

Date	Complaints FDA Received Associated with NECC and Ameridose
March 2002	Two adverse events were reported to FDA involving NECC betamethasone injections causing meningitis-like symptoms in patients.
July-August 2002	Three adverse events were reported to FDA involving NECC methylprednisolone acetate injections causing meningitis-like symptoms in patients.
February 2004	FDA received complaint from a law firm relating to NECC's promotion of trypan blue, a product reportedly being used for capsular staining during cataract surgery that was approved in other countries at the time, but not in the U.S.
May 2004	The Massachusetts Board of Pharmacy (MBP) forwards FDA a copy of a complaint report regarding an Iowa hospital pharmacy director's complaint about NECC soliciting compounded products for cataract surgery, most likely trypan blue.
June 2004	The MBP forwards FDA a copy of a complaint report regarding NECC's solicitation of free samples of a standardized topical anesthetic cream to plastic surgeons under the name "Extra Strength Triple Anesthetic Cream." FDA was aware of two deaths associated with such creams compounded by two other companies.
October 2005	FDA receives complaint from a law firm relating to NECC's compounding and distribution of repackaged Avastin for use in treating age-related macular degeneration.
January 2006	FDA is made aware of NECC soliciting multiple-use vials of injectable methotrexate, informing potential purchasers "they only need the physician's name and telephone number" and they "do not need or desire to have the patient's name."
February 2006	FDA is forwarded another NECC solicitation. This time, in addition to the repackaged Avastin, NECC was offering several other sterile injectable products.
February 2007	FDA receives an envelope of documents from an anonymous sender highlighting that NECC continued with practices that were mentioned in the Warning Letter, including the repackaging of Avastin and compounding of other sterile injectable products.
May 2007	FDA receives a MedWatch report "alleging Ameridose is engaged in the manufacture of unapproved intravenous solutions that are not dispensed pursuant to a prescription."
June 2007	FDA receives a MedWatch report about a patient receiving an NECC-repackaged Avastin injection for macular degeneration in April 2007 and, on the same day, developing a severe eye infection and needing emergency surgery.
November 2007	Ohio Board of Pharmacy emails FDA stating, "I have a company named Ameridose (which appears to be a subsidiary or an associate of New England Compounding Center – same or similar corporate officers) who is offering to sell pre-filled syringes to hospitals . . . who have purchased . . . infusions pumps." The email concludes, "[T]his appears to be just another episode of drug manufacturing being self-classified as compounding in order to make everything appear to be legitimate."
December 2007	FDA receives a call from a physician who had administered epidural injections of betamethasone from NECC to numerous patients who then experienced severe flu-like symptoms. FDA investigator interviews the physician and several of his patients within a week of receiving the call. According to the report, the physician reported that he received several vials from NECC between August and October, 2007 that were discolored and contained particles. He discarded those particular vials but administered injections to patients from other NECC vials. The investigator collects samples remaining from the lot and had them analyzed for sterility, potency, and contaminants. No bacterial endotoxin was detected, and the samples met FDA requirements for assay and identification. FDA investigator forwards report to FDA's New England District Office for follow-up.
May 2008	Ohio Board of Pharmacy reaches out to FDA again, this time regarding lidocaine injections, stating, "Before the Board issues a Cease & Desist letter to [Ameridose], telling them to stop shipping manufactured products into Ohio under the guise of compounding, I wonder if you could verify for me whether or not this is a legitimately manufactured product that is made by an FDA approved manufacturer?"

