



NON-RESIDENT COMPOUNDING PHARMACY ONE-YEAR EXTENSION REQUEST

Statement to Be Completed by the Person who is Signing as Responsible Person (must be a Pharmacist) for a Terminal Distributor of Dangerous Drug (TDDD) license.

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

- A National Association of Boards of Pharmacy’s Verified Pharmacy Program documenting compliance with USP 797 and/or USP 795; or
- A recent state inspection that is less than two (2) years old documenting compliance with USP 797 and/or USP 795. This inspection report can be from any state licensing agency; or
- Proof of a current pharmacy compounding accreditation board (PCAB) accreditation provided by the accreditation commission for health care (ACHC); or
- The most recent inspection report that is less than two years old that demonstrates compliance with USP 795 and/or 797 conducted by accreditation commission for health care inspections services (a.k.a ACHS inspection services or AIS); or
- The board may grant a one-year, one-time extension to nonresident pharmacies in the event an inspection report is not available at the time of application or renewal and documentation is presented verifying intent to comply with this rule.

If an extension is requested, you shall provide the documents in the checklist included with this letter to the Ohio State Board of Pharmacy to ensure safe compounding practices in Ohio.

Business Name (name applicant will be DOING BUSINESS AS reflected by signage/how you will answer phone)	Terminal Distributor Number:
Street Address (No P.O. Box)	City, State, Zip Code

Printed Name of Responsible Person	Professional License No. / State Issued
Signature of Responsible Person	Date



**CHECKLIST ONLY FOR NON-RESIDENT COMPOUNDING PHARMACIES
REQUESTING A ONE-YEAR EXTENSION**

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

A List of the top ten (10) compounded products (sterile and/or non-sterile)

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 Sterile and/or non-sterile compounded product *(if applicable)*

Beyond-use-justification if different from USP 797 and/or USP 795

Copy of recent hood certification(s), who certified the hood, date of certification *(if applicable)*

Resident State Sterile Compounding License *(if applicable)*

Policy and procedure manual for **Sterile Compounding ONLY** pursuant to OAC 4729-19-04

A quality assurance program for monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education.

Justification for the chosen beyond use dates of compounded products.

Handling of cytotoxic waste, if applicable

Delivery Service, offer to counsel, and temperature controls