



U.S. Food and Drug Administration Guidance Document Applicability in Ohio

Updated 4/7/2026

This guidance highlights existing law and is intended for the benefit of licensees and the public to promote better understanding of the laws governing disciplinary action based on federal violations. Information contained in this document is not a substitute for consultation with legal counsel.

The Ohio Board of Pharmacy (Board) has received inquiries regarding how U.S. Food and Drug Administration (FDA) guidance impacts enforcement in Ohio. This document clarifies the Board's position on this topic.

Pursuant to the Ohio Revised Code (ORC) disciplinary sections applicable to entities licensed by the Board, violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 52 Stat. 1040 (1938); 21 U.S.C.A. 301; and/or federal law are also violations of state law that can result in sanctions against a Board licensee.ⁱ Similarly, pursuant to Ohio Administrative Code (OAC) rules adopted by the Board, federal law violations can result in sanctions imposed on licensees.ⁱⁱ

The FDA regularly issues guidance documents addressing various topics, which can be searched here: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. As noted in [21 CFR 10.115](#), the guidance documents are prepared for FDA staff, applicants/sponsors, and the public to describe the FDA's interpretation of, or policy on, a regulatory issue. The guidance documents do not establish legally enforceable rights or responsibilities and are not legally binding on the public or the FDA; however, they do represent the FDA's current thinking. Although parties may choose an alternative approach from that set forth in a guidance document, that alternative approach must comply with the relevant statutes and regulations.

Consistent with [21 CFR 10.115](#), the Board considers the FDA's guidance documents as strong persuasive evidence regarding the interpretation of the FD&C and other relevant federal law applicable to Ohio licensees. While an alternative approach may be taken by a licensee if it is consistent with federal statutes and regulations, the Board recommends that licensees first consult with counsel, the FDA, and/or the Board to determine if the alternative approach complies with federal and state law. If a licensee does not comply with an FDA guidance document and cannot satisfactorily demonstrate that its alternative approach was (1) approved by the FDA and/or the Board as compliant with federal statutes and regulations, or (2) independently demonstrate that the alternative approach is compliant, the Board may take disciplinary action against the licensee.

NOTICE ON DRAFT FDA GUIDANCE DOCUMENTS

21 CFR 10.115(g) outlines the process the FDA uses to develop and issue guidance. Absent some additional statement by the FDA, the Board would not consider a draft guidance document to be enforceable. However, the Board may consider the information contained therein as evidence of the direction the FDA is likely headed.

ⁱ See [ORC Section 4729.57\(B\)\(4\)](#) (terminal distributor of dangerous drugs can be disciplined for violating FD&C Act or 21 U.S.C. 301); [ORC Section 4729.56\(A\)\(2\)\(b\) & \(f\)](#) (wholesale distributors, manufacturers, outsourcing facilities, third-party logistics providers and repackagers can be disciplined for violating any federal drug law or provision of the FD&C Act).

ⁱⁱ See [OAC Rule 4729:5-4-01\(B\)\(4\)](#) (licensed terminal distributors of dangerous drugs may be disciplined for violating any provision of the FD&C Act or 21 U.S.C.A. 301); [OAC Rule 4729:6-4-01\(B\)\(2\) & \(7\)](#) (licensed distributors of dangerous drugs may be disciplined for violating any federal drug law or any provision of the FD&C Act); [OAC Rule 4729:1-4-01\(B\)\(2\)\(k\)](#) (pharmacists and applicants for a pharmacist license may be disciplined for violating any federal law, regulation or rule); [OAC Rule 4729:2-4-01\(B\)\(2\)\(i\)](#) (pharmacy interns or applicants for a pharmacy intern license may be disciplined for violating any federal law, regulation or rule); [OAC Rule 4729:3-4-01\(C\)\(2\)](#) (pharmacy technician trainees, registered pharmacy technicians, and certified pharmacy technicians or applicants for any such registration may be disciplined for violating any federal law or rule).