DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-34

June 7, 2004

James Peter Sumerville, President
Axium Healthcare Pharmacy
285 W. Central Parkway #1720
Altamonte Springs, FL 32714

Dear Mr. Sumerville:

On February 10-12, 2004, FDA Investigator Brunilda Torres and two individuals from the Florida State Bureau of Pharmacy Services and the Florida State Investigative Services inspected your firm. This inspection revealed that your firm compounds human prescription drugs in various strengths, including domperidone and ribavirin capsules.

As you may be aware, Section 127 of the FDA Modernization Act of 1997 amended 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 to exercise 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 Part 312. Another factor is whether a firm is compounding a copy, or essentially a copy, of a commercially available FDA-approved drug product.

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.

Health Risks Associated with Domperidone

The inspection revealed that your firm prepares and distributes 10mg and 20mg domperidone capsules for human use.

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.

New Drug and Misbranding Violations

All products compounded by your firm containing domperidone and ribavirin 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 use, the products are new drugs, as defined by section 201(p) of the Act. No approved application pursuant to section 505 of the Act is effective with respect to these products. Accordingly, introduction or delivery for introduction into interstate commerce of these products 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 they are not exempt from this requirement under 21 CFR § 201.115.

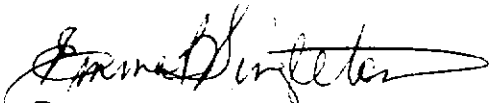
Domperidone is not an active ingredient contained in any FDA-approved drug product. FDA does not sanction its use in pharmacy compounding and will not exercise its enforcement discretion for compounded products containing domperidone.

FDA also does not condone your firm's compounding of ribavirin 400 mg and 600 mg capsules. Ribavirin is commercially available as FDA-approved 200 mg tablets and capsules. A 400 mg or 600 mg compounded capsule is essentially a copy of a commercially available product because the patient could simply take two or three commercially available 200 mg tablets or capsules, instead of the compounded product.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all drug products compounded and processed by any of your pharmacy locations comply with federal laws and regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in additional regulatory action without further notice. These actions include, but are not limited to, seizure of your products or injunction. Federal agencies are routinely advised of warning letters issued so that they may take this information into account when considering the award of government contracts.

Please notify this office within 15 working days of receipt of this letter of the specific steps that you have taken to correct these violations, including the steps taken to prevent the recurrence of the violations. You should address your reply to this letter to the U. S. Food and Drug Administration, Attention: Martin E. Katz, Compliance Officer, at the above address.

Sincerely,



Emma R. Singleton
Director, Florida District