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.

<u>*What is considered a significant chemical, physical, or other change or deterioration in the dispensed compounded drug preparation?</u>

77 S. High Street, 17th Floor
Columbus, OH 43215 U.S.A.
Phone: 614 | 466 4143
Fax: 614 | 752 4836

To determine whether a chemical, physical, or other change or deterioration in the dispensed compounded drug preparation is significant, licensees should evaluate the potential impact of the change or deterioration on the drug's identity, strength, purity, stability, and efficacy and how that change, or deterioration could impact an individual using the drug. Any such assessment should be based on factors specific to your distributed compounded drug preparation. These factors could include intended use, route of administration, dosage, length of treatment, and patient population.

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

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