U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

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

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

Meeting Date: **June 8, 2022**

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

On June 8, 2022, 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 ammonium tetrathiomolybdate (uses are evaluated for Wilson disease, use as copper (Cu) chelation therapy for the treatment of breast cancer, kidney cancer, prostate cancer, colorectal cancer, esophageal cancer, and malignant pleural mesothelioma); enclomiphene citrate (to increase serum testosterone, luteinizing hormone (LH), and follicle-stimulating hormone (FSH) to normal levels in the treatment of secondary hypogonadism); ferric subsulfate (for use as an astringent and hemostatic agent during minor surgical procedures); and glutathione (uses are evaluated for skin lightening, cystic fibrosis, asthma, chronic obstructive pulmonary disease, chronic lung disease, oxidative stress, reduction of the side effects of chemotherapy, inhibition of chemical induced carcinogenesis, prevention of radiation injury, treatment of heavy metal poisoning (cadmium and mercury), acetaminophen toxicity, autism spectrum disorder, Alzheimer's disease, Parkinson's disease, major depressive disorder, schizophrenia, helicobacter pylori infection, human immunodeficiency virus infection, tuberculosis, otitis media, peripheral obstructive arterial disease, anemia, diabetes, and septic shock).

The committee will also discuss revisions FDA is considering to the Withdrawn or Removed List.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 the following entry to the list: lorcaserin hydrochloride. 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 on the list.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family		
Stocks/investments	[redacted]PPI., stock in affected entity	$50,000 - 100,000

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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.

_/s/_____ ___5/13/2022_____
Signature Date