February 17, 2026

Food and Drug Administration
10903 New Hampshire Ave
WO 51, Room 2231
Silver Spring, MD 20993

Submitted via e-mail: Louis.An@fda.hhs.gov; Compounding@fda.hhs.gov

Re: Statement for the Record for FDA Drug Compounding Annual Listening Session on February 27, 2026

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) welcomes the opportunity to provide a statement for the record to the FDA Drug Compounding Annual Listening Session on November 13. NCPA appreciates the willingness of FDA to engage in discussion with impacted stakeholders and hopes this productive dialogue will continue in the future.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA hopes that FDA will address our concerns below.

Concerns with Desiccated Thyroid Extract Being Labelled as Biological Products

FDA has stated that it has concerns with the safety and effectiveness of the unapproved animal-derived thyroid medications, and argues that they are regulated as biological products under the Public Health Service Act.[1] Additionally, in August 2025, FDA sent a letter to manufacturers, distributors, and importers of products containing natural desiccated thyroid extract (NDT/ADT), including API used in compounded forms and commercial products like porcine thyroid, stating that these products are unapproved biologics and will be subject to enforcement. In its letter, FDA indicated it will exercise 12 months of enforcement discretion to allow patients time to transition to FDA-approved therapies.[2]

Patients will face multiple issues if DTE remains classified as a biologic and is not classified as a drug. Patients may not have access to this therapy at all if there is not an approved biologic

[1] FDA's Actions to Address Unapproved Thyroid Medications. FDA.
[2] FDA Letter to Manufacturers, Importers, and Distributors of Animal-Derived Thyroid Products. APC 06 Aug 2025.]

product by August. Patients needing compounded doses or needing to avoid an allergen will no longer have a way for this medication to be compounded.

Concerns with Patient Access to cBHT

NCPA expresses concern with maintaining appropriate access to cBHT. An April 2022 meta-analysis in *Menopause: Journal of The North American Menopause Society* concluded that there is no evidence that compounded hormones pose an increased clinical risk compared to FDA-approved products.[3] This article also demonstrates that clinically relevant information regarding cBHT was omitted from the 2020 report[4] that the National Academies of Sciences, Engineering, and Medicine (NASEM) provided to the FDA.

We also re-iterate our arguments made in a September 2020 letter to FDA, jointly written with the National Alliance of State Pharmacy Associations (NASPA) and the Alliance for Pharmacy Compounding (APC).[5] In this letter, we criticize the NASEM report, especially considering that the NASEM committee lacked experts on compounding, and the NASEM report went well beyond its charge, which was to focus on the clinical utility of therapies, particularly when recommending that almost all hormones that are used in cBHT be considered for FDA's difficult to compound list. NCPA and its members who compound hormone therapies have engaged in several advocacy opportunities to gather patient and prescriber feedback on cBHT, including participating in a cBHT testimonial portal conducted by The Partnership for Personalized Prescriptions, as well as a prescriber survey.

Insanitary Conditions Overreach

In November 2020, FDA issued its final guidance *Insanitary Conditions at Compounding Facilities: Guidance for Industry*. Unfortunately, FDA failed to respond to most of the comments NCPA provided on November 26, 2018, when the original draft guidance was released. Now, nearly six years after NCPA submitted comments, there are still unresolved questions regarding the differences between the guidance and the requirements of USP <797>. Specifically, the encouragement of recalls of possibly contaminated product, adequate coverage of hair and skin when compounding drugs in sterile environments, and terms used by the FDA in the guidance left undefined and vague which makes compliance difficult and burdensome for compounders.

[3] See "Menopause publishes cBHT meta-analysis," Alliance for Pharmacy Compounding. April 1, 2022. Available through the Wayback Machine.
[4] See "The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use (2020)," National Academies of Sciences, Engineering, and Medicine.
[5] See Microsoft Word - Joint Pharmacy Draft Letter to FDA NASEM Report.docx (ncpa.org).

Addressing Drug Shortages

NCPA also urges FDA to continue to dialogue with stakeholders on addressing drug shortages. NCPA recommends that FDA adopt a policy to permit 503A compounding pharmacies to be a tertiary supplier of office stock compounded medications when others are unable to provide medications, as shown by the issues with supply during the Public Health Emergency and recognized by the Agency's Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry.[6]

NCPA supports the Drug Shortage Compounding Patient Access Act of 2025 (H.R. 5316), which creates a narrow path for 503A to source shortage drugs (on the FDA or ASHP shortage list) to hospitals and clinics when they cannot be acquired from a manufacturer or 503B.[7]

Demonstrably Difficult to Compound Federal Register Notice

FDA has issued a proposed rule[8] to establish criteria for two lists of drug products or categories of drug products that present demonstrable difficulties for compounding (Demonstrable Difficulties for Compounding Lists or DDC Lists) under certain sections of the Federal Food, Drug, and Cosmetic Act. Drug products or categories of drug products that appear on the DDC Lists cannot qualify for certain statutory exemptions, and therefore may not be compounded under, either section 503A or section 503B, respectively. FDA is also proposing to establish criteria for evaluating drug products or categories of products for inclusion on one or both lists. For evaluating drug products or categories of drug products for inclusion on the DDC Lists, FDA is proposing to establish the following criteria: the formulation complexity, drug delivery mechanism complexity, dosage form complexity, complexity of achieving or assessing bioavailability, compounding process complexity, and complexity of physicochemical or analytical testing of the drug product or category of drug products. Additionally, FDA is proposing to identify the first three categories of drug products on both DDC Lists: (1) oral solid modified-release drug products that employ coated systems (MRCs), (2) liposome drug products (LDPs), and (3) drug products produced using hot melt extrusion (HMEs).

