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January 28, 2007

Sarah A. Della Fave
Compliance Officer
U.S. Food & Drug Administration
New Jersey District
10 Waterview Blvd., 3d Floor
Parsippany, NJ 07054

Re: In the Matter of Pharmacy Creations

Dear Ms. Della Fave:

We represent Pharmacy Creations in connection with this matter. This letter is submitted in response to the issues raised in your correspondence dated October 31, 2006.

* * *

As a threshold matter, Pharmacy Creations vigorously disputes the authority of the Food and Drug Administration to conduct a closeout inspection and to issue a "Warning Letter" to Pharmacy Creations based upon this unlawful inspection. These objections are based upon recent case law interpreting the compliance policy guide (CPG) that the FDA issued without public comment in May, 2002, as well as the Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 301, et seq.

As you are no doubt aware, the recent federal court decision in Medical Center Pharmacy v. Gonzales, 451 F. Supp. 854 (W.D.Tex. 2006) examined the issue of the FDA's authority to regulate compound drugs and to inspect state-licensed retail pharmacies under the Food, Drug and Cosmetic Act. Significantly, the court found that compounded drugs, prepared by

pharmacists in the regular course of their business pursuant to a prescription from a licensed practitioner, are not new drugs under the Act and are implicitly exempt from the new drug definitions contained in sec. 321. *Id.* at 858 (emphasis supplied). In interpreting the CPG, the court stated as follows:

Specifically, the CPG states “the FDA reiterates its long-standing position that it would not attempt to regulate traditional compounding practice.”

Id. at 864 [emphasis supplied] citing CPG 460.200.¹ The court ultimately held that compounded drugs created for an individual patient pursuant to a prescription from a licensed practitioner are exempt from the new drug definitions contained in 21 U.S.C. §§ 321(p)(1) and (v)(1). *Id.* at 858.

The court further held that pharmacies that comply with 21 U.S.C. § 374(a)(2)(A) are expressly exempt from inspections that exceed what is permitted pursuant to 21 U.S.C. § 374(a)(1). *Id.* at 866-7. In so holding, the court emphasized that:

If a pharmacy is compliant with local laws, and dispenses drugs pursuant to the receipt of a prescription from a licensed practitioner, and compounds in the regular course of its own individualized business, the pharmacy is exempt from the more detailed inspection of the records found in the third sentence of the section. In order to conduct a third sentence inspection of a pharmacy who meets the requirements found in the exemption, **the FDA must demonstrate why the pharmacy does not qualify for the exemption.**

Id. at 866 [emphasis supplied].

¹ The court noted that the CPG states that “the FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner.” *Id.*

Here, the FDA made no threshold determination whatsoever regarding whether or not Pharmacy Creations qualified for the exemption. As set forth in my initial letter dated April 10, 2006, Pharmacy Creations does not prepare any commercially available products. Rather, it compounds drugs in dosages that are substantially different than those available on the commercial market. The drugs also vary by types of preservatives, strength and formula. Moreover, Pharmacy Creations has never been cited for any violations of state or local regulations in connection with its compounding practices. Thus, Pharmacy Creations is responding to the purported “Warning Letter” under protest insofar that the FDA clearly lacked the requisite authority to conduct the February, 2006 closeout inspection.

With respect to the issue of misbranded drugs, the Gonzales court specifically rejected the FDA’s contention that drugs are considered to be misbranded because they fail to bear adequate instructions for use. Id. at 867. In so holding, the court relied upon the exemption in the regulations relating to the use of bulk ingredients. 21 C.F.R. § 201.122 (exempting bulk ingredients from the Act’s adequate directions for use requirement unless the finished product is a new drug). Significantly, the court found that the misbranding provision set forth at 21 U.S.C. § 352 does not apply to pharmacies in cases where such pharmacies:

...maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound or process drugs or devices for sale other than in the regular course of business of dispensing or selling drugs or devices at retail.

Id. at 868, citing 21 U.S.C. § 352.

In addition, Pharmacy Creations contends that the unsafe and unadulterated drug provision set forth at 21 U.S.C. § 351(a)(5) does not apply to its medications insofar as they are not “new drugs” within the meaning of the section for the reasons set forth at length above. Moreover, as reflected in Pharmacy Creations’ records, all of the ingredients utilized by the company are USP grade and are exclusively obtained through FDA sources. Each of the ingredients used by Pharmacy Creations has a certificate of analysis and pedigree.

With respect to the unsupported allegations that Pharmacy Creations manufactures drugs that are “commercially available” or “essentially copies of commercially available products”, the FDA has utterly failed to set forth any specific examples with respect to the commercial availability of these drugs. In fact, Pharmacy Creations notes that two of these drugs mentioned in the October 31 letter i.e., Isoproterenol and Methotrexate, are virtually unavailable on the commercial market in any dosage.

Finally, Pharmacy Creations vigorously disputes the FDA’s bald assertion that its products are produced in “excess of actual prescription orders.” Pharmacy Creations’ records amply demonstrate that all of its compound medications are compounded based upon patient profiles and physician prescriptions. Although the company does compound small excess quantities of drugs for use in batch testing, these insignificant amounts are insufficient to support any contention that Pharmacy Creations is somehow mass producing commercially available drugs.

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We trust that the foregoing fully responds to the issues raised in the October 30, 2006 correspondence. We hereby request that in view of recent case law which holds that the FDA lacks enforcement authority against pharmacies that specialize in compounding medications absent any allegations of violations of state law or regulations promulgated by the state Board of Pharmacy, the FDA refrain from any further attempt to unlawfully inspect Pharmacy Creations' facility. We further demand that the FDA refrain from posting any allegations with respect to Pharmacy Creations on its website or other media outlet insofar as such actions have caused substantial and irreparable harm to Pharmacy Creations business. If these actions continue, Pharmacy Creations will have no choice but to seek the appropriate relief from the courts.

If you have any questions or comments regarding the above, please do not hesitate to contact me.

Very truly yours,

Frank P. Arleo

FPA:hm
cc: Pharmacy Creations