Compounding Product Quality Reporting Form

Updated 6/18/2021

Pursuant to rules 4729:7-2-03 & 4729:5-8-04 of the Ohio Administrative Code, all pharmacies (both in-state and non-resident) must report to the Board of Pharmacy within seventy-two hours upon discovery any product quality issue attributed to a compounded drug preparation dispensed by the pharmacy.

This form is only required to be submitted for a quality issue related to a compounded drug:

- **Dispensed by an Ohio pharmacy regardless of whether the compounded drug is sold; OR**
- **Dispensed by a non-resident pharmacy to an Ohio patient.**

For the purposes of reporting, a product quality issue means any of the following:

(1) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;
(2) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or
(3) Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond use date.

NOTE: A product quality issue does not include an isolated allergic reaction to a substance included in a compounded drug preparation.

Submission Instructions

This form can be used to report a single product quality issue. Please submit additional forms to report multiple product issues.

Completed forms must be sent via email to: compliance@pharmacy.ohio.gov

State of Ohio Board of Pharmacy
Compounding Product Quality Reporting Form (Rev. 6/2021)

Name of Compounding Pharmacy		**Ohio TDDD License No.**	
Street Address	**City**	**State**	**Zip**
Contact E-mail		**Telephone No. (XXX) XXX-XXXX**	

Product Quality Report

1. Product Description

Name of Product	**Lot # or Unique ID**	**Beyond Use Date**
Product Components/Ingredients	**Quantity of Compounded Product**	

2. Type of Product Quality Issue (select all the apply):

☐ Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;

☐ Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or

☐ Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond use date.

3. Date Product Quality Issue Occurred	**4. Issue Discovery Date**

5. State Where Product was Dispensed

6. Have there been any adverse events reported by patients/customers?

7. Has this issue been reported to FDA?

◯ **Yes (Date Reported:)** ◯ **No**

8. Detailed Description of the Product Quality Issue *(if more space is needed may include as a separate attachment)*

9. Follow-Up Actions Following Discovery *(if more space is needed may include as a separate attachment)*

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921. AND 4729. OF THE OHIO REVISED CODE THAT THE INFORMATION PROVIDED IN THIS FORM IS **TRUE, CORRECT, AND COMPLETE**.		
Responsible Person Signature	**Date**	**Printed Name**

Attestation must be signed by the Responsible Person in wet ink. This form must be scanned and submitted, along with any attachment, via email to:
compliance@pharmacy.ohio.gov