While most of NCPA's compounders do not compound the above three categories under current technology, our compounders would like to reserve the right to compound such products in the future. NCPA advises that FDA include a process for the removal of items from the DDC list for

---

[6] https://www.fda.gov/media/137125/download.

[7] H.R.5316 - 119th Congress (2025-2026): Drug Shortage Compounding Patient Access Act of 2025 | Congress.gov | Library of Congress.

[8] See Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act (March 20, 2024). Federal Register, 19776. Available at: 2024-05801.pdf (govinfo.gov).

the future. Technology for compounding may evolve in the future and make certain things able to be compounded then that may not be possible now.

Additionally, NCPA opposes this proposed rule, as it does not believe that stakeholders had a sufficient notice and comment period.

Furthermore, FDA's proposed rule seeks to add categories of drug products to the 503A DDC list and 503B DDC list. Statutory language in Section 503B permits FDA to add categories to the 503B DDC list with the language "[…]**drugs or categories of drugs** that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients**,[…][NCPA emphasis]**."[9]

However, statutory language in the Section 503A states "such drug product is not a drug product identified by the Secretary by regulation **as a drug product** that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product;[…][**NCPA emphasis]**."[10] The omission of "categories" from the statutory language means that FDA is not allowed to add the 3 categories of products to the 503A DDC list. Therefore, FDA must not add the three proposed categories to the 503A DDC list.

FDA's Draft Report and Plan for Guidance Documents, Removing the Public Notice and Comment Period

FDA has also issued a notice of availability and request for comments for removing the comment period for draft guidance. Specifically, FDA sought input on whether there are any additional circumstances, categories of guidance documents, or topics for guidance for which it may be appropriate and consistent with the FD&C Act and FDA's GGP regulation for FDA to consider issuance as a Level 1 guidance document for immediate implementation without prior public comment. [11] Additionally, in the request for comments, FDA stated that for Level 2 guidance documents (i.e., guidance documents that set forth existing practices or minor changes in policy), the FD&C Act and FDA's GGP regulation require that FDA provide for public comment ***upon implementation*** [NCPA emphasis]. [12] Additionally, "FDA does not solicit public comment prior to

[9] See Compounding Quality Act, Section 503(B)(a)(6)(A), available at: https://www.fda.gov/drugs/human-drug-compounding/text-compounding-quality-act.
[10] See Federal Food, Drug, and Cosmetic Act, Section 503(A)(b)(3)(A), available at: https://www.fda.gov/drugs/human-drug-compounding/section-503a-federal-food-drug-and-cosmetic-act.
[11] See Food and Drug Administration's Draft Report and Plan on Best Practices for Guidance; Availability (January 3, 2024). Federal Register, 382. Available at: 2023-28872.pdf (govinfo.gov).
[12] See Food and Drug Administration's Draft Report and Plan on Best Practices for Guidance; Availability (January 3, 2024). Federal Register, 381. Available at: 2023-28872.pdf (govinfo.gov).

implementation of Level 2 guidance documents or of Level 1 guidance documents for which "prior public participation is not feasible or appropriate." [13]

NCPA is concerned that if finalized, FDA will use both Level 1 and Level 2 guidance to change compounding policy without proper notice and comment period for stakeholders, including from compounding pharmacies. NCPA did not have the opportunity to comment on this request for comment, as it did not explicitly mention compounding and thus evaded our search for comment opportunities. NCPA requests that FDA not use Level 1 and Level 2 guidance to circumvent the normal notice and comment period for compounding policies that FDA is considering. Instead, NCPA requests that FDA continue to use sufficient notice and comment periods in the Federal Register for stakeholders to comment on compounding policies prior to finalization.

Guidance for Industry #256

FDA should rescind its 2023 Guidance for Industry #256 (GFI 256). FDA seeks to regulate veterinary compounding, despite having no clear congressional mandate to do so. GFI 256 imposes broad restrictions on the use of bulk drug substances in veterinary compounding which undermine the clinical judgment of veterinarians and unnecessarily restricts access of compounded drugs for animals. If FDA insists on maintaining GFI 256, a much more revised GFI 256 would be appropriate – one which: respects veterinary practice, prescribing veterinarians, and the essential role of compounded medications in animal health, and one which streamlines the bulk substance nomination process, incorporating transparency in its evaluations.

Conclusion

NCPA believes there is a path forward on these issues which can meet the needs of patients and compounding pharmacists while ensuring the safety goals of the FDA. NCPA appreciates the opportunity to submit this statement for the record for the February 27 listening session. NCPA is committed to working with FDA and other stakeholders on these important matters. If the agency requires further information or has questions, please contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association

[13] See Food and Drug Administration's Draft Report and Plan on Best Practices for Guidance Federal Register, 6. Available at: Section 2505 Guidance Report and Plan (fda.gov).