DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

June 7, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stephen R. Caudle, Owner
Line Avenue Pharmacy
1822 Line Avenue
Shreveport, Louisiana 71101

Dear Mr. Caudle:

On October 9-24, 2003, an investigator from the U.S. Food and Drug Administration (FDA) inspected your firm, located at 1822 Line Avenue, Shreveport, Louisiana. This inspection revealed that your firm compounds human prescription drugs in various dosage forms and strengths.

As you may be aware, Section 127 of the FDA Modernization Act of 1997 amended the Federal Food, Drug, and Cosmetic Act (the Act) by adding Section 503A, which specified certain conditions under which compounded human drugs could be exempt from particular requirements of the Act. In April 2002, however, the United States Supreme Court struck down the commercial speech restrictions in Section 503A of the Act as unconstitutional. Accordingly, all of Section 503A is now invalid.

As a result, the agency now utilizes its longstanding policy of exercising its enforcement discretion regarding certain types of pharmacy compounding. This policy is articulated in Compliance Policy Guide (CPG), Section 460.200, issued on June 7, 2002. The CPG contains factors that the agency considers in deciding whether to exercise its enforcement discretion. One factor is whether a firm is compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application, as required by 21 U.S.C. § 355(i) and 21 CFR 312.

The factors listed in the CPG are not intended to be exhaustive, and other factors may also be appropriate for consideration, including factors that indicate that a compounded product may have a potential adverse affect on the public health.

The inspection revealed that your firm may be compounding and distributing products containing domperidone.

The agency 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arrhythmias, cardiac arrest and sudden death in patients receiving an intravenous form of domperidone that has been withdrawn from marketing in several countries.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 breastfeeding women not use domperidone to increase milk production.

Domperidone is not an active ingredient contained in any FDA-approved drug product. FDA does not sanction its use in pharmacy compounding and will not exercise its enforcement discretion for compounded products containing domperidone.

We also note that your firm may be compounding drug products containing dimethyl sulfone. This also is not an active ingredient contained in any FDA-approved drug product, and FDA will not sanction its use in pharmacy compounding and will not exercise its enforcement discretion for compounded products containing dimethyl sulfone.

Compounded products containing domperidone or dimethyl sulfone are drugs within the meaning of Section 201(g) of the Act. As they are not generally recognized by qualified experts as safe and effective for their labeled uses, they are new drugs, as defined by Section 201(p) of the Act. In addition, no approved application pursuant to Section 505 of the Act is effective with respect to these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates Section 505(a) of the Act. These products are also misbranded under Section 502(f)(1) of the Act because they do not bear adequate directions for use and are not exempt from this requirement under 21 CFR 201.115.

If you are compounding the above referenced drug products, we ask that you direct your attention to this matter. It is your responsibility to make sure you are complying with the law.

Please let us know the status of your firm's compounding of the above referenced products and any corrective action you intend to take. Your response, or any questions you may have, should be directed to: Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, New Orleans District Office, Compliance Branch, HFR-SE440, 6600 Plaza Drive, Suite 400, New Orleans, LA 70127.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District