

# Written Comments on Self-Assessments

**From:** [Bradshaw, Hal](#)  
**To:** [Rxwebmaster@DCA](mailto:Rxwebmaster@DCA)  
**Subject:** Draft Self-Assessments  
**Date:** Wednesday, June 17, 2026 10:04:26 AM  
**Attachments:** [image001.png](#)

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Because proof reading these takes a lot of time, please resend these after the board of pharmacy has proofread them for mistakes. This would allow me to focus on the content and clarity of the self-assessment.

For example,

Automated Drug Delivery System (ADDS) Self-Assessment

1.2 The use of the ADDS is consistent with legal CCR 1715.6 requirements, the ADDS is secure from access CCR 1715.65 and removal by **authorized** individuals, the 21 CFR 1301.76 pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion, and the pharmacy's policies and procedures include provisions for reporting to the Board and the DEA drug losses from the ADDS inventory, as required by law.

The highlighted word should be "unauthorized".

Thank you,

**Hal Bradshaw, PharmD**

Inpatient Pharmacy Manager - Operations

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**From:** [Chad Tinnes](#)  
**To:** [Rxwebmaster@DCA](mailto:Rxwebmaster@DCA)  
**Subject:** Compounding Self Assessment 1.4, 1.5  
**Date:** Sunday, June 14, 2026 9:03:15 AM  
**Attachments:** [thumbnail\\_outlook-jt05zjzj\\_7da60642-1f2d-4eac-96dc-edb67b3cf3ff.png](#)  
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Hello,

Regarding items 1.4 and 1.5 on the compounding self-assessment form:

If the prescription label already includes the statement “This medication is a compound...”, does this also satisfy the flavor requirements? Or is a separate flavor statement still required in addition to the compounded medication statement?

In my opinion, the compounded medication statement alone should suffice for compliance when it is already present on the Rx label. I agree that a separate statement about the flavor addition is appropriate if the pharmacist is simply adding flavor to a non-compounded product. However, in cases such as a compounded mouthwash that includes flavoring, the “This is a compounded medication” statement should be adequate.

I would appreciate it if this could be considered.

Thank you,

Chad Tinnes

**Chad Tinnes PharmD, RPh**

General Manager/Pharmacist-in-Charge



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**From:** [Shelby Bush](#)  
**To:** [Rxwebmaster@DCA](mailto:Rxwebmaster@DCA)  
**Subject:** Comments for Self Assessment Form  
**Date:** Monday, June 15, 2026 1:05:30 PM  
**Attachments:** [image002.png](#)  
[image004.png](#)  
[image005.png](#)  
[image006.png](#)  
[image007.png](#)  
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Hello CA BOP,

My only comment regarding the proposed self-assessment form would be in Section 1.7. Specifically, adding the red font (or something similar, to the following passage):

The facility does not compound:

- Drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective;
- A drug that is essentially a copy of one or more approved drugs **unless listed on the current FDA Drug Shortages list**;
- Drugs that have been determined to be demonstrably difficult to compound.

Thanks!

**Shelby Bush**  
Director of Quality, OurPharma

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June 22, 2026

California State Board of Pharmacy  
Business, Consumer Services and Housing Agency  
Department of Consumer Affairs  
2720 Gateway Oaks Drive, Suite 100  
Sacramento, CA 95833

**Re: Public Comment on Draft Outsourcing Facility Self-Assessment Form**

Dear Members of the Board of Pharmacy:

QuVa Pharma, Inc. (“Quva” or “we”) is an industry-leading provider of essential sterile injectable medications to more than 3,000 U.S. hospitals and the patients they serve. Quva operates two outsourcing facilities, each of which is registered with the U.S. Food & Drug Administration (“FDA”) under Section 503B of the Federal Food, Drug, & Cosmetic Act (“FDC Act”). The substantial majority of Quva’s compounded formulations rely on FDA-approved products (i.e., “sterile-to-sterile” compounding) as a starting point. Quva has held a non-resident California permit since 2017.

Quva shares the California Board of Pharmacy’s (the “Board”) sentiment set forth in the Board’s [Mission Statement](#) to promote “the health and safety of Californians by pursuing the highest quality of pharmacist’s care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.” Quva is also committed to a collaborative relationship with the Board, and appreciates the opportunity to provide the Board with its perspective on the draft Outsourcing Facility Self-Assessment Form (the “Self-Assessment Form”), which we understand will be considered by the Board for approval at its upcoming meetings on June 24, 2026 and June 25, 2026.

While Quva fully intends to comply with all California requirements, including those relating to the Self-Assessment Form should it be adopted, we note the below-listed concerns with the Self-Assessment Form as proposed:

**I. The Proposed Self-Assessment Form References FDA’s CGMP Regulations But Not FDA’s Guidance Documents Interpreting Such Regulations for 503B Outsourcing Facilities.**

California Business and Professions Code Section 4102 (Effective January 1, 2026) provides that each 503B outsourcing facility licensed by the Board shall complete a self-assessment of its compliance with federal and state laws identified on the form provided by the Board. Such self-assessment must be prepared biennially and as otherwise set forth in Section 4102.

