June 1, 2023

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

Submitted via e-mail: Alissa.Gold@fda.hhs.gov; Linda.Joy@fda.hhs.gov; Compounding@fda.hhs.gov

Re: Statement for the Record for FDA Drug Compounding Annual Listening Session on June 15, 2023

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 June 15. 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 19,400 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 represent a $78.5 billion healthcare marketplace, employ 240,000 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.

Implementation of GFI 256

NCPA is grateful for FDA's Center for Veterinary Medicine (CVM)'s willingness to participate in productive conversations on the GFI. However, we question whether ongoing conversations on the GFI will lead to patient-centered change.

NCPA reiterates concern with GFI #256, issued in its final form by FDA in August.[1] Our concerns are similar to the concerns we expressed in comments to FDA to the draft GFI #256 in October 2020, and to GFI #230, which the Agency issued in 2015 and withdrew in 2017 following serious objections from stakeholders, such as veterinarians, pharmacists, and pet owners. In addition, in the final appropriations bills for FY2017 and FY2018, Congress included report language asserting that GFI #230 exceeded FDA's statutory authority. This final GFI #256 will likely inhibit veterinarians from properly treating their animal patients. Our additional comments will focus on issues we believe will

[1] "#256: Compounding Animal Drugs from Bulk Drug Substances - Guidance for Industry," August 2022. *Food and Drug Administration.* Available at: https://www.fda.gov/media/132567/download.

lead to decreased access to compounds for veterinary use and undermine the triad of care that exists between prescribers, pharmacists, and animal patients.

For the reasons stated below and in earlier provided comments, NCPA continues to request the FDA withdraw GFI #256.

1. **The final guidance misinterprets federal law and regulations issued by the FDA.**

Federal law is silent on compounding for animals from active pharmaceutical ingredients (APIs). It remains incongruent to have federal law say you can compound with APIs for humans but have FDA interpretation that would disallow this for animals except in limited circumstances. NCPA requests FDA review these current regulations and draft new guidance which respects this shared authority in the compounding space.

2. **The GFI fails to properly recognize and accommodate animal drug shortages.**

FDA notes in the final guidance that it will "apply its process" to mitigate animal drugs that are temporarily in shortage. FDA further stipulates that "actions may include working with drug manufacturers and others in the animal health industry, speeding up the animal drug review and approval process, encouraging sponsors of alternate products to increase production, or refraining from taking action against imports of foreign-approved versions of the drug product."[2]

However, these processes fail to address the impact on animal patient care a shortage might have and impedes compounders from serving the needs of those patients. Additionally, the procedures established by FDA are inadequate to determine what is currently in shortage in the market.

3. **Compliance requirements set unobtainable standard for compounders to assess inactive ingredients.**

According to the final GFI, FDA generally does not intend to take enforcement action against the compounding of animal drugs from bulk drug substances as office stock for nonfood-producing animals for violations of the requirements for animal drug approval, adequate directions for use, and current good manufacturing practice (CGMP) when certain circumstances are present, including that "All bulk drug substances, inactive ingredients, and finished drug products used in compounding meet the standards set in any applicable USP-NF monograph and comply with other FD&C Act requirements for drug components."[3] This sets an unobtainable standard for compounders.

[2] *Id.*
[3] *Id.*

Compounders do not have the ability to assess inactive ingredients in manufactured animal drug products, as the package inserts for manufactured animal drug products do not disclose them.[4]

4. **Conclusion.**

NCPA appreciates the opportunity to share with you our additional comments and suggestions to the final GFI #256. For the reasons stated above and previously submitted, we urge FDA to withdraw the final GFI #256 as it did with its previous draft (GFI #230), which the Agency issued in 2015 and withdrew in 2017. NCPA is committed to working with FDA and other industry stakeholders in promoting efforts to preserve veterinary and human patient access to medically necessary compounded medications.

Concerns with patient access to cBHT

NCPA expresses concern with maintaining appropriate access to cBHT. An April 2022 article 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.[5] This article also demonstrates that clinically relevant information regarding cBHRT was omitted from the NASEM report on the clinical utility of cBHT.