June 2008	FDA's New Orleans District Office receives separate, though related, information from a drug distribution company about betamethasone being made and distributed by NECC. The company representatives were concerned that this compounded product was being injected into the spine. A memorandum of this meeting, along with three different sizes of NECC vials, is shared with the New England District Office.
October 2008	FDA's Los Angeles District Office receives a complaint about a patient being hospitalized after having been intravenously administered a mesotherapy product compounded with phosphatidylcholine by NECC. According to the report, the patient was hospitalized with blood clots in his arm and hand after receiving the injection. FDA conducts analysis of product, though results are not received until February 2009.
February 2009	Results from testing of samples from the suspect lot of mesotherapy injections are superpotent and show signs of degradation.
September 2009	FDA receives complaints about NECC mass producing and distributing sodium tetradecyl sulfate and erythromycin ointment without patient specific prescriptions.
October 2009	CDER receives an anonymous email from an Ameridose employee: "July/August 2008 the FDA came to Ameridose LLC in [F]ramingham, [MA] for an inspection. The company performed illegal and unethical actions. They directed the testing facilities they use to change reports, based on the drug[] results. They forged documents, forced employees to direct others to do so. . . . [Gregory Conigliaro] silently directs people to change results, doctor the findings but hides in his office. . . . VP is Sophia Pasedis, Pharm D all licenses are in her name, she too is frauduelent [sic]."
June 2010	FDA receives a complaint from a drug company who manufactures and markets nicardipine products regarding "Ameridose's pre-mixed nicardipine injection products."
July 2010	After the limited inspection, FDA receives an anonymous complaint from a "pharmacist in the manufacturing department" at Ameridose who raised concerns about a product potentially being contaminated with particulates and having been released.
July 2010	FDA receives MedWatch report associated with a nurse administering an Ameridose product to a patient before noticing "a white precipitate below the rubber plunger" which extended "about ¾ inch along the plunger's base."
August 2010	FDA receives another call from the Ameridose informant alleging that not only was the Ameridose sales team "assisting in labeling operations in a clean room" but that "one of the 3 clean rooms had a positive result for mold growth." The informant also alleged that Ameridose was tampering with its sampling procedures, stating that the company would "clean the area first before taking the [environmental] sample[s]."
August 2010	Informant called again a few days later stating that the mold was found in "the hood in which operations took place."
October 2010	FDA receives a letter from PharMEDium, another large scale compounding operations, regarding Ameridose's practices, specifically compounding from bulk APIs. The letter notes that if firms "are permitted to do this, it will drastically change the way such preparations are compounded nationwide and put the manufacture of large quantities of sterile drugs for use in compounding in the hands of those who are not approved or 'regulated' to perform that operation."
November 2010	FDA's Los Angeles District Office is informed by the state pharmacy board that Ameridose is repackaging succinylcholine and marketing the syringes to hospitals with expiration dates that far exceed the original manufacturer's, without corresponding package inserts explaining their justification.
February 2011	The Institute for Safe Medicine Practices (ISMP) notifies FDA of a concern they had with Ameridose's repackaging of concentrated Sodium Chloride into an IV bag. The complainant who contacted ISMP stated that the "drug is filled into an empty Hospira bag. This bag can be directly attached to any IV line and infused undiluted into a patient. The warning says 'May need to dilute'. There is no circumstance where this product would not need to be diluted prior to infusion. The commercial product is filled into vials and the cap reads 'MUST BE DILUTED'. It is not labeled as Sodium Chloride USP, nor does it say that it is sterile. As a practicing pharmacist, I am shocked that such a product would be allowed to be distributed for use in the United States."

May 2011	FDA's Denver District Office is informed by Colorado Board of Pharmacy that they issued a Cease and Desist Order to NECC for shipping compounded products to hospitals in Denver for office stock, as opposed to in response to patient-specific prescriptions.
May 2011	FDA hears from an optometrist with the Veterans Affairs Administration who questioned whether they could take advantage of NECC's Avastin repackaging services.
August 2011	An Ameridose informant notifies FDA "when packages are dropped on the floor employees are told to pick up and ship. He further stated that the bubble wrap is stored directly on the floor and that this room is dirty and is never cleaned."
October 2011	FDA's Office of Criminal Investigations (OCI) refers a confidential informant from Ameridose to the New England District Office. The informant alleged that Ameridose was repackaging Avastin and that sales people were in the clean room filling products. The head of CDER's Compounding Team informs the District Office to interview the informant but states that "CDER is in the process of drafting guidance on compounding and manufacturing" and that no inspections would be conducted until it was issued. Informant interview proceeds but is brief and the informant does not return for fear of retaliation on the part of Ameridose management.
November 2011	CDER receives a MedWatch report associated with Ameridose-produced Fentanyl—the same product that was recalled in 2008 for super-potency. This report stated that three pregnant women who were in labor had complained of poor pain control after receiving epidural fentanyl injections subsequently determined to have been made and distributed by Ameridose. The women ultimately had C-sections. The reporting physician or hospital pharmacist stated that they had "[n]otified [Ameridose] for investigation" and had "attempted to contact Ameridose numerous times over the last several weeks to find the outcome of the investigation."
January 2012	FDA receives an adverse event report associated with Heparin IV bags produced and distributed by Ameridose. According to the complaint, "We had a patient that the doctor had ordered a Heparin drip for. The patient had a bad and the labs came back that their level had not changed. They increased the drip and rechecked labs still no change. They changed the bag same processes and still not level. Pharmacy had lab test the lot number of the 2 bags on Tuesday and neither bag had any Heparin in the bags. These bags were made by Ameridose, a compounding pharmacy in Framingham, MA."
January 2012	FDA receives an additional report associated with fentanyl produced and distributed by Ameridose. This time, the complaint related to confusing labeling resulting in "2 near misses" where nurses had stated that "they almost gave their patient's [sic] 100mcg instead of 50mcg."
March 2012	FDA receives another adverse event report was submitted to FDA, again involving potency issues with pain medications produced by Ameridose. Again, according to the complaint, "Ameridose was contacted about the potential problem and is conducting an investigation."
March 2012	Less than two weeks later, FDA receives yet another report involving another "Hospital Close-call" associated with confusing Ameridose labeling.
May 2012	OCI again reaches out to the District Office noting that "they had recently received a complaint for Ameridose." The "anonymous complaint" that generated the discussion was "from HHS [U.S. Department of Health and Human Services] IG" and involved "drugs [being] misbranded, [and] not complying with GMPs."
July 2012	FDA's Denver District Office again reaches out to the New England District Office informing them that NECC had violated the Cease and Desist Order.