Timeline of FDA Interactions with NECC and Ameridose

Background

Please find below an overview of certain facts related to the Food and Drug Administration's (FDA, or the Agency) past interactions with the New England Compounding Company (NECC) and Ameridose. No information related to FDA's ongoing investigations of these companies is included. The information in these timelines is representative of our current understanding, based upon the records and information we have been able to review to date. We continue to collect information related to our history with these companies. We would be pleased to provide additional information if and when it becomes available.

Timeline for NECC

- According to the records FDA has reviewed to date, our earliest record of contact with NECC was an April 2002 inspection to follow-up on two adverse event reports submitted to FDA associated with betamethasone compounded by NECC. On April 16, 2002, FDA issued a Form FDA 483, which included three observations voicing concerns regarding NECC's process for producing sterile drugs.

- From October 24, 2002, until February 10, 2003, FDA and the Massachusetts Board of Pharmacy (MABP) conducted a jointly coordinated inspection to follow-up on adverse event reports received in July and August 2002 of bacterial meningitis associated with methylprednisolone compounded by NECC.

- In a meeting held on February 5, 2003, toward the end of the 2002-2003 inspection, FDA and MABP jointly decided that MABP would take the lead in enforcement and inspections of NECC's compounding operations since NECC was functioning as a compounding pharmacy. On February 10, 2003, FDA issued a 483 closing out its inspection. The firm responded on February 26, 2003, and supplemented its response on May 20, 2003, describing the corrective steps the firm was taking in response to the 483.

- FDA inspected NECC from September 23, 2004, until January 19, 2005, in a focused inspection related to a competitor's complaint that NECC had compounded a drug using bulk active ingredients that were not a component of an FDA-approved drug. FDA subsequently approved another firm's application to market the drug, and FDA issued a Warning Letter in December 2006 to NECC stating the firm was compounding copies of commercially available products; compounding standardized anesthetic drug products, which was outside the scope of traditional pharmacy compounding; and repackaging Avastin. The Warning letter charged that the copies of the FDA approved drugs and the anesthetic cream were misbranded and that the repackaged Avastin was an unapproved new drug. The Warning Letter did not pertain to sterility failures at NECC. During the 2004-05 inspection, FDA reviewed NECC's procedures in light of the February 10, 2003 483 and concluded that corrective actions had been implemented.

- In January 2006, NECC entered into a consent agreement with the Commonwealth of Massachusetts related to inadequacies in the firm's sterile and non-sterile compounding

practices. The consent agreement required NECC to hire a consultant and take corrective actions, which would be verified by the consultant. In June 2006, MABP notified NECC that the firm had fulfilled the terms of the consent decree.

- In January 2007, NECC responded to the 2006 Warning Letter.

- FDA responded to NECC's Warning Letter response in October 2008.

Timeline for Ameridose

- Ameridose first registered with FDA in September 2006, but never listed any drugs.

- FDA and MABP conducted a jointly coordinated inspection of Ameridose in December 2007 to follow-up on a complaint related to the company making IV solutions without receipt of patient-specific prescriptions and to gather facts since the firm had recently registered with FDA. FDA advised the firm to validate and verify its aseptic processes since it was making sterile products.

- FDA performed a second inspection of Ameridose seven months later (July-Aug. 2008). This was an inspection to review the firm's "good manufacturing practices." The agency issued the firm a 483 on August 6, 2008, citing several observations, such as not confirming the sterility of products before distribution. Ameridose responded in August 2008 stating that it would take corrective actions to address FDA's observations in the 483.

- During the 2008 inspection, FDA also collected samples of Fentanyl (a strong pain medication), which was found to be super-potent, leading to a Class I recall in September 2008.

- In September 2008 and November 2008, FDA returned to the firm to review shipping records specific to the super-potent Fentanyl, to review the firm's corrective and preventative actions since the September 2008 recall, and to follow-up on questions discussed during the prior inspection.

- In June 2010, FDA received a commercial complaint related to the compounded product nicardipine and conducted at the same time as MABP a limited inspection in response. In January 2011, FDA was informed that the complainant and Ameridose reached an amicable resolution. Massachusetts officially dismissed the complaint in June 2011.