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November 11, 2004

Susan Manning, Esq.
The Commonwealth of Massachusetts
Board of Registration in Pharmacy
239 Causeway Street
Boston, MA 02114

Re: Docket Number DS-03-055/PH-03-066/New England Compounding
Center (Lic. No. 2848) and Barry Cadden, R.Ph. License No. 21239

Dear Ms. Manning:

On behalf of my clients, Barry Cadden, R.Ph., and New England Compounding Center ("NECC"), I am writing to respond to Mr. Young's October 4, 2004 letter regarding the above-referenced matters. Thank you for the courtesy of extending the time for this reply.

As you may be aware, NECC is now licensed in 44 states, and has applications pending in 2 others.¹ That resume speaks volumes to the quality of its products, and to its reputation. More significantly, its success in passing the due diligence inquires and inspections that are attendant to those licenses is a testament to both NECC's and Mr. Cadden's commitment to quality assurance and regulatory compliance. Indeed, since contracting with a national expert in Aseptic Compounding ([REDACTED]) in 2002, NECC has implemented policies and procedures that address – and in some instances exceed – the proposed probationary conditions in paragraph 3.c. of Mr. Young's letter. With Mr. Brennan's guidance, NECC already has:

- Conducted an independent review and evaluation of its sterile compounding practices

¹ NECC currently does business in 4 states that do not require a license/permit Georgia, New Jersey, Pennsylvania, Wisconsin, and plans to apply for licensure in the two remaining states Tennessee and Arkansas.

- Developed a comprehensive set of sterile products compounding standard operating procedures
- Implemented a comprehensive quality management program that includes:
 - Sterile products specifications.
 - Staff, facilities, and process controls.
 - Aseptic process validation.
 - Ongoing environmental bioburden monitoring.
 - Batch quality control release testing that includes pH, absence of visible foreign particulates, closure integrity, sterility and endotoxin.
 - Frequent monitoring of drug content potency.
- Implemented a formal complaint management/corrective and preventive action (CAPA) program.
- Established USP <797> gap-analysis and standards.

In addition, NECC has recently formalized a "Quality Assurance Team" which includes the director of pharmacy, the head technician, a sterile technician, the general manager and the marketing manager. The Team meets monthly with the stated mission of eliminating pharmacy error. Finally, following the suggestion in Mr. Young's letter (at paragraph 3.c.5), NECC has formalized an after business hours protocol to insure 24/7 consumer access. NECC's commitment to all these initiatives should be well known to the Board, which has inspected the facility three times since last February (twice, with a representative from the FDA):

- February 20, 2004 MA Board of Registration in Pharmacy
[REDACTED]
- September 23, 2004 MA Board of Registration in Pharmacy
[REDACTED]
and
FDA - [REDACTED]
- September 28, 2004 MA Board of Registration in Pharmacy
[REDACTED]
and
FDA - [REDACTED]

All of these inspections have been without incident.

While I think it fair to say that the product of NECC's interaction with the Board - as demonstrated above - is a success story, such would not be the case if the resolution were to include a disciplinary sanction (including the reprimand proposed in Mr. Young's

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letter). The collateral consequences to many, if not all of NECC's 42 other licenses, would be potentially fatal to the business.² Such a catastrophe is clearly not the intended result of the Board's proposed reprimand, nor is it warranted in this case. The Board's mandate is to protect the public health safety and welfare, not to punish its licensees (see, e.g., Gurry v. Board of Public Accounting 394 Mass. 118, 127-128 (1985); Levy v. Board of Registration in Medicine 378 Mass. 519, 527 (1979)).

Mr. Cadden and NECC have demonstrated their commitment to remediation, and are prepared to continue to do so. In that regard, NECC and Mr. Cadden will agree to all of the probationary terms offered in Mr. Young's letter, and will further agree to bear the burden and cost of monitoring and reporting their compliance.³ That result could be accomplished through a non-disciplinary resolution such as a continuance (pending a period of monitoring) or a "stayed probation." Whatever the vehicle, Mr. Cadden and NECC are ready, willing and able to insure all of the public protection components of Mr. Young's proposed resolution, but respectfully request that the Board do so without also imposing discipline which may destroy their business.

Both Mr. Cadden and I are available to meet with you, Mr. Young and/or the Board itself to discuss resolution of this matter. We look forward to your reply.

Very truly yours,



PC/mjc

² Once disclosed, the reprimand will surely result in inquiries/investigations in those other jurisdictions. Regardless of the derivative actions taken, the attendant legal and administrative costs will be devastating.

³ NECC is prepared to extend  contract to provide ongoing monitoring – on such matters as the Board may prescribe – with regularly scheduled written reports to the Board.