Ohio Licensed Outsourcing Facilities

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The Drug Quality and Security Act, signed into law on November 27, 2013, created a new section 503B in the United States Federal Food, Drug, and Cosmetic Act. Under section 503B, a compounder can become an "outsourcing facility."

Federal law defines an "outsourcing facility" as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register with the FDA as an outsourcing facility; and complies with all the requirements of section 503B.

These facilities are permitted to provide non-patient specific compounded sterile drug products that must meet current good manufacturing practice (CGMP) requirements. A list of registered FDA outsourcing facilities can be accessed here: https://www.fda.gov/drugs/human-drug- compounding/registered-outsourcing-facilities

Pursuant to section 4729.52 of the Revised Code, an outsourcing facility is prohibited from selling compounded products in Ohio unless they hold a valid license as outsourcing facility.

The FDA has recently developed a product report that lists drug products that outsourcing facilities produce. This report can be accessed here: https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities#reporting

Visit www.pharmacy.ohio.gov/list to download a spreadsheet of current licensed outsourcing facilities (download the drug distributor spreadsheet, then filter the "Business Type Code" column by OSC).

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