HFD-310 R/F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

JUL 11 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Tom Wilson, Owner
Cape Drugs
1384 Cape St. Claire Road,
Annapolis, MD 21401

Dear Mr. Wilson,

On February 25, 2005, you advised a Special Agent with FDA's Office of Criminal Investigations that you have compounded drugs containing domperidone and that it is your view that it is legal to do so.

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, section 460.200 ("the CPG"), 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.

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

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arrhythmias, cardiac arrest and sudden death in patients receiving an intravenous form of domperidone that has been withdrawn from marketing in several countries.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.

All products compounded by your firm containing domperidone are drugs within the meaning of section 201(g) of the Act [21 U.S.C. § 321(g)]. As they are not generally recognized by qualified experts as safe and effective for their labeled uses, the products are new drugs, as defined by section 201(p) [21 U.S.C. § 321(p)] of the Act. No approved application pursuant to section 505 of the Act [21 U.S.C. § 355] is effective with respect to these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates section 505(a) of the Act [21 U.S.C. § 355(a)].

These products are also misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] in that their labeling fails to bear adequate directions for their use. Further, these products are not exempt from this requirement under 21 CFR § 201.115, because they are new drugs within the meaning of section 201(p) of the Act [21 U.S.C. § 321(p)] and they lack approved applications filed pursuant to section 505 of the Act [21 U.S.C. § 355].

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. You should take prompt action to correct these deviations. Failure to do so may result in additional regulatory action without further notice, including, seizure of your products or injunction. Federal agencies are routinely advised of the issuance of warning letters so that they may take this information into account when considering the award of government contracts.

Please notify this office in writing within 15 working days of receipt of this letter, of the steps that you will take to correct the noted violations, and to prevent their recurrence.

You should address your reply to this letter to the U.S. Food and Drug Administration, Mark Askine, 11919 Rockville Pike, HFD-317, Rockville, MD 20852. Please also provide a copy of your response to Steven Barber, Compliance Officer, FDA, Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215.

Sincerely,

Steven D. Silverman
Director
Division of New Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research