



California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

ORDER TO CEASE AND DESIST

Date: February 27, 2018

Permit No.: NSF 110

Name as shown on Permit: PHARMEDIUM SERVICES LLC

Address: 12620 W AIRPORT BLVD STE 130 SUGARLAND TX 77478

California Business and Professions Code Section 4129.4 provides that whenever the board has a reasonable belief, based on information obtained during an inspection or investigation, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

California Business and Professions Code Section 4129.2 (b) requires a nonresident outsourcing facility to compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

Pharmedium Services LLC, a non-resident outsourcing facility compounded products to be distributed into California without complying with regulations of the board and with federal current good manufacturing practices (cGMPs) applicable to outsourcing facilities, including but not limited to:

1. 21 CFR 211.42(d): cefazolin (penicillin derivative) produced in same primary engineering control (PEC) as other products and stored with other products.
2. 21 CFR 211.46(d): cefazolin (penicillin derivative) produced in same PEC in room with 24 hoods with same air handling system and stored with other products with the same air handling system.
3. 21 CFR 211.84(b): components and container closures not sampled and tested prior to use.
4. 21 CFR 211.84(d)(2): no testing of components for compounded products prior to compounding process. Out of date vendor qualifications.
5. 21 CFR 211.94(a): no container closure integrity studies available for review.
6. 21 CFR 211.122(a): dosage and administration specified by Section 503B (a)(10)(B)(iii) not evident on all labels. One product repackaged from original container labeled "Not for Direct Intravenous Use" did not include this warning on the label. Products labeled injection without specifying intravenous, intramuscular or subcutaneous.

7. 21 CFR 211.137(a): expiration dates assigned without sound scientific support.
8. 21 CFR 211.160(a): visual product inspection did not occur 100% of the time and a black and white board with a light was not available during inspection.
9. 21 CFR 211.166(a)(3): inadequate data used to determine expiration dating.
10. 21 CFR 211.170(a): no retained samples or standard operating procedure describing retained samples.
11. 21 CFR 211.188(b)(7): no statement of actual yield or percentage of theoretical yield on batch records.
12. 16 CCR 1735.2(i)(2): beyond use dates assigned without sound scientific data
13. 16 CCR 1735.2(i)(3): beyond use dates assigned without method suitability test, container closure integrity test, and stability studies.
14. 16 CCR 1751.8(a): beyond use dates exceeded the allowance of the law.

Pharmedium Services LLC has failed to remedy these areas of non-compliance, despite being given multiple opportunities.

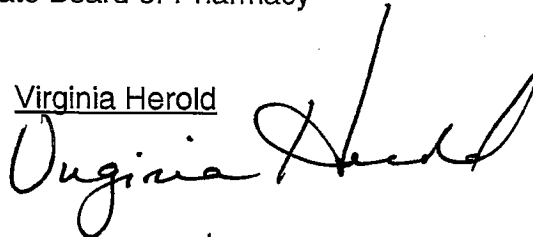
On the basis of the foregoing, the Board, through its Executive Officer, has a reasonable belief that drug preparations by Pharmedium Services LLC pose an immediate threat to the public health and safety in California, and therefore **ORDERS**:

Pharmedium Services LLC shall immediately **CEASE AND DESIST** compounding sterile drug products or nonsterile drug products for shipment into California. This cease and desist order shall remain in effect for 30 days or until the date of a hearing seeking an interim suspension order, whichever is earlier. Pursuant to Business and Professions Code section 4129.4(c), within 15 days of the receipt of this notice Pharmedium Services LLC may request a hearing before the president of the board to contest the cease and desist order.

California State Board of Pharmacy

By: Virginia Herold

Signed:



Date:

2/27/18

Title:

Executive Officer