Food and Drug Administration
Center for Drug Evaluation and Research

Final Summary Minutes of the Pharmacy Compounding Advisory Committee Meeting
October 29, 2024

Location: FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503), 10903 New Hampshire Avenue, Silver Spring, Maryland. The public also had the option to participate via an online teleconferencing and/or video conferencing platform, and the meeting presentations were heard, viewed, captioned, and recorded through an online video conferencing platform.

Topic: The Committee discussed the following bulk drug substances being considered for inclusion on the 503A Bulks List: ibutamoren mesylate, L-theanine, ipamorelin-related bulk drug substances (ipamorelin acetate and ipamorelin (free base)), and kisspeptin-10. The chart below identifies the use(s) FDA reviewed for each of the bulk drug substances being discussed at this advisory committee meeting. For nominated bulk drug substances, the nominators of these substances were invited to make a short presentation supporting the nomination.

Bulk Drug Substance	**Uses Evaluated**
Ibutamoren mesylate	Treatment of growth hormone deficiency (GHD), osteoporosis, hip fracture, sarcopenia, obesity, and Alzheimer's disease.
L-theanine	Sleep disorders and anxiety disorders.
Ipamorelin acetate Ipamorelin (free base)	GHD and postoperative ileus.
Kisspeptin-10	Treatment of secondary hypogonadism in men.

The Committee also discussed a revision FDA is considering to the Withdrawn or Removed List.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 sought the Committee's advice concerning the inclusion of this entry on the list.

These summary minutes for the October 29, 2024 meeting of the Pharmacy Compounding Advisory Committee (PCAC) of the Food and Drug Administration were approved on January 15, 2025.

I certify that I attended the October 29, 2024 meeting of the PCAC of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
Takyiah Stevenson, PharmD
Designated Federal Officer, PCAC

/s/
Padma Gulur, MD, FASA
Chairperson, PCAC

Summary Minutes of the Pharmacy Compounding Advisory Committee Meeting
October 29, 2024

The Pharmacy Compounding Advisory Committee (PCAC) of the Food and Drug Administration, Center for Drug Evaluation and Research, met on October 29, 2024. FDA and invited participants attended the meeting at the FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503), 10903 New Hampshire Avenue, Silver Spring, Maryland. The public also had the option to participate via an online teleconferencing and/or video conferencing platform, and the meeting presentations were heard, viewed, captioned, and recorded through an online video conferencing platform. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA. The meeting was called to order by Padma Gulur, MD, FASA (Chairperson). The conflict-of-interest statement was read into the record by Takyiah Stevenson, PharmD (Designated Federal Officer). There were approximately 85 people in attendance in-person and approximately 164 people online. There was a total of 7 Open Public Hearing (OPH) speaker presentations.

A verbatim transcript will be available, in most instances, at approximately ten to twelve weeks following the meeting date.

Agenda: The Committee discussed the following bulk drug substances being considered for inclusion on the 503A Bulks List: ibutamoren mesylate, L-theanine, ipamorelin-related bulk drug substances (ipamorelin acetate and ipamorelin (free base)), and kisspeptin-10. The chart below identifies the use(s) FDA reviewed for each of the bulk drug substances being discussed at this advisory committee meeting. For nominated bulk drug substances, the nominators of these substances were invited to make a short presentation supporting the nomination.

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Attendance:

Pharmacy Compounding Advisory Committee Members Present (Voting): Robin H. Bogner, PhD; Seemal R. Desai, MD, FAAD (*via video conferencing platform*) Padma Gulur, MD, FASA (*Chairperson*); Kathleen M. Gura, PharmD, BCNSP, FASHP, FASPEN; Elizabeth Rebello, RPh, MD, FASA, CPPS, CMQ (*via video conferencing platform*); Brian Serumaga, PhD (*United States Pharmacopeia (USP) Representative*); Allen J. Vaida, BSc, PharmD, FASHP

Pharmacy Compounding Advisory Committee Members Not Present (Voting): Timothy D. Fensky, RPh, DPh, FACA (*National Association of Boards of Pharmacy Representative*); Anita Gupta, DO, MPP, GMP, PharmD, FASA; Linda F. McElhiney, PharmD, RPh, MSP, FAPC, FACA, FASHP, DPLA

Pharmacy Compounding Advisory Committee Members Present (Non-Voting): Thomas J. Lupton, PharmD, MBA, BCPS (*Industry Representative*); Donnette D. Staas, PhD (*Industry Representative*)

