Steven W. Schierholt, Esq.
Executive Director

John R. Kasich
Governor

STATE OF OHIO BOARD OF PHARMACY

NONRESIDENT COMPOUNDING PHARMACY - ONE-YEAR EXTENSION REQUEST

Part 1 – Responsible Person Information - *To be completed by the applicant's Responsible Person.*

☐ **I certify that I will provide the State of Ohio Board of Pharmacy one (1) year from this application date any of the following:**

1. A National Association of Boards of Pharmacy's Verified Pharmacy Program documenting compliance with USP 797 and USP 795; or
2. A recent state inspection that is less than two (2) years old documenting compliance with USP 797 and USP 795. This inspection report can be from any state licensing agency.
3. A recent inspection conducted by conducted by the Accreditation Commission for Health Care Inspection Services that is less than two (2) years old documenting compliance with USP 797 and USP 795.
4. Proof of current Pharmacy Compounding Accreditation Board (PCAB) accreditation provided by the Accreditation Commission for Health Care (ACHC).

☐ **I will provide the requested compounding documents with this application to the State of Ohio Board of Pharmacy to ensure safe compounding practices in Ohio. (*See checklist on next page*)**

Responsible Person First Name	Responsible Person Last Name
Date of Birth	Social Security Number
Applicant Business Name	

Part 2 – Attestation by Responsible Person - *To be completed by the applicant's Responsible Person. Must be manually signed in ink.*

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921. AND 4729. OF THE OHIO REVISED CODE THAT THE ANSWERS PROVIDED ON THIS FORM ARE **TRUE, CORRECT, AND COMPLETE.**	
Signature of Applicant's Responsible Person	Date Signed
Print Name of Responsible Person	

CHECKLIST FOR NON-RESIDENT COMPOUNDING PHARMACIES REQUESTING AN ONE-YEAR EXTENSION

Please submit all the following if requesting a one-year extension:

□ List of the top ten (10) compounded products (sterile and/or non-sterile)
□ Floor lay-out/plan & Photo of compounding area
□ Copy of a prescriber provided prescription for sterile and/or non-sterile product
□ Copy of a pharmacy generated fax prescription for sterile and/or non-sterile product
□ Completed master formula and compounding record for a sterile and/or non-sterile prescription provided above
□ Copy of a patient label for prescription provided above
□ Recent potency testing for non-sterile compounded product *(if applicable*)
□ Recent potency and sterility testing for sterile compounded products
□ Beyond-use-justification if different than USP 797 & USP 795
□ Copy of recent hood certification(s), who certified the hood, date of certification
□ Types of Hoods
□ List of compounding references in the pharmacy
□ Policy and procedure manual for Sterile compounding pursuant to OAC 4729-19-04
    □ *Compounding* - Low, medium, high-risk, and or hazardous dangerous drugs
    □ *Dispensing* - proper storage, patient training, stabilities or incompatibilities of the medications, dosage form, dosage, route of administration, and duration of drug therapy
    □ *Delivery of sterile Products*: Deliver, offer to counsel, temperature controls
    □ *Quality Assurance Programs*:
        □ monitoring personnel qualifications
        □ Training, competency, and performance of all personnel
        □ Proper attire
        □ Aseptic technique
        □ Clean room conduct
        □ Clean room disinfecting procedures
        □ Product integrity
        □ End product testing
□ Resident State Sterile Compounding License (*if applicable)*