



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Public Health Service
Food and Drug Administration
Central Region

Telephone (973) 526-6005

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

TRANSMITTED VIA FACSIMILE

June 7, 2004

Mr. Paul Burg, President
Spectrum Chemicals & Laboratory Products
1422 South Pedro Street
Gardena, CA 90248-9985

File # 04-NWJ-15

Dear Mr. Burg:

On January 29 – February 5, 2004, investigators from the U.S. Food and Drug Administration (FDA) inspected your firm, located at 755 Jersey Avenue, New Brunswick, New Jersey. This inspection revealed that your firm receives active pharmaceutical ingredients (APIs) from manufacturers and distributors. These APIs are subsequently repackaged and relabeled for further distribution to pharmacies for compounding.

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 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.

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 is repacking and distributing the bulk API domperidone for use in pharmacy compounding.

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.

Misbranding Violations

The domperidone that you repack and distribute to pharmacies for compounding violates section 502(f)(1) of the Act because its labeling does not contain adequate directions for use and is not otherwise exempt from this requirement under the Act. 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. Accordingly, we also will not exercise our enforcement discretion with regard to the bulk drug substance.

This violation is not intended as an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all your drug products are in compliance with federal laws and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct the 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 in writing within 15 working days of receipt of this letter of the steps that you will take to correct these violations, including an explanation of the steps taken to prevent the recurrence of the violations. You should address your reply to the U.S. Food and Drug Administration, 10 Waterview Blvd., Parsippany, New Jersey 07054, Attn: Joseph F. McGinnis, R.Ph, Compliance Officer.

Sincerely,



Douglas I. Ellsworth
District Director
New Jersey District