DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Central Region

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

Telephone (973) 526-6005

WARNING LETTER

TRANSMITTED VIA FACSIMILE

June 7, 2004

Mr. Gene Ragazzo, R.Ph
Mr. James Palmieri, R.Ph
Co-owners
Drugs Are Us, Inc. DBA Hopewell Pharmacy
1 W. Broad Street
Hopewell, NJ 08525

File #04-NWJ-14

Dear Mr. Ragazzo and Mr. Palmieri:

On October 8-24, 2003, investigators from the U.S. Food and Drug Administration (FDA) and the New Jersey Board of Pharmacy inspected your firm, located at 1 W. Broad Street, Hopewell, New Jersey. 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 Part 312. Another factor is whether a firm is compounding drugs that are "versions" of drugs that were withdrawn or removed from the market for safety reasons.

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 effect on the public health.

The inspection revealed that your firm is preparing and distributing domperidone 5mg, 10mg, 20mg, 30mg, 40mg capsules and 1mg/ml and 10mg/ml liquid suspension 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.

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 is compounding drug products containing polidocanol. This also is not an active ingredient contained in any FDA-approved drug product, and FDA will not sanction its use in pharmacy compounding.

All products compounded by your firm containing domperidone and polidocanol 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, 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, 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 they are not exempt from this requirement under 21 CFR § 201.115.

Your firm's website also identifies adenosine monophosphate as a product that you offer to compound. Drugs containing adenosine-5-monophosphate were removed from the market in 1973 because they were determined to be neither safe nor effective. FDA will not exercise its enforcement discretion regarding the compounding of products containing adenosine monophosphate, and you will violate the Act if you compound such products.

Your firm's website also contains a list of injectable products that you offer to compound, including human growth hormone. For your information, 21 U.S.C. § 333(e) states that, "whoever knowingly distributes, or possesses with the intent to distribute,

human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under 21 U.S.C. 355 and pursuant to the order of a physician, is guilty by not more than 5 years in prison, such fines are authorized by Title 18, United States Code, or both." Compounding human growth hormone for anti-aging treatment or any other unapproved use would violate 21 U.S.C. § 333(e).

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 your firm are in compliance 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 in writing within 15 working days of receipt of this letter of the additional specific steps you will take to correct these violations, including an explanation of each step being taken to prevent the recurrence of the violations. You should address your reply to this letter to the U.S. Food and Drug Administration, 10 Waterview Blvd., Parsippany, New Jersey, 07054, Attn: Joseph F. McGinnis, R. Ph., Compliance Officer.

Sincerely,

Ray Abrahams for

Douglas I. Ellsworth
District Director
New Jersey District