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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item IV. Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations Repeal of Sections 1708.3, 1708.4, 1735 et seq and 1751 et seq and Addition of Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq Related to Compounded Drug Preparations, Including Review of Any Comments Received During the 45-Day Comment Period and Regulation Hearing

Background:

At the April 2023, Board meeting, the Board approved proposed regulation text related to Compounded Drug Preparations. This proposal amends the board's regulations regarding compounded drug preparations to implement, clarify, or make more specific requirements related to the United States Pharmacopeia-National Formulary, Chapter <795> for nonsterile compounding, Chapter <797> for sterile compounding, Chapter <800> for hazardous compounding, and Chapter <825> for radiopharmaceutical compounding.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on April 19, 2024, which ended on June 3, 2024. Additionally, Board staff held a regulation hearing on June 18, 2024 to accept oral comments. Numerous comments were received.

Attached following this memo are the following:

1. The proposed text released for the 45-day public comment period.
2. Board staff prepared summarized comments with recommendations.
3. Board staff recommended modified text.
4. Comments received during the 45-day comment period. (Comments from the regulation hearing are available to hear at the following website: <https://youtu.be/VDderHcJsEY>)

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed on April 19, 2024.
2. Amend the regulation to address concerns expressed by stakeholders and notice a second modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses and approved the Board staff recommended modified regulation text for a 15-day comment

period. Additionally, should no adverse comments be received, authorize the Executive Officer to take all steps necessary adopt the proposed regulation at Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq and complete the rulemaking process. Finally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.