NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

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June 3, 2022

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

Submitted via e-mail: navdeep.bhandari@fda.hhs.gov; jacquin.jones@fda.hhs.gov; Compounding@fda.hhs.gov

Re: Testimony of Steven C. Hoffart for FDA Drug Compounding Annual Listening Session on June 17, 2022

Dear Sir or Madam:

Below please find the prepared testimony for Steven C. Hoffart, PharmD, FAAFM, Owner of Magnolia Pharmacy in Magnolia, TX, and representing the National Community Pharmacists Association (NCPA) at the FDA Drug Compounding Annual Listening Session on June 17.

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 $67 billion healthcare marketplace, employ 215,000 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 greatly appreciates the opportunity to share our views on various topics during the listening session. NCPA is committed to working with the 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

Statement of Steven C. Hoffart, PharmD, FAAFM
Owner of Magnolia Pharmacy in Magnolia, TX
Representing the National Community Pharmacists Association (NCPA)

Good morning. My name is Steven Hoffart, and I am the owner of Magnolia Pharmacy in Magnolia, TX, representing the National Community Pharmacists Association, or NCPA. NCPA appreciates the opportunity to share our comments and perspectives as we continue to work with FDA on issues in drug compounding.

We have several concerns that we would like to address. This statement is an abridged version of a longer statement for the record submitted by NCPA ahead of this session.

1. Concerns with GFI #256

First, NCPA reiterates concerns with GFI #256, finalized by FDA in April.[1] NCPA continues to request FDA withdraw GFI #256.

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.

Furthermore, FDA's stated logic that compounding from APIs for animals is not in federal law, and is thus illegal, creates a legal uncertainty for FDA's lists for veterinary office stock; these lists are also not grounded in any statutory authority.

Also, FDA's creation of a list of bulk drug substances for compounding office stock drugs for use in nonfood-producing animals has essentially created approved specific compounds with indications. This is inconsistent with FDA policy that compounds cannot have indications, as indications are only for approved drugs.

And lastly, compounders do not have the ability to assess inactive ingredients, as the package inserts for manufactured animal drug products do not disclose them.[2] Without this information, it is unreasonable for the FDA in their final GFI to require that compounded medication from bulk drug substances meet certain standards when this information is not available.

[1] "#256: Compounding Animal Drugs from Bulk Drug Substances - Guidance for Industry," April 22, 2022. *Food and Drug Administration.* Available at: https://www.fda.gov/media/132567/download.

[2] 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.

2. Concerns with patient access to cBHT

Secondly, NCPA expresses concern about maintaining appropriate access to compounded hormone therapies. An April 2022 article in the *Menopause* journal 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 cBHRT was omitted from the report.

3. Strong support for addition of glutathione to the 503A Bulks List

Thirdly, NCPA strongly supports the inclusion of glutathione on the 503A Bulks List. NCPA supports the testimony of A.J. Day, given to PCAC on June 8, 2022. As indicated in the FDA briefing packet, NCPA strongly supports the addition of glutathione for chemotherapy-induced neuropathy and cystic fibrosis.[4]

4. Additional compounding issues

Finally, NCPA also wishes to urge the FDA to continue to dialogue with stakeholders on the following topics, as addressed in greater length in NCPA's statement for the record:

- The condensed timeline and review process for the June 8 PCAC meeting;
- FDA's final guidance on insanitary conditions;
- Any future MOU;
- Addressing drug shortages; and
- The proper role, responsibilities, and repercussions for adverse event reporting.

5. Conclusion

In 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. Thank you again for the opportunity to discuss these issues.

[3] See "Menopause publishes cBHT meta-analysis," *Alliance for Pharmacy Compounding.* April 1, 2022. Available at: APC: Menopause publishes cBHT meta-analysis (a4pc.org).
[4] https://www.fda.gov/media/158541/download, page 544-546.