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**SUMMARY:** Wedgewood Village Pharmacy will vigorously defend against FDA allegations

*(Swedesboro NJ, November 6, 2006)* — In an October 31 “warning letter,” the Federal Drug Administration (FDA) made claims and allegations against Wedgewood Village Pharmacy of Swedesboro NJ that pharmacy-prepared compounds are “new drugs” and, therefore, under the authority of the FDA and subject to pre-market clinical trials. The company is a 26-year-old traditional compounding pharmacy that prepares custom prescription medicines to meet the specialized needs of individual patients with drugs not otherwise available.

George Malmberg, the pharmacist-president and CEO of Wedgewood, said: “The FDA is wrong once again. The allegations in this letter are unproven. They are based on internal FDA policies that are more than 10 years old that the FDA itself and a Federal Court say are not binding on anyone. We have not yet discussed, confronted, rebutted or litigated these claims against us. We will vigorously defend ourselves, our profession and the tens of thousands of human and animal patients who depend upon compounded custom medications for their lives.”

A compounding pharmacy makes medications when they are not commercially available for a variety of reasons. For example, medications may no longer be profitable enough for large pharmaceutical companies to manufacture. Physicians and veterinarians also prescribe compounded medications when their patients require a different form, flavor or dosage than is commercially available.

The FDA sent its letter just weeks after a Federal District Court in Midland Texas explicitly ruled that the internal FDA “Compliance Policy Guidelines” (CPG) on which the agency’s charges against Wedgewood are based are not enforceable. The letter also follows, by more than a year, the FDA’s month-long inspection of the pharmacy, which was conducted after legal efforts to prevent it failed.

The clash between the FDA and the compounding pharmacy profession is not new. It stems from the FDA’s now-debunked contention that compounded medications made from pure pharmaceutical ingredients are “new and unapproved drugs” and thus should be subject to FDA jurisdiction. Compounding pharmacies are regulated by the states and

every state legislature and the District of Columbia specifically require that every pharmacist have compounding skills and equipment. Compounding fills a critical gap in the U.S. drug supply system. The FDA even agrees: in its letter to Wedgewood, the agency wrote: "FDA has long recognized the important public health function served by traditional pharmacy compounding."

In 2002 the U.S. Supreme Court ruled that compounded medications are legal. In the recent Midland case, Judge Robert Junell ruled that it is "in the best interest of public health to keep the practice of pharmacy compounding legal" and specifically ruled that using pure pharmaceutical ingredients to compound medicines is a legal practice. Junell said that the FDA had overstepped its authority by attempting to inspect the records of pharmacists who operate legally according to their state regulations.

Of the FDA argument that it should regulate compounding pharmacists, Junell wrote "If compounded drugs were required to undergo the new drug approval process, the result would be that patients needing individually tailored prescriptions would not be able to receive the necessary medication due to the cost and time associated with obtaining approval." Malmberg explained: "This means that thousands of people, companion animals and horses could suffer needlessly or die."

The tension between the FDA and the compounding profession has grown with the demand for compounded medications. Some compounding pharmacies, like Wedgewood, have grown in size because they responded to the demand with high-quality preparations, responsive customer service and fast delivery, all of which can mean life or death for patients who are dependent on medications that are otherwise not available. Wedgewood, for example, counts 17,000 doctors, 80 percent of them veterinarians, among its prescribers. According to the respected Brakke Consulting survey, 92% of U.S. veterinarians say that compounded medications are important to their practices. Every U.S. hospital compounds medications, compounding is part of the core curriculum of every pharmacy school and compounding is a required pharmacy skill for pharmacist licensure.

"We *share* the FDA's goals to fill prescriptions with pure, sterile and consistently potent medicines," Malmberg said. "Ironically, this creates a Catch 22 for pharmacies like Wedgewood. As demand for custom medicines increases, we invest in more sophisticated facilities, equipment and quality systems to maintain those high standards. But then the FDA charges us with filling too *many* prescriptions and claims we're manufacturing drugs. As a Las Vegas District Court said, 'volume is not a proxy for manufacturing;' it is a measure of patient needs as determined by medical professionals and the absence of

suitable alternatives in the marketplace. The FDA creates an unfair and unpredictable environment that casts doubt over the legality and ethics of our businesses and our entire profession.”

Malmberg added, “If we were posing a threat to public health or safety, the FDA would not have waited more than a year between its inspection and sending this letter. This is a disagreement about a legal technicality that has been litigated repeatedly. The FDA disagrees with our entire profession, 51 boards of pharmacy, every major pharmacy and medical organization, the required curricula of every college of pharmacy and several courts including the U.S. Supreme Court. We must act to protect our profession’s birthright, prescribers’ legal authority to prescribe the medicines they see fit and the lives of the patients who depend on compounded medicines.”

The FDA keeps compounding pharmacy in a legal limbo saying only that it “as a matter of policy has not historically brought enforcement actions against pharmacies engaged in traditional compounding.” This allows the FDA to pick and choose when to assert its authority over a compounding pharmacy, a practice that fuels the repeated legal clashes between compounders and the FDA.

In a November 3 letter to the FDA, Wedgewood requested a 30-day extension beyond the FDA’s 15-day deadline to respond to the warning letter, which demands that the pharmacy address, as the Wedgewood letter notes, “approximately 27 different compounds, five separate judicial decisions, two CPGs and at least seven sections of the Federal Drug and Cosmetic Act.”

Malmberg concluded: “The FDA has a habit of making its allegations widely available on its Web site, sending notices to Federal agencies and releasing information to the news media. They rarely present the responses of those they accuse of wrongdoing, even when requested to do so, leaving a cloud of doubt that the company ‘must be doing something wrong if the FDA says so.’ We will not allow this to happen to us and we will broadly publish our responses to the charges against us.”

#### **BACKGROUND: ABOUT COMPOUNDING**

Because every patient is different and has different needs, customized, compounded medications are a vital part of quality medical care.

The basis of the profession of pharmacy has always been the "triad," the patient-physician-pharmacist relationship. Compounding is extremely important to the veterinary community, which often requires more flavors, dosages and potency levels than commercially available medications supply. Through this relationship, patient needs are

determined by a doctor, who chooses a treatment regimen that may include a compounded medication. Physicians and veterinarians often prescribe compounded medications for reasons that include (but are not limited to) the following situations:

- ➔ When needed medications are discontinued by or generally unavailable from pharmaceutical companies, often because the medications are no longer profitable to manufacture;
- ➔ When the patient is allergic to certain preservatives, dyes or binders in available off-the shelf medications;
- ➔ When treatment requires tailored dosage strengths for patients with unique needs (for example, an infant);
- ➔ When a pharmacist can combine several medications the patient is taking to increase compliance;
- ➔ When the patient cannot ingest the medication in its commercially available form and a pharmacist can prepare the medication in cream, liquid or other form that the patient can easily take; and
- ➔ When medications require flavor additives to make them more palatable for some patients, most often children and pets.

For additional information, visit the International Academy of Compounding Pharmacists' Web site at [www.iacprx.org](http://www.iacprx.org) and [www.compoundingfacts.org](http://www.compoundingfacts.org).

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