The proposed Self-Assessment Form seems to require each 503B outsourcing facility to certify its compliance with FDA’s current good manufacturing practice regulations (“CGMP”), but omits any reference to FDA’s guidance documents interpreting the applicability of such CGMP to 503B outsourcing facilities, including FDA’s guidance titled, “Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Guidance for Industry” (Draft Guidance) (Jan. 2020) (“FDA’s 503B CGMP Guidance”).

As the Board may be aware, multiple sections of FDA’s 503B CGMP Guidance significantly modify in whole or in part FDA’s CGMP regulations set forth at 21 C.F.R. Part 211 as they apply to outsourcing facilities. As

just one illustrative example, Section 9.1 of the Self-Assessment Form (at p. 11) cites to 21 C.F.R. Part 211 Subpart I, and requests that each 503B outsourcing facility confirm that such facility “is in compliance with 21 C.F.R. sections 211.160 through 211.176 **in their entirety.**” (Emphasis added). Title 21 C.F.R. § 211.170(a)(1) states: “[f]or an active ingredient in a drug product ... [t]he reserve sample shall be retained for **1 year** after the expiration date of the last lot of the drug product containing the active ingredient.” (Emphasis added.) However, FDA’s 503B CGMP Guidance does **not** include a one-year retention requirement. Instead, FDA’s 503B CGMP Guidance provides that, “FDA generally does not intend to take regulatory action against an outsourcing facility regarding reserve sample requirements if ... the reserve sample **is held for at least 30 days following the expiration date.**” (Emphasis added). FDA’s 503B CGMP Guidance at 31-32.

If the Board intends to require outsourcing facilities to use the proposed Self-Assessment Form as a self-assessment tool, then we respectfully request the Board consider amending the proposed Self-Assessment Form to incorporate one of the three below-listed alternative approaches:

1. Remove in their entirety any draft sections or provisions that are inconsistent with FDA guidance documents for 503B outsourcing facilities.
2. Modify the proposed Self-Assessment Form to ensure that any references to FDA’s Code of Federal Regulations incorporate published FDA guidance documents applicable to 503B outsourcing facilities.
3. Simply add the following language (shown in underline) to the footnote at the bottom of page one of the proposed Self-Assessment Form:

1 Note: This self-assessment is not an all-inclusive compilation of all laws and regulations that may be applicable to an outsourcing facility. The facility is responsible for complying with all applicable laws and regulations, regardless of whether they are referenced on this self-assessment. The Board recognizes that compliance with applicable law is a complex matter, and responses to this self-assessment may rely on interpretive guidance published by federal or state regulatory bodies.

## **II. The Proposed Self-Assessment Form Appears to be Unnecessary to Ensure Compliance and Imposes Unnecessary Incremental Burdens on 503B Outsourcing Facilities, California Board Inspectors, and the Board.**

Quva understands that, if the Board adopts the proposed Self-Assessment Form, each resident and non-resident 503B outsourcing facility would be required to complete and maintain the Self-Assessment Form on a biennial basis and as otherwise required under Section 4102. We respectfully assert that such a requirement is unnecessary to ensure compliance with California and FDA requirements applicable to 503B outsourcing facilities. Specifically, California’s well-trained Board inspectors already comprehensively inspect resident and non-resident 503B outsourcing facilities on a yearly basis as part of Board’s rigorous license renewal process. In addition, prior to each inspection, California’s Board inspectors request and review detailed information and documentation concerning each 503B outsourcing facility’s current operations and processes. These responses, together with the comprehensive annual California renewal inspection ensure that compliance with each of the topics covered on the proposed Self-Assessment Form is maintained. To require each 503B outsourcing facility to continually repopulate the proposed Self-Assessment Form imposes an unnecessary incremental burden on each facility as well as the Board’s

June 22, 2026  
QuVa Pharma, Inc.  
California Board of Pharmacy

inspectors reviewing such Self-Assessments. In addition, it burdens the Board with the responsibility to monitor CGMP and other legal and regulatory requirements covered by the proposed Self-Assessment Form and update the proposed Self-Assessment Form each time a change is required. In summary, the proposed Self-Assessment Form appears to (i) be unnecessary to ensure compliance, and (ii) impose an unnecessary incremental burden on 503B outsourcing facilities, California Board inspectors and the Board itself.

Quva again thanks the Board for providing industry the opportunity to comment on the proposed Self-Assessment Form.

Respectfully submitted,



Amber Lucas, PharmD, MBA, BCPS, FASHP  
Vice President, Pharmacy Operations