



California State Board of Pharmacy

2720 Gateway Oaks, Suite 100

Sacramento, CA 95833

Phone: (916) 518-3100 Fax: (916) 574-8618

www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency

Department of Consumer Affairs

Gavin Newsom, Governor



July 3, 2024

Scott Brunner, CEO
Alliance for Pharmacy Compounding

Sent via email: scott@a4pc.org

Dear Mr. Brunner:

This is in response to the November 9, 2023, correspondence wherein you seek clarification on the California Board of Pharmacy's position and enforcement posture regarding the compounding of a drug that is "essentially a copy" of an FDA-approved drug when that drug appears as "currently in shortage" on the FDA shortage list. I apologize for the delay in providing this response.

Your letter indicates that the Alliance for Pharmacy Compounding has received reports from your members suggesting conflicting and confusing statements by California State Board of Pharmacy inspectors regarding semaglutide compounding. The Board cannot comment on any specific investigation, as each investigation is determined by the specific facts of that matter. Your letter asks the Board to provide specific responses to three items. The Board cannot provide such responses because the facts unique to each situation may alter the conclusions reached.

In general, the Board does try to align with FDA when possible. However, pharmacies providing compounded medications for California patients must comply with a myriad of state and federal laws including, but not limited to, provisions of the Federal Food, Drug, and Cosmetic Act; the Sherman Food, Drug and Cosmetic Act; California Pharmacy Law and its regulations and the standards of the United States Pharmacopeia. In addition, it is the Board's expectation that pharmacies that are compounding medications consider information released by FDA, including compounding alerts and other warnings supplied by FDA, when deciding to compound and with which substances.

Specifically related to semaglutide, FDA has released direction on at least two separate occasions specifically related to the issue. Here is a link to the FDA website regarding "Medications containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss:"
<https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss>

Sincerely,

Anne Sodergren

Anne Sodergren
Executive Officer, California State Board of Pharmacy

Cc: Seung Oh, President, California State Board of Pharmacy