The Florida Academy of
PAIN MEDICINE
Integration & Innovation

New FDA guidance urges patient outreach regarding important drug recall related to Aspergillus Meningitis

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FLORIDA DEPARTMENT OF HEALTH COLLABORATES WITH HEALTH CARE PROFESSIONALS IN ONGOING FUNGAL MENINGITIS OUTBREAK INVESTIGATION

~New FDA guidance urges patient outreach~

The Florida Department of Health (DOH) continues to work in partnership with the Food and Drug Administration (FDA) and Centers for Disease Control in the evolving investigation of the multi-state fungal meningitis outbreak associated with New England Compounding Center (NECC) contaminated steroids. The FDA now questions the sterility of any injectable drugs, including drugs used in conjunction with eye surgery and open heart surgery, produced by NECC. **Based on new guidance from the FDA and with an abundance of caution, DOH is advising healthcare professionals to follow-up with patients at a minimum by letter, who received any NECC medication, after May 21, 2012, and to alert these patients to the potential risk of infection at the site of injection or adjacent tissue space.**

Link to FDA Advisement

"As the ongoing federal investigation has expanded to all NECC injectable products, we strongly urge all Florida health care professionals and health care facilities that used NECC products to alert patients to the possibility of infection," said State Surgeon General and Secretary of Health Dr. John Armstrong. "Any patient who received an NECC medication after May 21, 2012, and who has symptoms of infection, should seek medical attention immediately. At this time, the risk to public health is uncertain; we remain vigilant to ensure that the public is aware of this concern."

The NECC, in coordination with the FDA, the Massachusetts Board of Pharmacy and Centers for Disease Control and Prevention, initially recalled three lots of methylprednisolone acetate principally used for epidural back injections on Sept. 25. The recall notice was expanded to include 12 injectable products from NECC on Oct. 5. With FDA guidance, NECC voluntarily recalled all NECC medications on Oct. 6. On Oct. 15, the FDA issued a MedWatch Alert advising health care professionals and facilities to conduct outreach to any patient who may have received any injectable NECC medications, including those used in eye or heart surgeries, since May 21, 2012. DOH continues to collaborate with the Florida Department of Business and Professional Regulation, professional medical associations, and affected clinics to ensure that NECC medications are recalled appropriately in Florida.

The signs and symptoms of meningitis related to epidural NECC medication injections include fever, headache, stiff neck, nausea and vomiting, sensitivity to light, and altered mental status. Symptoms for other possible infections related to NECC medications include fever; swelling, increasing pain, redness, warmth at injection site; vision changes, pain, redness or discharge from the eye; chest pain, or drainage from the surgical site (infection within the chest).

DOH will continue to update our website at http://newsroom.doh.state.fl.us/.

We have set up a toll-free hotline at 1-866-523-7339 for those who may have additional questions. To view the FDA's list of NECC products, please visit http://www.fda.gov/Safety/Recalls/ucm322979.htm.

The Department works to protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.