May 26, 2021

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments (FDA-2021-N-0357)

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Pharmacy Compounding Advisory Committee (PCAC), which provides advice to the Food and Drug Administration (FDA), in advance of the June 9, 2021 meeting. NCPA appreciates the opportunity to share our comments and perspective on the topics of discussion on the meeting agenda as we continue to work with PCAC and FDA on regulatory issues in drug compounding arising from the authority granted to the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA).

NCPA represents America's community pharmacists, including 21,000 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 $74 billion healthcare marketplace, employ 250,000 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 submits these comments on behalf of community and long-term care pharmacies.

As the participants on the PCAC are fully aware, the majority of NCPA membership engaging in drug compounding do so under the rubric of 503A of the FDCA. Although NCPA has raised concerns[1] over the PCAC process for considering substances for the 503A Bulks List and the Withdrawn or Removed List, the focus of this comment focused on the discussion of choline chloride, oxitriptan (also known as 5-hydroxytryptophan or 5-HTP), melatonin, and methylcobalamin for inclusion on the Bulks List and Neomycin Sulfate for the Withdrawn or Removed List.

[1] https://www.fda.gov/media/149084/download, pg 12

NCPA Strongly Supports the Addition of oxitriptan (also known as 5-hydroxytryptophan or 5-HTP), melatonin, and methylcobalamin to the 503A Bulks List

Oxitriptan

NCPA strongly supports the inclusion of oxitriptan (also known as 5-hydroxytryptophan or 5-HTP) on the 503A Bulks List for BH4 deficiency and originally nominated it for inclusion in 2014.

5-Hydroxytryptophan (5-HTP) is a naturally occurring amino acid and metabolic intermediate in the synthesis of serotonin and melatonin. 5-HTP is sold over-the-counter in the United Kingdom, United States and Canada as a dietary supplement.

NCPA agrees with FDA that oxitriptan should be included on the Bulks List for BH4 deficiency.

Melatonin

NCPA has previously advocated for the inclusion of melatonin on the 503A Bulks List in 2014 for Autism Spectrum Disorders (ASD).

Melatonin is a hormone produced by the pineal gland believed to play a role in regulation of the sleep-wake cycle. Melatonin is involved in numerous biological functions and is available over-the-counter.

NCPA agrees with FDA that melatonin should be included on the List.

Methylcobalamin (B12)

NCPA has previously advocated for the addition of methylcobalamin (B12) on the 503A Bulks List in 2014.

NCPA's support relates to injectable solutions for the treatment of Autism Spectrum Disorders (ASD).

Methylcobalamin injections are useful for patients – Patients with Autism Spectrum Disorders are known to have high incidences of altered gastrointestinal health, which likely impairs their absorption of vitamin B12 from the GI tract.

While there is clinical literature about the positive efficacy for methylcobalamin in a variety of disease states, the primary patient need for compounded methylcobalamin is for patients with Autism Spectrum Disorders with over 250,000 prescriptions per year. It is believed by researchers in the autism community that some children with autism spectrum disorder have a central cobalamin deficiency thus requiring high blood levels of cobalamin to cross the blood

brain barrier[2], and it is reasonable to hypothesize that injected methylcobalamin is more effective than oral administration.

Additionally, NCPA wishes to highlight these clinical trials for autism have only been performed with methylcobalamin and not any of the cobalamin analogues the FDA has already approved. Because all clinical data has been generated on methylcobalamin, it is inappropriate for FDA to exclude methylcobalamin with the intent of forcing the use of other forms of vitamin B12 simply because FDA has already approved them.

NCPA, along with other stakeholders, strenuously disagrees with the FDA assessment that methylcobalamin should not be included on the 503A Bulks List.

Choline Chloride

NCPA is agnostic on the inclusion of choline chloride.

Bulks List Additions

It seems odd that a patient could come in and buy as much of a particular substance as they want over the counter with no intervention from a healthcare practitioner, but that pharmacists might not be able to compound with these substances to assist patients with their ailments upon the receipt of a valid prescription. Compounding requires a patient-prescriber-pharmacist relationship. If there are concerns about side effects and drug interactions, there is a much better chance of monitoring a patient with a compounded version of oxitriptan, melatonin, or methylcobalamin.

NCPA Is Agnostic on the Addition of Neomycin Sulfate on the Withdrawn or Removed List

NCPA is agnostic on the inclusion of neomycin sulfate on the Withdrawn or Removed List.

[2] https://www.fda.gov/media/149084/download, pg. 227

Conclusion

NCPA greatly appreciates the opportunity to share our views on the substances being considered by the PCAC at their June 9 meeting. NCPA is committed to working with the FDA and other stakeholders on these important matters.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy & Government Affairs Operations