



## Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: **Kathleen Gura, PharmD, BCNSP**

Committee: **Pharmacy Compounding Advisory Committee (PCAC)**

Meeting Date: **June 9, 2021**

I acknowledge that contingent upon public disclosure of the following financial interest related to the agenda item described below, I may be considered for participation in the advisory committee meeting.

On June 9, 2021, the committee will discuss bulk drug substances nominated for inclusion on the 503A Bulk List. The nominators of these substances or another interested party will be invited to make a short presentation supporting the nomination. The four bulk drug substances to be discussed are choline chloride (uses are for the treatment of liver diseases (including non-alcoholic fatty liver disease), hepatic steatosis, atherosclerosis, fetal alcohol spectrum disorder, and supplementation in long term total parenteral nutrition); melatonin for the treatment of sleep disorders in patients with autism spectrum disorder (specifically children and adolescents); methylcobalamin uses are evaluated for amyotrophic lateral sclerosis (also known as ALS), pain management, peripheral neuropathy (including diabetic neuropathy), inborn errors of metabolism (also known as genetic metabolic disorders) (including methylenetetrahydrofolate reductase deficiency (also known as MTHFR)), hyperhomocysteinemia (including conjunctive therapy in hemodialysis patients), vitamin B12 deficiency, and autism spectrum disorder; and oxitriptan (5-HTP) for the treatment for patients with tetrahydrobiopterin (BH4) deficiency.

The committee will also discuss revisions FDA is considering to the Withdrawn or Removed List. FDA now is considering whether to amend the rule to add one more entry to the list: Neomycin Sulfate: All parenteral drug products containing neomycin sulfate (except for ophthalmic or otic use, or when combined with polymyxin B sulfate for irrigation of the intact bladder). As previously explained in the Federal Register of July 2, 2014 (79 FR 37687 at 37689 through 37690), the list may specify that a drug may not be compounded in any form, or, alternatively, may expressly exclude a particular formulation, indication, dosage form, or route of administration from an entry on the list. Moreover, a drug may be listed only with regard to certain formulations, indications, routes of administration, or dosage forms because it has been found to be unsafe or not effective in those particular formulations, indications, routes of administration, or dosage forms. FDA plans to seek the committee's advice concerning the inclusion of this drug product on the list.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
I. Personal/Immediate Family		
Stocks/investments	(b) (6) . stock	\$50,000 - 100,000

II. Other Imputed Interests		
None		

I hereby request that FDA make this information publicly available on my behalf if the agency grants a waiver allowing me to participate in the meeting described above. I understand that without public disclosure of these interests, I will not participate in the advisory committee meeting described above.

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Signature /s/

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Date 05/25/2021