MINNESOTA
BOARD OF PHARMACY

Guidance: Addition of flavoring agents to manufactured non-sterile drug products

Pursuant to Minnesota Statutes 214.108, the Minnesota Board of Pharmacy (Board) can offer guidance to licensees about the application of the statutes and rules that the Board enforces. Such guidance is not binding in any court or other adjudicatory body. Some of the areas addressed below contain recommendations that do not have the force of law, while other areas concern issues that *are* addressed in statutes or rules; for those areas, the requirements in the law control. The Board strongly recommends that policies and procedures be developed with all these issues in mind, even those that are not addressed in statutes and rules. This document has been approved by the Board to offer guidance to pharmacists regarding the addition of flavoring agents to manufactured non-sterile drug products.

Introduction

Under USP's definition of compounding, adding a substance to a conventionally manufactured non-sterile drug product is generally considered compounding and is subject to USP <795> standards.

Minnesota has adopted USP <795> as compounding standards. Minnesota Rule 6800.3300, subpart 1 sets forth the standards for nonsterile compounding. The rule states that if pharmacies engage in non-sterile compounding, they must follow USP <795> standards.

As of the 2026 legislative session, MN Statute 151.01 Subd. 35 now reads in part, "*Compounding does not include the use of a flavoring agent to flavor a drug."* Subd. 44 defines **Flavoring agent.** "*Flavoring agent" means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug's taste and palatability*.

Board Guidance

Because of the conflict between statute and rules, the Minnesota Board of Pharmacy (Board) is providing the following information to clarify how these provisions will be interpreted and enforced.

The Board recognizes the importance of this service, particularly in the pediatric population. **Licensees that add flavoring agents to a conventionally manufactured product for the purpose of improving palatability must ensure that:**

- Individuals participating in adding a flavoring agent to a prescription must be knowledgeable on the process and competent.
- Flavoring agents must consist of inactive ingredients meeting the statutory definition, and their addition must not result in the final product concentration

varying by more than 10% from the labeled strength.

- If a pharmacy adds a flavoring agent to a manufactured product, it must still take into account the manufacturer's Beyond Use Date ("BUD") and the effect on stability caused by adding flavoring.
- Documentation maintained when adding a flavoring agent must include the required information below and be available for inspection and copying upon the request of the Board or an agent of the Board:
    - The flavoring agents, manufacturers and ancillary products, as well as their lot numbers, and expiration dates, and who added them.
    - Any relevant calculations and quantities/volumes of additives (e.g., water, flavoring agent(s), etc.).
- All dispensing steps must be accountable to the individuals completing each step.

SUMMARY

Based on the new MN Statute, a pharmacy may add flavoring to a non-sterile manufactured product, and it will not be considered compounding per USP <795> standards. Statutory language supersedes the Minnesota rule in this case. A pharmacy must follow the guidance above when adding flavoring agents to manufactured non-sterile drug products.

References:

Minnesota Statutes 214.108
Minnesota Statute 151.01 Subd. 35
Minnesota Statute 151.01 Subd. 44
Minnesota Rule 6800.3300 Subp. 1
Minnesota Rule 6800.0350
Minnesota Rule 6800.3100