Compliance Officer, at the above address.

Sincerely,

Michael A. Chappell
Director, Dallas District

MAC: JRL