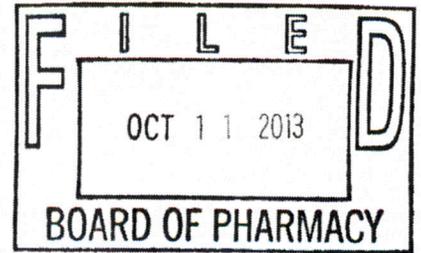


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STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF THE PERMIT OF

Administrative Action

BURGESS CHEMIST #2
Permit No. 28RS00400000

INTERIM CONSENT ORDER

TO OPERATE AS A PHARMACY
IN THE STATE OF NEW JERSEY

This matter was opened to the New Jersey State Board of Pharmacy ("Board") upon receipt of inspection reports of the facility at Burgess Chemist #2 ("Burgess"), located at 559 Franklin Avenue, Nutley, New Jersey. The reports appear to document myriad 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. These violations include concerns in the areas of general sterile compounding operations, training, environment, cleaning and disinfection, and compounding procedures. Moreover, it appears that Burgess began its sterile compounding operations prior to receiving written approval of the Board to do so, as required by N.J.A.C. 13:39-11.3.

Because of the danger to the public presented by improper practices in connection with compounded sterile products, the Board has determined that immediate cessation of all sterile compounding by Burgess is necessary to protect the public health, safety and welfare. The regular retail operations of the pharmacy, located on a separate floor from the compounding operations, would be permitted to continue its normal operations.

The parties, having agreed to entry of this Interim Order without further formal proceedings, and Burgess, 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 OCT, 2013,

ORDERED AND AGREED that

1. Burgess shall immediately cease and desist from all sterile compounding operations until further Order of the Board. Sterile compounding may only be performed for the limited purpose of allowing monitored observation of operations and compounding procedures by the Monitor as set forth below.
2. Burgess shall contract with a third party monitor ("the Monitor") pre-approved by the Board to review all compounding operations of the pharmacy. The Monitor shall ensure personnel follow proper aseptic techniques as well as proper gowning, garbing and gloving processes. The Monitor shall advise on proper batch testing protocol and air and surface sampline procedures. The Monitor shall further ensure that all necessary policies and procedures are in place for compounding operations in full compliance with Board regulations, USP <797> and all other applicable laws.
3. Prior to any application to resume sterile compounding operations, Burgess shall furnish the Board with a report from the Monitor, which demonstrates review of all processes and

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procedures, and attests to compliance with all Board regulations and USP standards. Burgess shall also provide proof of environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, Burgess.

4. Upon receipt of a request by Burgess to resume sterile compounding operations, the Board will schedule a reinspection of the pharmacy to ensure that all violations noted in prior inspection reports have been addressed. If requested by the Board, the RPIC of Burgess shall appear and testify before the Board or a committee thereof, attesting to the pharmacy's adherence to all applicable laws, regulations, and USP standards.

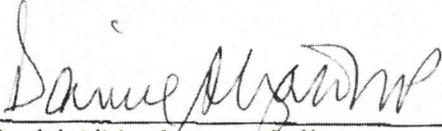
5. This Consent Order is not and shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability or wrongdoing by the Pharmacy.

6. The entry of the 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 the Pharmacy of any statutes or regulations governing the practice of pharmacy in the State or any violations of law, including but not limited to any 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.



Daniel Albizati

TITLE: owner RPh-in-charge
on behalf of and duly authorized
by Apteka, Inc. d/b/a Burgess Chemist #2

Dated: 10/8/13