



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: October 29, 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 October 29, 2024, the committee will discuss the following 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 four bulk drug substances to be discussed are ibutamoren mesylate (uses are for the treatment of growth hormone deficiency (GHD), osteoporosis, hip fracture, sarcopenia, obesity, and Alzheimer’s disease (AD); L-theanine (for the treatment of sleep disorders and anxiety disorders); ipamorelin-related bulk drug substances, ipamorelin acetate and ipamorelin (free base) (for the treatment of GHD and postoperative ileus); and kisspeptin-10 (for the treatment of secondary hypogonadism in men).

The Committee will also discuss a revision FDA is considering to the Withdrawn or Removed List. Specifically, FDA is considering whether to amend § 216.24 to add an entry to the list:

hydroxyprogesterone caproate: all drug products containing hydroxyprogesterone caproate to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous birth. As previously explained in the Federal Register of July 2, 2014 (79 FR 37687 at 37689 through 37690), the list entry may specify that a drug may not be compounded in any form. Alternatively, the list entry may expressly exclude a particular formulation, indication, dosage form, or route of administration from an entry on the list, or a drug may be listed only with regard to certain formulations, indications, routes of administration, or dosage forms. FDA plans to seek the Committee’s advice concerning the inclusion of this entry on the list.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family		
Stocks/investments	(b) (6), stock holdings in competing/affected entity	\$25,000 - \$50,000
Stocks/investments	(b) (6) stock holdings, competing firm for kisspeptin, L-theanine, and hydroxyprogesterone topics	\$0,000 - \$10,000