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 (A4PC).[6] In this letter, we criticized the NASEM report, especially considering that the NASEM committee lacked experts on compounding, and the NASEM report went well beyond its charge, 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. Congress has also sent numerous letters to FDA in support of patient access to cBHT.[7]

Any Future MOU

NCPA welcomes FDA's delay of implementation of the MOU on October 21, 2022 until the effective date of a final rule regarding certain distributions of compounded human drug products and

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[4] One example is Vetmedin. While the package insert discusses the active ingredient it does not disclose the inactive ingredients. See: https://www.bi-vetmedica.com/sites/default/files/dam/internet/ah/vetmedica/com_EN/product_files/vetmedin/vetmedin_label.pdf. On the other hand, human drug products list all the ingredients including the inactive ingredients. See Section 11, the Description, here for example: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/019777s064lbl.pdf.

[5] See "Menopause publishes cBHT meta-analysis," *Alliance for Pharmacy Compounding.* April 1, 2022. Available at: APC: Menopause publishes cBHT meta-analysis (a4pc.org).

[6] See Microsoft Word - Joint Pharmacy Draft Letter to FDA NASEM Report.docx (ncpa.org).

[7] See 12.14.21_compounded_hormone_therapies_access.pdf (house.gov) and letter-fda-re-cbht.pdf (ncpa.org).

publication of an updated standard MOU.[8] NCPA also supported FDA's past suspension of the October 2020 MOU, its plans to establish a new MOU through rulemaking, and its "plans to further extend the period during which FDA does not intend to enforce the statutory 5 percent limit during the rulemaking process."[9]

NCPA hopes that any future MOU will address our previously stated concerns. First, we hope that states are given sufficient time to assess any conflicts of law, and if they choose to sign, modify existing laws to comply with the MOU. Already, several state boards of pharmacy have raised issues about the potential conflicts between the old MOU and existing state laws regarding confidentiality of information – which conflicts with the reporting requirements of the old MOU. Some of these states have significant patient populations who use compounded drugs.

We also remain concerned about the consequences of not signing the MOU on patient access to essential compounded medications. Pharmacies in states that sign the MOU will be permitted to provide patients with personalized medications unimpeded. In states that choose not to sign, a five percent cap on interstate shipments would be imposed on pharmacies. NCPA is also concerned that patients who rely on compounded medications from pharmacies in states that cannot or do not sign the final MOU deadline will be penalized by disruption of care and inability to receive therapy from their pharmacy of choice.

NCPA also disapproves of the way FDA has structured the past MOU. NCPA continues to have issues with both the process and the content of the old MOU – we believe FDA conflates the definitions of "distribute" and "dispense" without Congressional authorization.

The statutory language in section 503A of the FDCA directing FDA to establish an MOU with states requiring reporting of interstate distributions of compounded drugs is now outdated and does not make sense in the context of the establishment of 503B outsourcing facilities under the DQSA. That being said, we hope that FDA will work with NCPA, NABP and other pharmacy stakeholders on consensus legislation to update this statute to require reporting by pharmacies of interstate dispensing and distributions of compounded drugs without the need for states to sign an MOU that may conflict with state laws and without the arbitrary and punitive 5% cap in the current law.

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 tertiary suppliers 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

[8] See 2022-22876.pdf (govinfo.gov).
[9] See Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs | FDA.

Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry.[10]

NCPA supports the Patient Access to Urgent-Use Pharmacy Compounding Act (HR 167), 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.[11]

Adverse Event Reporting

Lastly, NCPA requests that FDA engage stakeholders in addressing the proper role, responsibilities, and repercussions for adverse event reporting.

Conclusion

NCPA feels 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 June 15 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
Director, Policy & Regulatory Affairs
National Community Pharmacists Association

[10] https://www.fda.gov/media/137125/download.
[11] H.R.167 - 118th Congress (2023-2024): Patient Access to Urgent-Use Pharmacy Compounding Act of 2023 | Congress.gov | Library of Congress.