Temporary Members (Voting): Joseph P. Alukal, MD, MBA (*Kisspeptin-10 Topic Only*); Charles Billington, MD (*Ibutamoren Mesylate Topic Only*); David W. Cooke, MD (*Ibutamoren and Ipamorelin Topics Only*); Nancy Diazgranados, MD, MS, DFAPA (*L-theanine Topic Only*); Roger R. Dmochowski, MD, MA (CM), MMHC, FACS (*Kisspeptin-10 Topic Only*); Todd Durham, PhD (*Acting Consumer Representative*); Jonathan Emens, MD, FAASM, DFAPA (*L-theanine Topic Only*); Eliot Katz, MD (*L-theanine Topic Only*); Brian P. Lee, MD, MAS (*Ipamorelin Topic Only*); Francis J. McMahon, MD (*L-theanine Topic Only*); Connie B. Newman, MD, MACP (*Ibutamoren Mesylate Topic Only*); Steven F. Solga, MD (*Ipamorelin Topic Only*); Thomas J. Weber, MD (*Ibutamoren Mesylate Topic Only*); Rita Weiss, PharmD, JD (*Acting National Association of Boards of Pharmacy Representative*); Jack A. Yanovski, MD, PhD (*via video conferencing platform; Ibutamoren and Ipamorelin topics only*)

FDA Participants (Non-Voting): Frances Gail Bormel, RPh, JD; Ian F. Deveau, PhD; Gabrielle Cosel, MSc (*via video conferencing platform*); Charles Ganley, MD; Daiva Shetty, MD; Tracy Rupp, PharmD, MPH, BCPS, RD; Kemi Asante, PharmD, MPH, RAC; Russell Wesdyk, BS, MBA; Elizabeth Hankla, PharmD (*Kisspeptin-10 Topic Only*); Emily Kneeream, PharmD (*Hydroxyprogesterone Caproate Topic Only*); Katie Park, PharmD, MPH (*Ipamorelin acetate/ Ipamorelin Topic Only*); Marianne San Antonio, DO (*L-Theanine Topic Only*); Madeline Wolfert, MD (*Ibutamoren Mesylate Topic Only*)

Designated Federal Officer (Non-Voting): Takyiah Stevenson, PharmD

Open Public Hearing Speakers Present:

- L-Theanine (Topic 1) – James Lavalle and Lee Rosebush (Farmakeio and Evexias)
- Ibutamoren Mesylate (Topic 2) – James Lavalle and Lee Rosebush (Farmakeio and Evexias)
- Ipamorelin acetate/Ipamorelin (Topic 3) – James Lavalle and Lee Rosebush (Farmakeio and Evexias)

- Kisspeptin-10 (Topic 4) – James Lavalle and Lee Rosebush (Farmakeio and Evexias)
- Hydroxyprogesterone Caproate (Topic 5) – Robert Steinbrook, MD (Public Citizen; *via video conferencing platform*); Rich Moon (National Community Pharmacists Association; *via video conferencing platform*); Adam C. Urato, MD (*via video conferencing platform*)

The agenda was as follows:

October 29, 2024, AM Session

Call to Order and Introduction of Committee	**Padma Gulur, MD, FASA** Chairperson, PCAC
Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Designated Federal Officer, PCAC
FDA INTRODUCTORY REMARKS	**Frances Gail Bormel, RPh, JD** Director Office of Compounding Quality and Compliance (OCQC) Office of Compliance (OC), CDER, FDA
FDA Investigational New Drug and Expanded Access Presentation	**Lori Bickel, JD** Regulatory Counsel Division of Regulatory Policy Office of New Drug Policy Office of New Drugs (OND), CDER, FDA

SECTION 503A BULK DRUG SUBSTANCES LIST – L-THEANINE

NOMINATOR PRESENTATION

Clarifying Questions from the Committee

FDA PRESENTATION	**Marianne San Antonio, DO** Physician Pharmacy Compounding Review Team (PCRT) Office of Specialty Medicine (OSM) OND, CDER, FDA

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

BREAK

SECTION 503A BULK DRUG SUBSTANCES LIST – IBUTAMOREN MESYLATE

NOMINATOR PRESENTATION

Clarifying Questions from the Committee

FDA PRESENTATION

Madeline Wolfert, MD
Physician
PCRT, OSM, OND, CDER, FDA

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

LUNCH

October 29, 2024, PM Session

FDA IMMUNOGENICITY RISK OF COMPOUNDED PEPTIDES PRESENTATION

Daniela Verthelyi, MD, PhD
Supervisory Biologist, Division IV
Office of Pharmaceutical Quality (OPQ), CDER, FDA

BULK DRUG SUBSTANCE DISCUSSION

Russell Wesdyk, BS, MBA
Associate Director for Regulatory Affairs
Office of Product Quality Assessment II
OPQ, CDER, FDA

Clarifying Questions from the Committee

SECTION 503A BULK DRUG SUBSTANCES LIST – IPAMORELIN-RELATED BULK DRUG SUBSTANCES (IPAMORELIN ACETATE AND IPAMORELIN (FREE BASE))

FDA PRESENTATION

Katie Park, PharmD, MPH
Clinical Analyst
PCRT, OSM, OND, CDER, FDA

And

Russell Wesdyk, BS, MBA

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

BREAK

SECTION 503A BULK DRUG SUBSTANCES LIST – KISSPEPTIN-10

NOMINATOR PRESENTATION

Clarifying Questions from the Committee

FDA PRESENTATION	**Elizabeth Hankla, PharmD** Senior Clinical Analyst PCRT, OSM, OND, CDER, FDA

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

BREAK

Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Designated Federal Officer, PCAC
WITHDRAWN OR REMOVED LIST PROCESS	**Gabrielle Cosel, MSc** Director Division of Compounding Policy and Outreach OCQC, OC, CDER, FDA

DRUGS TO BE CONSIDERED FOR THE WITHDRAWN OR REMOVED LIST – HYDROXYPROGESTERONE CAPROATE

FDA PRESENTATION	**Emily Kneeream, PharmD** Clinical Analyst PCRT, OSM, OND, CDER, FDA

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

ADJOURNMENT

Questions to the Committee:

1. **VOTE:** FDA is proposing that L-theanine NOT be included on the 503A Bulks List. Should L-theanine be placed on the list?

