PHARMACY BADASS UNIVERSITY

MEMBER ACTION GUIDE

HOW TO COMMENT ON THE HHS PEPTIDE POLICY

A 15-minute guide to getting your voice on the official record, with a fill-in-the-blank template you can use today.

DOCKET **HHS-OASH-2026-0496**

COMMENTS DUE NOV 13, 2026

> Comments on the HHS peptide compounding policy are due **November 13, 2026** on Docket **HHS-OASH-2026-0496** at regulations.gov. It takes about 15 minutes, and pharmacy owners are the people who know where this policy works and where it doesn't.

01 WHY YOUR COMMENT MATTERS

HHS says it may revisit this policy, and the comment docket is the official record it will read. Groups opposed to the policy are already on record against it. If independent pharmacies stay quiet, the record shows only one side.

Your comment can help:

- **Keep the door open.** A clear record that 503A pharmacies can do this safely, with real sourcing and testing, beats the alternative: patients buying "research use only" peptides online.
- **Fix the fuzzy parts.** Several conditions are vague enough that a careful pharmacy can't tell whether it's compliant. HHS can only clarify what people point out.
- **Shape the final rule.** This interim policy runs until FDA decides through rulemaking whether each peptide goes on the 503A bulks list. Comments now set the tone for that.

02 STEP-BY-STEP: SUBMITTING ON REGULATIONS.GOV

1. **Write your comment first** in a Word doc or email draft, using the template in section 04. Keep it to one or two pages.
2. **Go to** regulations.gov and search for the docket number: **HHS-OASH-2026-0496**.
3. **Open the docket** and find the document titled "Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances."
4. **Click "Comment."** Paste your text into the comment box, or attach your comment as a PDF or Word file.
5. **Fill in who you are.** Choose to comment as an individual or on behalf of your pharmacy, and add your name, credentials and pharmacy name. Comments from an identifiable pharmacist or owner carry more weight than anonymous ones.
6. **Leave out anything private.** Comments are posted publicly. No patient names or details, and nothing you'd mind a competitor reading.
7. **Submit and save your tracking number.** Screenshot the confirmation page for your records.
8. **Don't wait until the last day.** The window closes two weeks after the October 30 publication. Aim to submit by November 12.

QUESTIONS ABOUT THE DOCKET?

Contact the HHS person listed in the notice: Victoria Marshall, Office of the Assistant Secretary for Health, OASH-RFI@hhs.gov, 202-690-7694. Submit the comment itself through regulations.gov, not by email.

03 WHAT TO ASK FOR

Pick the two or three issues that matter most to your pharmacy. A focused comment with a specific ask is stronger than a long list.

ISSUE	WHAT THE POLICY SAYS NOW	WHAT TO ASK HHS FOR
Oral bioavailability (Condition 8)	Compounders must keep documentation that the specific oral formula is adequately bioavailable in humans. "Adequate" and the type of documentation aren't defined	Define what documentation satisfies the condition, and confirm whether a 503A pharmacy needs an IND to generate it
Semax nasal device (Conditions 2 and 9)	Appendix B allows Semax only for intranasal use, which requires a nasal delivery device. But Condition 9 names a 510(k)-cleared syringe as the only permitted drug delivery device	Confirm that a nasal spray pump is permitted for Semax, since HHS approved intranasal as its only route
COA acceptance limits (Condition 3, Appendix B)	Most tests just say "comply" with a USP or ICH chapter, with no peptide-specific numbers	Publish the specific acceptance limits (purity, impurities, endotoxin) pharmacies should expect on a COA
Reporting (Condition 5)	Report adverse events, quality issues and "products compounded" to MedWatch and each state. No deadline or format given	Give a timeframe, a format, and what "report products compounded" means in practice
Policy stability	Can be changed or withdrawn without notice	Commit to advance notice and a wind-down period before any withdrawal, so patients on therapy aren't cut off mid-course
Patient safety case	Policy aims to steer patients away from "research use only" products	Support keeping the policy, describing what you see when patients come in using unregulated online peptides (no patient identifiers)

THE WINNING POSITION

You can support the policy overall and still ask for clarifications. That's the most persuasive stance: **"Keep it, and make it workable."**

04 FILL-IN-THE-BLANK COMMENT TEMPLATE

Copy this, fill in the highlighted brackets, delete the issues you don't want to raise, and make it sound like you. HHS reads identical form letters as one comment, so change the wording and add your own story.

Re: Docket No. HHS-OASH-2026-0496
Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances

My name is **[Name, credentials]**. I am the **[owner / pharmacist-in-charge]** of **[Pharmacy name]**, a 503A pharmacy in **[City, State]**. We have served our community for **[X]** years and compound for **[types of patients/prescribers]**.

I support HHS's interim policy. In my pharmacy, I regularly see **[describe what you see, with no patient identifiers: e.g., patients who bought peptides online labeled "research use only" with no idea where they were made]**. A pathway that requires FDA-registered manufacturers, full certificates of analysis, a patient-specific prescription and adverse event reporting is far safer than what patients are doing today.

To make the policy workable for pharmacies that want to follow it carefully, I ask HHS to clarify the following:

1. Oral bioavailability (Condition 8): Please define what documentation satisfies "adequate oral bioavailability in humans" and confirm whether a 503A pharmacy must obtain an IND to generate it.

2. Semax nasal delivery device (Conditions 2 and 9): Appendix B permits Semax only for intranasal use, which necessarily requires a nasal delivery device, yet Condition 9 names a 510(k)-cleared syringe as the only permitted drug delivery device. Please confirm that a nasal spray pump may be used to dispense intranasal Semax.

3. COA acceptance limits (Appendix B): Please publish the specific acceptance limits pharmacies should expect to see on a certificate of analysis for each peptide.

4. Reporting (Condition 5): Please specify a reporting timeframe and format, and explain what reporting "products compounded" requires.

5. Stability: Please commit to advance notice and a reasonable wind-down period before any change or withdrawal, so patients mid-therapy are not cut off.

Thank you for the opportunity to comment.

[Name, credentials]
[Pharmacy name, City, State]

05 TIPS FOR A COMMENT THAT GETS READ

- [ ] **Be specific.** "Please define adequate bioavailability" lands. "This policy is confusing" doesn't.
- [ ] **Name the condition number.** It tells the reviewer exactly which part you mean.

- [ ] **Use your real experience.** What you see at your counter is the one thing nobody else can add. Keep patients anonymous.
- [ ] **Stay professional.** No attacks on FDA, HHS or other commenters.
- [ ] **Keep it short.** One or two pages beats ten.
- [ ] **Ask your team to comment too.** Pharmacists, technicians and prescribers you work with can each file their own comment.

06 SOURCES

- Federal Register notice, 91 FR 68526 (Oct 30, 2026)
- HHS Enforcement Discretion Policy (full text)
- Appendix B
- regulations.gov, Docket HHS-OASH-2026-0496

For the full breakdown of the policy's requirements, see our companion guide, *Peptide Policy Compliance Guide: The 6 Interim Peptides*.

This guide is for education, not legal advice. Current as of November 4, 2026.



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