DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office One Montvale Avenue Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	2/21-2/25/13, 2/28/13, 3/5 & 3/13/13 FEI NUMBER 3008335877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Stuart P. Levine, President and Owner

FIRM NAME	STREET ADDRESS
Village Fertility Pharmacy, Inc.	335 Bear Hill Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Waltham, MA 02451	Producer of Sterile Drug Products

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

1. Visible particulates were seen in the following drug product lots which had been stored at the firm:
   - On 02/21/2013, we observed eighty-four (84) vials out of a bin containing (b) vials of Progesterone in Ethyl Oleate (with preservative) 50mg/mL from Lot EO31 (shipped to customers between 02/6/2013 – 02/16/2013 according to distribution data), a sterile injectable drug, to contain what appeared to be dark colored foreign matter.
   - On 02/22/2013, we observed 7 vials out of a bin containing (b) vials of Progesterone in Sesame Oil (with preservative) 50mg/mL from lot SO36 (shipped to customers between 02/13/2013 and 02/20/2013 according to distribution data), a sterile injectable drug, to contain what appeared to be whitish fibers or translucent filaments.

2. The firm failed to adequately evaluate product integrity incident reports, received from patients and healthcare practitioners, for injectable Progesterone produced in various solutions (e.g. sesame oil and ethyl oleate). Neither root-cause analysis nor corrective/preventive actions were identified or documented by the firm to avoid future occurrences of the incidents. For example:

   A. Two different incident reports were received for Progesterone in Ethyl Oleate which were not evaluated:

      - Product integrity incident report with date 07/01/2012 states a registered nurse reported black particles in Progesterone in Ethyl Oleate (Lot EO09).

      - Product integrity incident report dated 02/18/2013, states patient had a vial from the last order of Progesterone in Ethyl Oleate with particles floating in it. The patients' prescription for this product had been filled last on 01/07/2013. The lot number dispensed was not recorded.

      During a field examination on 02/21/2013, visible particulate (i.e. dark, black particles) was observed in approximately 84 of (b) vials examined of Progesterone in Ethyl Oleate Injectable 50mg/mL (Lot EO31, beyond use date 04/15/2013). This lot of Progesterone was made at the firm on 01/15/2013.

   B. A product integrity incident report with date 07/10/2012 states a patient used Progesterone in Sesame Oil and had a bad reaction. The medical doctor told the patient the medication was contaminated and to throw it away.

      During a field examination on 02/22/2013, visible particulate (i.e. whitish fibers) was observed in approximately 7 of (b) vials examined of Progesterone in Sesame Oil Injectable 50mg/mL (Lot SO36, beyond use date 04/09/2013). This lot of progesterone was made at the firm on 01/09/2013.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Philip Kreiter, Investigator Debra M. Emerson, Investigator	3/13/13

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

3. Although the formula worksheets state that the API and raw materials are non-sterile and the vials are sterile, the pharmacy technician responsible for mixing and filling all compounded products explained that the vials and stoppers are received non-sterile. The technician stated as of late 2012 she began to place some of the vials and stoppers into the (b) (4) prior to being used in filling. Of note, there is no documentation on the formula worksheet to indicate whether or not the stoppers and vials used in the filling of each lot had been previously processed through the (b) (4).

   The firm provided no documentation or evidence to support that the (b) (4) cycle that is used to sterilize the glass vials and stoppers is effective. In addition, the firm provided no documentation or evidence to support that the (b) (4) which used to sterilize progesterone and hydroxyprogesterone formulations using non-sterile API and raw materials is effective.

4. On 11/23/2012, the firm made Leuprolide 40mcg/0.1ml, lot K2312-20, 5ml filled vials. The firm made a total of (b) vials. One vial was sent for potency testing on 11/30/2012, and the result was 78.72mcg/0.1ml (196.8% of the expected dose) which was reported on 12/10/2012. The firm dispensed eight of these vials to patients between 11/28/12 and 11/30/12. On 12/10/2012, the firm sent a second vial for testing, the potency result was 39.138mcg/0.1ml (97.8% of the expected dose). No investigation was performed by the firm.

***Dates of Inspection:**

02/21/2013 (Thu), 02/22/2013 (Fri), 02/25/2013(Mon), 02/28/2013 (Thu), 03/5/2013 (Tue), 3/13/13 (Wed)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."