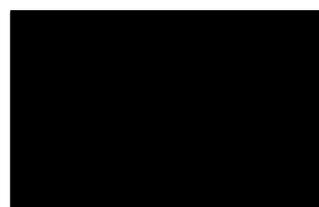


ARLEO & DONOHUE, L.L.C.
ATTORNEYS AT LAW

Frank P. Arleo
Timothy M. Donohue

Of Counsel:
Jo Ann K. Dobransky
Dawn M. Donohue



December 28, 2007

Maryann Munson
Project Management Officer
Office of Compliance
Center for Drug Evaluation & Research
5600 Fishers Lane, HFD-240
Rockville, MD 20857

Re: Pharmacy Creations

Dear Ms. Munson:

We represent Pharmacy Creations in connection with several issues relating to our client's compounding business. We have had an ongoing dialogue with Sarah A. Della Fave, Compliance Officer at the FDA's office in Parsippany, New Jersey, regarding compounding in general and particular compound formulas sold by Pharmacy Creations. I recently received your e-mail regarding the meeting we are attempting to schedule at your office in Rockville, Maryland to address the issues raised by the Parsippany office. Please allow this letter to serve as Pharmacy Creations' submission to address the requirements set forth in your e-mail.

1. Statement of Purpose of Meeting

The issues underlying Pharmacy Creations' request for a meeting with FDA representatives date back to a closeout inspection conducted by FDA officials on February 8, 2006 and subsequent "warning letters" received by Pharmacy Creations based upon issues arising out of this inspection. Essentially, the FDA has expressed concern that Pharmacy Creations is operating as a manufacturer of pharmaceuticals rather than a compounding facility. In addition, the FDA is apparently concerned about Pharmacy Creations' use of several compounding ingredients, notably Domperidone, Polidocanol and Adenosine Phosphate.

Pharmacy Creations has set forth its response to the FDA's concerns in a number of written submissions. Due to the fact that these concerns relate to a number of specific practices and ingredients, we believe the most expeditious and cost effective method of resolving these issues would be to conduct a meeting directly with the appropriate FDA representatives so that we can respond at length to these concerns and come to a consensus as to how Pharmacy Creations can structure its operations to remediate them to the satisfaction of the FDA.

December 28, 2007

Page 2

With respect to the FDA's concern over Pharmacy Creations use of Domperidome, Pharmacy Creations has in its possession a substantial body of literature which establishes that this product has been utilized effectively in the treatment of disgestive diseases (including gastroparesis) for nearly 20 years. Moreover, the safety and efficacy of this product has been established through clinical trials, and the fact that the FDA's division of gastrointestinal drugs has approved Domperidome. Pharmacy Creations believes that the FDA's concern over this product is fueled by justifiable safety concerns that Domperidome may, in certain cases, be misused by patients for inappropriate medical indications, i.e., lactation. In this regard, Pharmacy Creations has instituted procedures which carefully track all patients receiving medications compounded with Domperidome to insure that these patients are not in fact pregnant or nursing, and to document medical necessity.

With respect to Polidocanol, there appears to be a misunderstanding as to whether or not this product (which is recognized as a chemical and not a drug) has safety or efficacy issues. Pharmacy Creations notes that Polidocanol is universally recognized as an important component of compounding and has been utilized in this regard for nearly 80 to 100 years. In addition, FDA approval for this product appears to be imminent.

Regarding the use of Adenosine Phosphate, Pharmacy Creations notes that this product has been utilized on the commercial market as a chemotherapy drug, Adjuvant. Pursuant to the FDA's patent certification list, a new drug application was submitted for Adenosine in or about April 2005, and the commercial product is currently on the market.

In connection with the FDA's concerns regarding the volume of compounding being conducted at Pharmacy Creations, it should be noted that the volume of compounding at a specific facility is not, in and of itself, an indicator of commercial manufacturing in cases where specific medical need for each patient is documented as it is with Pharmacy Creations. Each of the compounds formulated by Pharmacy Creations is patient specific and dispensed based on established medical need. Moreover, Pharmacy Creations does not produce any commercially available drug unless they are currently unavailable. For example, the American Society of Health Systems Pharmacists website (as well as the FDA's own website) designated Methotrexate as currently "unavailable" at the time of the FDA inspection of the Pharmacy Creations facility.

Pharmacy Creations has also advised the FDA that the compounds it provides to prescribing physicians are not merely "slightly" but substantially different from commercially available products. In this regard, Pharmacy Creations has offered to make available to the FDA, once again, the specific formulas utilized for each of these compounds, as well as the precise number of vials of each drug compounded to allay any concern by the FDA that it is essentially operating improperly as a commercial drug manufacturer.

IACP002848

In response to the concerns raised by the FDA, Pharmacy Creations has implemented a number of systems and procedures to further insure the safety and efficacy of its products. These procedures have been the subject of substantial correspondence between the FDA and pharmacy creations. After discussions with my client, we proposed to Sarah Della Fave of the Parsippany office that the most expeditious means to resolve each of these outstanding concerns would be a formal meeting with the FDA representatives most knowledgeable in this area to address the FDA's concerns seriatim. This would allow both sides to come to a meaningful resolution to each of the issues raised in the FDA's prior correspondence and would be more effective than simply exchanging the parties' respective positions on paper.

2. Listed External Participants

Scott Karolchyk, Pharmacy Creations; Frank Arleo, Esq.; Bernard Kovalsky, Pharmacy Creations; L.D. King, Executive Director, International Academy of Compounding Pharmacists (IACP), *dermed*

3. FDA Participants

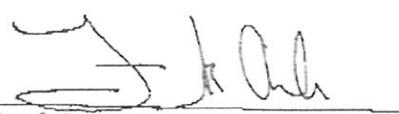
At this time, Pharmacy Creations requests a meeting with FDA representatives specific to the area of compounding.

We trust the foregoing sufficiently responds to the inquiry in your email dated December 12, 2007. We look forward to finalizing a meeting date and await further information from your office regarding the time and location.

Thank you for your continued assistance.

Very truly yours,

ARLEO & DONOHUE, L.L.C.

By: 

Frank P. Arleo

FPA:hm

cc: Pharmacy Creations