

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Rick Scott
Governor

John H. Armstrong, MD, FACS
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Vision: To be the **Healthiest State** in the Nation

FOR IMMEDIATE RELEASE
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FLORIDA DEPARTMENT OF HEALTH RESTRICTS PERMIT FOR VILLAGE FERTILITY
~Pharmacy restricted from shipping or dispensing in Florida~

TALLAHASSEE- On February 26, 2013 the Florida Department of Health executed a voluntary agreement to restrict practice with Village Fertility Pharmacy in Waltham, MA. The state of Massachusetts issued a Cease and Desist order and a notice of Quarantine against the pharmacy on February 20 after possible contamination of vials of progesterone, a hormone used to aid in fertility. Village Fertility is a sterile compounding pharmacy which also holds a non-resident pharmacy permit in Florida.

Black particulate matter was observed in 10 ml multi-use vials of the intramuscular progesterone oleate. Particulates have not been observed in other products manufactured by the company, however, the Massachusetts Board of Pharmacy has advised Village Fertility to recall all products based on the common production involved. Vials containing contaminant have been sent for testing to a Food and Drug Administration lab and after five days of culture there has been no growth of any biological material. Final results will be available March 7, 2013. There have been no reported adverse reactions to these products.

The notice issued by the state of Massachusetts requires Village Fertility to cease and desist all sterile compounding, quarantine all compounded sterile products on its premises and notify all patients who received certain vials. The voluntary agreement to restrict practice instructs Village Fertility Pharmacy to immediately cease compounding medications for Florida residents and to cease dispensing or shipping medications it has previously compounded to Florida residents.

There were 95 patients in Florida who received the recalled compounded products, leuprolide acetate and progesterone oleate. The Department of Health is proactively reaching out to recipients of these products to insure they were in fact notified by Village Fertility and that they are no longer in possession of any of the recalled products.

The Department remains vigilant to assure the safety of Florida's drug supply. The Department's inspectors receive comprehensive training in sterile compounding and carry out a prioritized inspection schedule based upon the results of a mandatory pharmacy compounding survey. That survey resulted in 55 complaints being opened and two emergency suspension orders being issued. The Florida Board of Pharmacy is also conducting a series of workshops to amend its rules governing the practice of compounding. The next workshop is scheduled for March 22, 2013 in Orlando.

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