

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

Meeting Date: December 4, 2024

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

On December 4, 2024, the committee will discuss bulk drug substances being considered for inclusion on the 503A Bulks List. The nominators of these substances will be invited to make a short presentation supporting the nomination. The three bulk drug substances to be discussed are AOD-9604-related bulk drug substances (use is for growth hormone deficiency); Thymosin alpha-1 (uses are for hepatitis B, hepatitis C, human immunodeficiency virus (HIV), COVID-19, depressed response to vaccinations; adjuvant to flu vaccines, malignant melanoma, hepatocellular carcinoma (HCC), non-small cell lung cancer (NSCLC), sepsis, infections after hematopoietic stem cell transplantation (HSCT), chronic obstructive pulmonary disease (COPD), myalgic encephalomyelitis and chronic fatigue syndrome (ME/CFS).

Type of Interest	<u>Nature</u>	Magnitude
I. Personal/Immediate Fan	nily	
Stocks/investments	stock holdings, competing/affected entities	\$50,000 - \$75,000
Stocks/investments	stock holdings, competing firm for Thymosin alpha-1 topic	\$0 - \$10,000
Stocks/investments	competing firm for AOD-9604 and Thymosin alpha-1 topics	\$0 - \$10,000
Stocks/investments	firm for AOD-9604, CJC-1295, and Thymosin alpha-1 topics	\$0 - \$10,000

Stocks/investments	competing firm for CJC-1295 and Thymosin alpha-1 topics	\$0 - \$10,000		
II. Other Imputed Interes	sts			
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/_ Signature		11/13/2024 te		