



Atlanta Office  
171 17th Street NW, Suite 2100  
Atlanta, GA 30363-1031  
Direct phone: 404.873.8690  
Direct fax: 404.873.8691  
E-mail: alan.minsk@agg.com

August 15, 2013

**VIA FEDERAL EXPRESS**

Re: Unlawful Compounding of Mitosol® (mitomycin for solution)

Dear Mr. Lunardini:

It has come to our attention that [redacted] Pharmacy is compounding a form of Mitosol® (mitomycin for solution) for ophthalmic use, which we believe is in violation of federal law. Therefore, we strongly encourage you to stop immediately such compounding.

As you are likely aware, FDA's Compliance Policy Guide Section 460.200 describes its position on pharmacy compounding. While the agency recognizes the benefit of compounding and typically defers to State agencies in such matters, FDA reserves the right to initiate enforcement action if it considers the activities to cross into manufacturing. For example, FDA may take action if a compounding pharmacy is compounding drugs that are essentially copies of commercially-available drugs.

FDA has approved Mitosol and found it to be safe and effective for its intended use. In addition, FDA granted orphan drug exclusivity to Mitosol. Therefore, we believe FDA will consider your actions to be similar to manufacturing an unapproved new drug (and undermining Mitosol's orphan drug exclusivity), which is unlawful and should cease immediately. We have no doubt that the pharmacy's primary concern is to benefit patients and not to harm anyone. We also recognize that it is likely aware of the increased Congressional and FDA scrutiny of compounding pharmacies, with a particular focus on sterile preparations. Because the manufacture of unapproved new drugs presents a serious public health concern, we believe FDA would take prompt regulatory action if the pharmacy continues such activity.

We request a response to this letter by August 26, 2013. If we do not hear from the pharmacy, we will contact the State Board of Pharmacy and FDA to share our concerns.

5789456v1

**Arnall  
Golden  
Gregory LLP**

Thank you for your prompt attention to this matter. We look forward to hearing from you soon.

Sincerely,

ARNALL GOLDEN GREGORY LLP



Alan G. Minsk

AGM/cdbi