DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

WARNING LETTER
2007-DT-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 27, 2006

Mr. Scott T. Popyk, Owner
Health Dimensions, Inc.
39303 Country Club Dr., Suite A-26
Farmington Hills, MI 48331

On August 7, 2006, Investigators from the U.S. Food and Drug Administration (FDA) inspected your firm, located at 39303 Country Club Drive, Suite A-26, Farmington Hills, MI. This inspection revealed that your firm produces human prescription drugs in various dosage forms and strengths.

FDA's position is that the Federal Food, Drug, and Cosmetic Act (FDCA) establishes agency jurisdiction over "new drugs," including compounded drugs. FDA's view that compounded drugs are "new drugs" within the meaning of 21 U.S.C. § 321(p), because they are not "generally recognized, among experts . . . as safe and effective," is supported by substantial judicial authority. *See Weinberger v. Hynson, Westcott & Dunning,* 412 U.S. 609, 619, 629-30 (1973) (explaining the definition of "new drug"); *Prof'ls & Patients for Customized Care v. Shalala,* 56 F.3d 592, 593 n.3.(5th Cir. 1995) (the FDCA does not expressly exempt pharmacies or compounded drugs from its new drug provisions); *In the Matter of Establishment Inspection of: Wedgewood Village Pharmacy,* 270 F. Supp. 2d 525, 543-44 (D.N.J. 2003), *aff'd, Wedgewood Village Pharmacy v. United States,* 421 F.3d 263, 269 (3d Cir. 2005) ("The FDCA contains provisions with explicit exemptions from the new drug . . . provisions. Neither pharmacies nor compounded drugs are expressly exempted."). FDA maintains that, because they are "new drugs" under the FDCA, compounded drugs may not be introduced into interstate commerce without FDA approval.

The drugs that pharmacists compound are not FDA-approved and lack an FDA finding of safety and efficacy. However, FDA has long recognized the important public health function served by traditional pharmacy compounding. FDA regards traditional compounding as the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient. *See Thompson v. Western States Medical Center,* 535 U.S. 357, 360-61 (2002). Traditional compounding typically is

used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.

Through the exercise of enforcement discretion, FDA historically has not taken enforcement actions against pharmacies engaged in traditional pharmacy compounding. Rather, FDA has directed its enforcement resources against establishments whose activities raise the kinds of concerns normally associated with a drug manufacturer and whose compounding practices result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA.

FDA's current enforcement policy with respect to pharmacy compounding is articulated in Compliance Policy Guide (CPG), section 460.200 ["Pharmacy Compounding"], issued by FDA on May 29, 2002 (*see Notice of Availability*, 67 *Fed. Reg.* 39,409 (June 7, 2002)).[1] The CPG identifies factors that the Agency considers in deciding whether to initiate enforcement action with respect to compounding. These factors help differentiate the traditional practice of pharmacy compounding from the manufacture of unapproved new drugs. They further address compounding practices that result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA. These factors include considering whether a firm compounds finished drugs from bulk active ingredients that are not components of FDA-approved drugs, without an FDA sanctioned investigational new drug application (IND). The factors in the CPG are not intended to be exhaustive and other factors may also be appropriate for consideration.

Our inspection revealed that your firm is preparing and distributing [redacted] in orally administered dosage forms. [redacted] is not an active ingredient in any FDA-approved drug products. FDA does not sanction its use in pharmacy compounding and will not exercise enforcement discretion with respect to products that contain [redacted]

FDA is concerned with the public health risks associated with the compounding of [redacted] There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest and sudden death in patients receiving an intravenous form of [redacted] that has been withdrawn from marketing in several countries. FDA has

[1] Although Section 503A of the FDCA (21 U.S.C. § 353a) addresses pharmacy compounding, this provision was invalidated by the Supreme Court's ruling in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), that Section 503A included unconstitutional restrictions on commercial speech. And those restrictions could not be severed from the rest of 503A. In *Thompson v. Western States Medical Center*, 535 U.S. 357 (20020), the Supreme Court affirmed the Ninth Circuit ruling that the provisions in question violated the First Amendment.

become aware of the use of [redacted] by lactating women to increase breast milk production because of its effect on prolactin levels. While [redacted] is approved in several other countries for the treatment of gastric stasis and gastroparesis, [redacted] is not approved in any country for enhancing breast milk production in lactating women.. In several countries where the oral form of [redacted] continues to be marketed, labels for the product note that [redacted] is excreted in the breast milk of lactating women and recommend that women taking [redacted] avoid breast-feeding. Because of this, FDA recommends that breastfeeding women not use [redacted] to increase milk production.

FDA understands that some patients with gastroparesis may need [redacted] to maintain their quality of life. In response to this concern, the agency encourages physicians who would like to prescribe [redacted] for their patients with severe gastrointestinal disorders that are refractory to standard therapy to open an IND. An IND is a request for FDA authorization to administer an investigational drug to humans. Such authorization would allow the importation, interstate shipment, and administration of the drug, subject to certain legal restrictions and conditions, even though it is not approved for sale in the U.S.

For questions relating to [redacted] INDs, please contact Ms. Maureen Dewey, Regulatory Project Manager, Division of Gastroenterology Products. Ms. Dewey can be reached at (301) 796-0845 or at Maureen.dewey@fda.hhs.gov. Additional information is available at the website: http://www.fda.gov/cder/news/[redacted]htm.

In addition, our inspection revealed that your firm is preparing and distributing [redacted] injectables. [redacted] is not an active ingredient contained in any FDA-approved drug products. FDA does not sanction its use in pharmacy compounding and will not exercise its enforcement discretion with respect to compounded products that contain [redacted].

The agency is seriously concerned about the public health risks associated with the compounding of [redacted] for injection. Known adverse events include deep venous thromboses, necrosis, and ulceration at the treated site. Additionally, reversible cardiac arrest after [redacted] sclerotherapy has been reported.

These products containing [redacted] and [redacted] are drugs within the meaning of section 201(g) of the FDCA (21 U.S.C. § 321(g)). They are also new drugs under section 201(p) of the FDCA (21 U.S.C. § 321(p)), and may not be introduced or delivered for introduction into interstate commerce under section 505 of the FDCA (21 U.S.C. § 355) because no approval of an application filed pursuant to section 505(b) or (j) of the FDCA (21 U.S.C. § 355(b),(j)) is in effect for such drugs.

In addition, these drugs are misbranded under section 502(f)(1) of the FDCA (21 U.S.C. § 352(f)(1)) in that their labeling fails to bear adequate directions for use. Further these

drugs are not exempt from this requirement under 21 CFR § 201.115, and do not otherwise comply with section 505(i) of the FDCA (21 U.S.C. 355(i)).

The above violations are not intended to be an all-inclusive list of deficiencies. 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 against you and your firm. 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 any steps you will take to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the correction will be completed.

You should address your reply to this letter to the U.S. Food and Drug Administration, Detroit District Office, 300 River Place, Suite 5900, Detroit, MI 48207 Attn: Judith A. Putz, Compliance Officer. If you have any further questions, please feel free to contact Ms. Putz at 313-393-8120.

Sincerely,

David M. Kaszubski

David M. Kaszubski
Acting District Director
Detroit District Office