SC Regs 99-43 (D)

D. Outsourcing Facility (503B) Permit

1. An Outsourcing Facility Permit is required for a facility engaged in the compounding of drug products at one geographic location or address which has elected to register with the U.S. Food and Drug Administration (FDA) as a 503B outsourcing facility.

a. Outsourcing facilities must establish and maintain compliance with section 503B of the Food, Drug, Cosmetic Act (FD&C Act) and FDA's current Good Manufacturing Practice (cGMP) requirements in section 501(a)(2)(B) of the FD&C Act pursuant to 21 CFR Parts 210 and 211.

b. An outsourcing facility dispensing patient specific prescriptions in this State must also be permitted as a South Carolina Pharmacy.

2. Outsourcing Facility Permit applicants must provide the following:

a. written application(s) on the form(s) prescribed by the Board along with the appropriate application fee(s);

b. the name, title and active South Carolina pharmacist license number for the designated Pharmacist-in-Charge;

c. a copy of policies and procedures for:

i. shipping refrigerated products

ii. monitoring temperature and humidity

iii. quality control

iv. quality assurance

v. product recalls

vi. complaint handling

d. a copy of a finished product label demonstrating compliance with applicable federal requirements.

3. In addition to requirements of SC Regs 99-43 (D) (2), applicants physically located in this State must also undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provisions of the Pharmacy Practice Act and cGMP requirements in section 501(a)(2)(B) of the FD&C Act.

4. In addition to SC Regs 99-43 (D) (2), applicants physically located outside of this State must submit the following:

a. a copy of the resident state outsourcing facility permit and DEA registration (if applicable); and

b. a list of all additional state permits and controlled substance registrations (if applicable); and

c. a copy of the facility's most recent FDA inspection report, including any 483s issued, the applicant's response thereto, the establishment inspection report (if applicable), and any warning letters issued (if applicable); and

d. a copy of all reports from operational inspections conducted within the last two years; and

5. Compounded or repackaged drug products obtained from outsourcing facilities:

a. must be obtained from facilities permitted to do business in South Carolina;

b. shall not be distributed by any entity other than the outsourcing facility that compounded the drug product.

6. The Pharmacist-in-Charge shall notify the Board within 30 days of occurrence of any of the

following:

a. disciplinary action issued by other states or the FDA to the outsourcing facility

b. FDA inspections of the outsourcing facility that resulted in issuance of a form 483