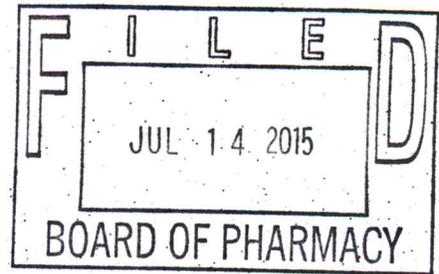


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STATE OF NEW JERSEY  
DEPARTMENT OF LAW & PUBLIC SAFETY  
DIVISION OF CONSUMER AFFAIRS  
STATE BOARD OF PHARMACY

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IN THE MATTER OF THE	:	<b>Administrative Action</b>
PERMIT OF	:	
	:	
<b>LIBERTY DRUG AND SURGICAL</b>	:	<b>INTERIM CONSENT ORDER</b>
PERMIT #28RS00390900	:	
	:	
TO OPERATE AS A PHARMACY	:	
IN THE STATE OF NEW JERSEY	:	

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This matter was opened to the New Jersey State Board of Pharmacy (the "Board") in or about May 2015, upon the receipt of information that Liberty Drug and Surgical ("Liberty"), located at 195 Main Street, Chatham, New Jersey, was engaging in sterile compounding with alleged violations of the Board's regulations regarding sterile compounding as well as the requirements set forth in Chapter <797> of the United States Pharmacopeial Convention ("USP"), and had allegedly violated a prior Board Order.

Liberty had entered into two prior interim consent orders with the Board related to its sterile compounding practices. The first Interim Consent Order, filed December 19, 2013, required Liberty to immediately cease and desist sterile compounding until further order of the Board. Liberty was required to obtain a third-party monitor to review compounding operations, and ensure that issues identified in the sterile compounding practices were addressed. By Interim Consent Order filed on January 31, 2014, Liberty was permitted to recommence sterile compounding operations. The order required Liberty to contract with a monitor to review compounding operations on at least two occasions before February 1, 2015 to ensure continued compliance. The Monitor was required to evaluate Liberty at unannounced visits and provide reports to the Board at approximately six-month intervals.

The Board's records do not reflect the receipt of any reports from the Monitor at the intervals required in the January 2014 interim order. Moreover, inspectors went into Liberty on several occasions, including on May 6, 2015, and found numerous alleged violations and concerns with the sterile compounding practices. These potential violations include an ante area that is not of sufficient size and that appears to have been constructed without notice to and inspection by the Board, unsupported beyond use dating on products, as well as

lack of proper environmental monitoring and documentation, cleaning and disinfecting, training and garbing, and failure to follow the written policies and procedures for compounding. It also appears that Liberty is shipping compounding products into states where Liberty does not hold a non-resident permit.

The Board recognizes that the volume of sterile compounding performed by Liberty is relatively small. Nevertheless, the Board finds that Liberty has demonstrated an inability to comply with the Board's regulations and USP <797> practices, even when it is subject to oversight by a third-party monitor. Thus, the Board has determined once again that cessation of all sterile compounding by Liberty is necessary to protect the public health, safety and welfare. The regular retail operations of the pharmacy will be permitted to continue normal operations.

The parties, having agreed to entry of this Interim Order without further formal proceedings, and Liberty, although disputing the Board's findings without admitting to any of the conduct alleged herein, 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 14TH day of JULY,  
2015,

**ORDERED AND AGREED THAT:**

1. Liberty shall immediately cease and desist from all sterile compounding operations, including both human and veterinary products.

2. Upon any application to resume sterile compounding operations, Liberty shall submit to the Board:

a. Its response to the alleged violations noted by the Board's inspector on May 6, 2015 as indicated on documentation furnished to Liberty at the time of the inspections;

b. Proof that Liberty will test all sterile compounded products, including doxycycline injectable, consistent with USP standards for sterility and stability;

c. Evidence that Liberty has made modifications to the ante area so that it addresses the Board's concerns. Liberty shall submit a remodeling application to the Board for approval prior to any construction, which will be reviewed within two weeks of receipt of the application by the Board office;

d. Results of all surface and environmental testing in the cleanroom and ante area following completion of construction and other corrective measures; and

e. Proof that it has submitted applications to all states where the pharmacy intends to ship medications to obtain the necessary permits for dispensing in those states.

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3. The Board will schedule an inspection of the pharmacy which will occur within seven business days of receipt of the pharmacy's request to resume sterile compounding, along with the information required by paragraph 2 above. In the event of an emergency leading to the unavailability of an inspector, the Board will notify counsel for Liberty. The purpose of the inspection is to ensure that Liberty is in compliance with the Board regulations and USP standards for sterile compounding and that all alleged violations noted in prior inspection reports have been addressed. The report of the inspection shall be presented to the Board for review.

4. On or about September 2, 2015, the RPIC and the compounding pharmacist shall appear before a committee of the Board, and testify regarding the pharmacy's adherence to all applicable State and Federal laws, regulations and USP standards, the failure to comply with the prior Board Order, and the practice of pharmacy in general. The recommendation of the committee shall be reviewed by the full Board at the September 30, 2015 Board meeting. In the event that Liberty has not completed all of the requirements of paragraph 2 of this order or the inspection of the pharmacy required by paragraph 3 has occurred less than three weeks prior to September 2, the inquiries will be rescheduled to a date convenient to all

parties and the ensuing committee recommendation will be reviewed by the full Board at next scheduled Board meeting following the inquiries.

5. Following full Board review of the Investigative Inquiry and all other information, the Board will determine whether to allow sterile compounding to resume and under what conditions. At that time the Board may also seek to impose final discipline relating to the events underlying the various interim orders and the pharmacy inspection reports.

6. This Consent Order shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability of the pharmacy.

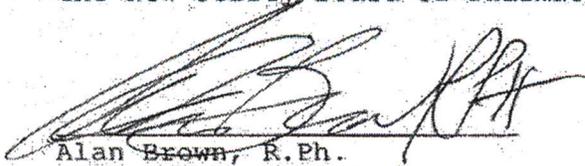
7. The entry of within Order is without prejudice to the further investigation and/or prosecution by the Board, the Attorney General, or any other regulatory or law enforcement agency of any violations by Liberty of any statutes or regulations governing the practice of pharmacy in the State of New Jersey or any violations of law, including but not limited to this or any other pending matters under investigation.

NEW JERSEY STATE BOARD OF PHARMACY

By:

*Thomas F.X. Bender, Jr. R.Ph.*  
Thomas F.X. Bender, R.Ph.,  
President

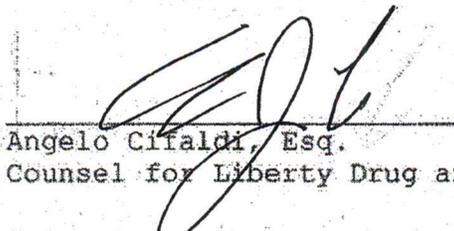
I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.



Alan Brown, R.Ph.  
Owner and RPIC, Liberty Drug and Surgical

Dated: 7/11/15

Consent as to form and entry of this Order:



Angelo Cifaldi, Esq.  
Counsel for Liberty Drug and Surgical

Dated: 7/15/15