   Vote Result: Yes: 1 No: 12 Abstain: 0

Committee Discussion*: The majority of the Committee members voted against placing L-theanine on the 503A Bulks List. Several Committee members who voted "No" agreed there was no compelling evidence presented supporting clinical efficacy and safety of L-theanine for sleep disorders and anxiety disorders. A few members noted that the lack of a USP monograph or a certificate of analysis for L-theanine were additional reasons for voting against placing this substance on the 503A Bulks List. One Committee member who voted in favor of placing L-theanine on the 503A Bulks List mentioned there was some evidence of efficacy demonstrated in some patients and that according to the non-clinical data, there is a high safety margin. Please see the transcript for details of the Committee's discussion.*

2. **VOTE:** FDA is proposing that Ibutamoren mesylate NOT be included on the 503A Bulks List. Should Ibutamoren mesylate be placed on the list?

   Vote Result: Yes: 1 No: 13 Abstain: 0

   Committee Discussion: *The majority of the Committee members voted against placing Ibutamoren mesylate on the 503A Bulks List. Several Committee members who voted "No" mentioned that the evidence presented did not support clinical efficacy and safety. Several Committee members expressed concerns over the adverse effects reported including fluid retention, congestive heart failure, and hyperglycemia. One Committee member who voted in favor of placing Ibutamoren mesylate on the 503A Bulks List was convinced by the extensive use of Ibutamoren mesylate and the pediatric data. Please see the transcript for details of the Committee's discussion.*

3. **VOTE:** Do Committee members agree to vote on Ipamorelin-related bulk drug substances discussed today (Ipamorelin (free base) and Ipamorelin acetate) as a group (Yes or No)? If any member of the Committee votes no, FDA will take individual votes on each of these substances.

   Vote Result: Yes: 12 No: 1 Abstain: 0

   Question 3a was skipped based on the answer to Question 3.

   If yes:
   a. **VOTE:** FDA is proposing that Ipamorelin (free base) and Ipamorelin acetate NOT be included on the 503A Bulks List. Should Ipamorelin (free base) and Ipamorelin acetate be placed on the list?

   If no:
   b. **VOTE:** FDA is proposing that Ipamorelin (free base) NOT be included on the 503A Bulks List. Should Ipamorelin (free base) be placed on the list?

   Vote Result: Yes: 0 No: 12 Abstain: 1

   Committee Discussion: *The majority of the Committee members voted against placing Ipamorelin (free base) on the 503A Bulks List. Committee members who voted "No" agreed*

that there was a lack of information supporting safety and efficacy shown in the available data for the use of Ipamorelin (free base) for GHD and postoperative ileus. One Committee member commented that the high frequency of a drug being prescribed does not necessarily mean the drug is safe and effective. One Committee member who abstained acknowledged that there were conflicting comments causing confusion between deliberations on the safety and efficacy of ipamorelin acetate and the data presented. Please see the transcript for details of the Committee's discussion.

c. **VOTE:** FDA is proposing that Ipamorelin acetate NOT be included on the 503A Bulks List. Should Ipamorelin acetate be placed on the list?

Vote Result: Yes: 0 No: 12 Abstain: 1

Committee Discussion: *The majority of the Committee members voted against placing Ipamorelin acetate on the 503A Bulks List for the same reasons as stated for Ipamorelin (free base). One Committee member abstained for the same reasons as stated for Ipamorelin (free base). Please see the transcript for details of the Committee's discussion.*

4. **VOTE:** FDA is proposing that Kisspeptin-10 NOT be included on the 503A Bulks List. Should Kisspeptin-10 be placed on the list?

Vote Result: Yes: 0 No: 11 Abstain: 0

Committee Discussion*: The committee unanimously agreed that Kisspeptin-10 should not be included on the 503A Bulks List due to the lack of convincing safety and efficacy data. Please see the transcript for details of the Committee's discussion.*

5. **VOTE:** FDA is proposing that "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 preterm birth" be ADDED to the Withdrawn or Removed List under sections 503A and 503B of the FD&C Act. Should this entry be placed on the list?

Vote Result: Yes: 9 No: 0 Abstain: 0

Committee Discussion*: The committee unanimously agreed that an entry for "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 preterm birth" should be added to the Withdrawn or Removed List based on lack of efficacy. One Committee member noted that there are USP monographs available for Hydroxyprogesterone caproate and this drug can continue to be compounded for use in non-pregnant women for other indications. Please see the transcript for details of the Committee's discussion.*

The meeting was adjourned at approximately 4:05 pm ET.