New England Compounding Center

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January 5, 2007

BY FACSIMILE & FEDEX

Ann Simoneau
Compliance Officer
U.S. Food and Drug Administration
New England District Office
One Montvale Avenue, 4th Floor
Stoneham, Massachusetts 02180

Re: Warning Letter to New England Compounding Center, NEW-06-07W

Dear Ms. Simoneau:

We are writing to respond to the Warning Letter issued to New England Compounding Center ("NECC") dated December 4, 2006. Thank you for extending our response due date to January 5, 2007. NECC is committed to complying with applicable laws and regulations and to ensuring high quality care for our patients. We appreciate the opportunity to clarify the nature of our pharmacy operations and to respond to the issues raised in the Warning Letter.

At the outset, we note that the Warning Letter is based on an inspection of NECC that started on September 23, 2004, approximately twenty-eight months ago, and ended on January 19, 2005, approximately twenty-three months ago. FDA has not contacted us since concluding the inspection. Some of the letter's assertions no longer apply to NECC's operations.

We have been advised by our counsel that the five most recent Warning Letters issued by FDA's New England District Office to non-pharmacy medical device and drug manufacturers were sent, on average, 110 days after the recipients' facilities had been inspected. The Warning Letter we received arrived 684 days after FDA's inspection of our pharmacy was completed. This twenty-three month delay is nearly a year and a half longer than the District's recent average response time. This prolonged gap between

inspection and Warning Letter does not comply with FDA's procedures, which establish that decisions to issue Warning Letters must be made in a timely fashion, because they are "the agency's principal means of notifying the regulated industry of violations and achieving prompt voluntary correction."[1] The Warning Letter also mentions FDA's concerns about potentially serious health risks associated with the misuse by physicians and patients of compounded topical anesthetic drug products. We take the welfare of our patients very seriously. We believe that FDA's nearly two year delay in issuing the Warning Letter contradicts FDA's rhetoric regarding the asserted risks associated with our compounded products.

The Warning Letter states that FDA believes that it has jurisdiction over compounded drugs because such drugs are "new drugs" within the meaning of Section 201(p) of the Food, Drug, and Cosmetic Act (FDC Act). The Warning Letter cites several court cases. However, it ignores the fact that the only federal court to have directly considered the issue recently rejected FDA's legal theory. In Medical Center Pharmacy v. Gonzales, the federal District Court for the District of Western Texas granted the plaintiff pharmacies' summary judgment on their "claim that compounded drugs do not fall under the [FDC Act's] new drug definitions."[2] The court based this conclusion on "relevant case and statutory law, as well as legislative intent."[3] We do not understand why the Warning Letter ignores the single most relevant judicial opinion.

The Warning Letter also refers to the Supreme Court's pharmacy compounding decision in Thompson v. Western States Medical Center,[4] but neglects to mention that the Medical Center Pharmacy court's opinion stated that "the language of Western States

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1 FDA, Regulatory Procedures Manual 4-10 (March 2006).

2 Med. Ctr. Pharmacy v. Gonzales, 451 F. Supp. 2d 854, 865 (W.D. Tex. 2006), appeal docketed, No. 06-51583 (5th Cir. Dec. 11, 2006).

3 Id. at 858.

4 535 U.S. 357 (2002).

demonstrates that compounding is a process that has been approved by the Supreme Court."[5] Accordingly, we believe that compounded drugs are not automatically new drugs.

Contrary to the Warning Letter's assertion, NECC does not compound copies of FDA-approved commercially available drugs, introduce unapproved new drugs into interstate commerce, does not need approved NDAs before dispensing its compounded medications, and does not process or repackage approved drugs in a manner that would subject us to FDA regulation. Nor are our compounded medications misbranded. NECC dispenses compounded medications upon the receipt of valid prescriptions. We are engaged in the practice of pharmacy and comply with the Massachusetts Board of Registration in Pharmacy's laws and rules. We engage in the kind of activity that the Medical Center Pharmacy court determined does not result in the introduction of new drugs into interstate commerce.

Copies of Commercially Available Drug Products

Your letter asserts that NECC is compounding trypan blue ophthalmic medications and 20% aminolevulinic acid solution (ALA), and that these medications are copies of commercially available, FDA-approved drugs. Without agreeing with the correctness of the Warning Letter's assertions, please note that we stopped filling prescriptions for trypan blue in August 2005 (16 months before the Warning Letter) and for ALA in May 2006 (7 months before the Warning Letter) for business reasons completely unrelated to the FDA's assertions.

