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FILED

MAY 03 2013

BOARD OF PHARMACY

By: Megan Cordoma
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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 :
: **Pallimed Solutions, Inc.** : Administrative Action
Registration No. 28RO00068100 :
: **Interim Consent Order**
TO OPERATE AS AN "OUT-OF-STATE" :
PHARMACY PURSUANT TO :
N.J.A.C. 13:39-4.19 :
:

This matter was opened to the New Jersey State Board of Pharmacy ("Board") upon receipt of information that on or about March 23, 2013, the Massachusetts Board of Registration in Pharmacy issued a Cease and Desist and Quarantine Notice ("Notice") to Pallimed Solutions, Inc., located in Woburn, Massachusetts, concerning sterile products compounded and dispensed by the Pharmacy. To date, there have been no reports of patient harm related to the observed contamination. Nevertheless, Pallimed Solutions, Inc. issued a voluntary recall of 16 sterile compound products, including injectable testosterone, and agreed to stop all sterile compounding activities following an inspection conducted by

the Food and Drug Administration and the Massachusetts Board of Registration in Pharmacy. Inspectors observed filaments in vials of Trimix, Bimix (Lot 02252013@3), Alprostadil, bacteriostatic water for injection (Lot 01072013@28) and DMSO 50 percent irrigation (Lot 03122013@19). The recall is limited to sterile compounded products dispensed on or after January 1, 2013.

The Massachusetts Notice required the Pharmacy to: cease and desist all sterile compounding and quarantine all compounded sterile products on its premises.

Pallimed Solutions, Inc. is registered to operate as an "out-of-state" pharmacy in New Jersey pursuant to N.J.A.C. 13:39-4.20, with registration number 28R000068100.

The parties, having agreed to resolution of this matter without further formal proceedings, and Pallimed Solutions, Inc., 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 3RD day of MAY, 2013,

ORDERED AND AGREED that:

1. Pallimed Solutions, Inc. 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. Pallimed Solutions, Inc. 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 to the manner in which each patient has been contacted and alerted regarding the recall. The New Jersey Board of Pharmacy will hold all patient information confidential.

3. Pallimed Solutions, Inc. 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 Pallimed Solutions, Inc. 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.

James Nahill, RP
Owner and RPIC
on behalf of and duly authorized
by Pallimed Solutions, Inc.

Dated: _____

Consent as to form and entry:

Print Name:
Attorney for Pallimed Solutions, Inc.

Dated: _____

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.



James Nahill, RP
Owner and RPIC
on behalf of and duly authorized
by Pallimed Solutions, Inc.

Dated: 4/14/2013

Consent as to Form and entry:

Print Name:
Attorney for Pallimed Solutions, Inc.

Dated: _____