

95 776

FILED

MAR 08 2013

BOARD OF PHARMACY

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street, 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

By: Megan Cordoma
Deputy Attorney General
Tel. (973) 648-3453

STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF THE REGISTRATION OF :	:
VILLAGE FERTILITY PHARMACY :	Administrative Action
Registration No. 28RO00042100 :	
TO OPERATE AS AN "OUT-OF-STATE" :	Interim Consent Order
PHARMACY PURSUANT TO :	
<u>N.J.A.C. 13:39-4.19</u> :	

This matter was opened to the New Jersey State Board of Pharmacy ("Board") upon receipt of information that on or about February 20, 2013, the Massachusetts Board of Registration in Pharmacy issued a Cease and Desist and Quarantine Notice ("Notice") to Village Fertility Pharmacy, located in Waltham, Massachusetts, concerning particulate matter observed in vials of progesterone oleate and progesterone in sesame oil, sterile products compounded and dispensed by the Pharmacy. Village Fertility Pharmacy is registered to operate as an "out-of-state" pharmacy in New Jersey pursuant to N.J.A.C. 13:39-4.9, with registration number 28RO00042100.

The Massachusetts Notice required the Pharmacy to: (1) cease and desist all sterile compounding; (2) quarantine all compounded sterile products on its premises; (3) notify all patients who received vials from the lot of the recall, as well as notify the prescribers and patient care providers; and (4) arrange for patient continuity of care. The Pharmacy has also expanded its recall to include all compounded sterile products produced since November 22, 2012.

The Board has been advised that Village Fertility Pharmacy has already contacted all New Jersey patients who received medication subject to the recall via telephone and written correspondence.

The parties, having agreed to resolution of this matter without further formal proceedings, and Village Fertility Pharmacy, having agreed and given voluntary consent to the within Order and waiving any right to a hearing, and the Board finding the within disposition adequately protective of the public health, safety, and welfare, and other good cause having been shown;

IT IS THEREFORE on this 8th day of MARCH, 2013,

ORDERED AND AGREED that:

1. Village Fertility Pharmacy shall immediately cease and desist shipping, mailing, distributing or delivering in any manner, sterile compounded products pursuant to a prescription into the State of New Jersey; and cease and desist participation in any and

all central prescription handling arrangements involving New Jersey facilities.

2. Village Fertility Pharmacy shall provide a certification to the New Jersey Board of Pharmacy within ten days of the date this Order is filed identifying the name and address of each New Jersey patient who received medications subject to recall and attesting that each patient has been properly contacted and alerted pursuant to the directives of the Massachusetts Board of Registration in Pharmacy. The New Jersey Board of Pharmacy will hold all patient information confidential.

3. Village Fertility Pharmacy shall not commence shipping, mailing distributing or delivering in any manner, sterile compounded products into the State of New Jersey until the State of Massachusetts lifts all requirements in the current and any future Cease and Desist and Quarantine Notices and until further Order of this Board.

4. This Agreement is not and shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability or wrongdoing by any of the Registrants including their officers, directors, managers, and employees.

5. The entry of the within Order is without prejudice to the further investigation and/or prosecution of any violations by respondent of any statutes or regulations governing the practice of Village Fertility Pharmacy in the State or any violations of law, by the Board, the Attorney General or any other regulatory or law

enforcement agency, including but not limited to any pending matters under investigation.

NEW JERSEY STATE BOARD OF PHARMACY

By: Edward G. McGinley
Edward G. McGinley, R.P.
Board President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Dated: _____

PRINT NAME: _____

TITLE: _____
on behalf of and duly authorized
by Village Fertility Pharmacy

enforcement agency, including but not limited to any pending matters under investigation.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Edward G. McGinley, R.P.
Board President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Stuart Levine

Dated: 3-6-13

PRINT NAME: STUART LEVINE

TITLE: PRESIDENT.
on behalf of and duly authorized
by Village Fertility Pharmacy