Anesthetic Drug Products

The letter also asserts that NECC has developed a standardized line of topical anesthetic drug products. This is not the case. NECC compounds a number of different

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[5] 451 F. Supp. 2d at 864.

topical anesthetic formulas containing a variety of component ratios. The formulation depends on the prescribing physicians' requests. Physicians do prescribe certain formulations more frequently than others, but these choices by physicians do not mean that NECC has developed a standardized formula and therefore acts as if it were a drug manufacturer. We compound solely in accordance with formulas determined by the prescribing physicians. Moreover, NECC compounds a small volume of topical anesthetic medications.

NECC currently uses the term "triple anesthetic cream," (not "extra strength triple anesthetic cream"), but only as a way to literally describe the compounded medication as a convenience to our prescribing physicians. The term is in no way trademarked or branded. Assigning names to formulas is common in pharmacy practice, and does not mean that a pharmacy is a manufacturer. Nonetheless, to address FDA's concerns on this point, should the FDA believe that our use of the term "triple anesthetic cream" is problematic, please advise and we will consider discontinuing that description of the compounded medication. As always, we will continue to require physicians to specify the desired chemical formulation in each patient-specific prescription.

The Warning Letter alleges that there are potentially serious health risks associated with the misuse of compounded local anesthetic products because of the potential for systemic toxicity. Virtually all drugs, including manufactured drugs, pose serious health risks if they are misused by physicians or patients.

The Warning Letter also states that the courtesy prescriptions NECC provides in limited circumstances constitute "free samples," and that this is inconsistent with the traditional practice of pharmacy compounding. Although we do provide a very small quantity of medications (less than (b)(4) per month) free of charge, we do so only upon receipt of a valid prescription from a licensed practitioner to meet the unique medical needs of a particular patient. The provision of a prescribed medication at no charge is within our rights and is certainly not inconsistent with the practice of pharmacy. Thus,

these are not samples as that term is defined in the Prescription Drug Marketing Act. A valid prescription does not become unlawful just because we do not charge the physician or patient. Should the FDA believe our position on this matter is incorrect, please advise.

Repackaging

The Warning Letter asserts that NECC's repacking of Avastin into syringes constitutes manufacturing. However, your letter also explains that "[g]enerally, the agency regards mixing, packaging, and other manipulations of approved drugs by licensed pharmacists, consistent with the approved labeling of the product, as an approved use of the product if conducted within the practice of pharmacy, i.e., filling prescriptions for identified patients."[6] This is precisely what we do. NECC's repacking activity constitutes the practice of pharmacy because we repackage Avastin only upon receipt of a valid, patient-specific prescription from a licensed practitioner. NECC also maintains an ongoing Quality Assurance Program including Sterile Compounding Standard Operating Procedures. All aspects of our sterile compounding and repacking operations were recently reviewed by an independent expert, who confirmed that NECC is in compliance with all aspects of U.S. Pharmacopoeia ("USP") 797. In fact, NECC is one of only several preferred compounding pharmacy vendors approved nationwide by Genentech, the manufacturer of Avastin, to perform patient-specific repackaging services. This preferred vendor status was only awarded by Genentech after careful consideration of NECC's capabilities and track record in the performance of patient-specific compounding/repackaging services.

The Warning Letter alleges that NECC promotes Avastin for unapproved ophthalmologic uses. However, NECC does not promote Avastin for any particular uses but rather only promotes our own ability to compound representative medications to licensed practitioners for their patients. The physician's decision to prescribe a drug for

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6 Warning Letter at 4.

an off-label use, within the scope of the practice of medicine, does not cause our repackaging to be improper.

Finally, the Warning Letter states that NECC "reportedly" told physicians that we would fill prescriptions written in the name of a staff member rather than in the name of an actual patient. This allegation contradicts all of our standard operating procedures. NECC has not made such a representation to anyone, and has no idea how or why FDA arrived at this allegation. Should the FDA have specific knowledge of anyone on our staff making such an assertion to any physician, please provide same and we will address the matter immediately.

We believe that this response to the December 4th Warning Letter addresses FDA's concerns in full. We understand that FDA has a policy whereby responses to Warning Letters will be posted on the FDA website at the Warning Letter recipient's request. We therefore ask that this letter be posted on the FDA's website. We further request, of course, that FDA redact all confidential business information and all other information that is otherwise exempt from public disclosure under the Freedom of Information Act before either posting this response on the website or releasing it in response to a FOI request. We also ask that you consult with us about the FDA's proposed redactions before posting or otherwise publicly releasing the letter.

Thank you, again, for your consideration.

Sincerely,

NEW ENGLAND COMPOUNDING CENTER

Barry Cadden, RPh
Director of Pharmacy

cc James D. Coffey, RPh
Interim Executive Director, MA BOP
Counsel