

**Food and Drug Administration
Center for Drug Evaluation and Research**

**Final Summary Minutes of the Pharmacy Compounding Advisory Committee Meeting
December 4, 2024**

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, Room 2047, 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: AOD-9604-related bulk drug substances (AOD-9604 acetate, and AOD-9604 (free base)), CJC-1295-related bulk drug substances (CJC-1295 (free base), CJC-1295 acetate, CJC-1295 with drug affinity complex (DAC) (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate)), and Thymosin alpha-1-related bulk drug substances (Thymosin alpha-1 acetate, and Thymosin alpha-1 (free base)). 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
AOD-9604 (free base) AOD-9604 Acetate	Obesity.
CJC-1295 (free base) CJC-1295 Acetate CJC-1295 DAC (free base) CJC-1295 DAC Acetate CJC-1295 DAC Trifluoroacetate	Growth hormone deficiency.
Thymosin alpha-1(free base) Thymosin alpha-1 Acetate	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).

These summary minutes for the December 4, 2024 meeting of the Pharmacy Compounding Advisory Committee (PCAC) of the Food and Drug Administration were approved on February 21, 2025.

I certify that I attended the December 4, 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/
Elizabeth Rebello, RPh, MD, FASA, CPPS, CMQ
Acting Chairperson, PCAC

**Summary Minutes of the Pharmacy Compounding
Advisory Committee Meeting
December 4, 2024**

The Pharmacy Compounding Advisory Committee (PCAC) of the Food and Drug Administration, Center for Drug Evaluation and Research, met on December 4, 2024. FDA and invited participants attended the meeting at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, Room 2047, 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 Elizabeth Rebello, RPh, MD, FASA, CPPS, CMQ (Acting Chairperson). The conflict-of-interest statement was read into the record by Takyiah Stevenson, PharmD (Designated Federal Officer). There were approximately 78 people in attendance in-person and approximately 146 people online. There was a total of 17 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: AOD-9604-related bulk drug substances (AOD-9604 acetate, and AOD-9604 (free base)), CJC-1295-related bulk drug substances (CJC-1295 (free base), CJC-1295 acetate, CJC-1295 with drug affinity complex (DAC) (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate)), and Thymosin alpha-1-related bulk drug substances (Thymosin alpha-1 acetate, and Thymosin alpha-1 (free base)). 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
AOD-9604 (free base) AOD-9604 Acetate	Obesity.
CJC-1295 (free base) CJC-1295 Acetate CJC-1295 DAC (free base) CJC-1295 DAC Acetate CJC-1295 DAC Trifluoroacetate	Growth hormone deficiency.
Thymosin alpha-1 (free base) Thymosin alpha-1 Acetate	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).

Attendance:

Pharmacy Compounding Advisory Committee Members Present (Voting): Robin H. Bogner, PhD; Timothy D. Fensky, RPh, DPh, FACA (*National Association of Boards of Pharmacy Representative*); Padma Gulur, MD, FASA (*via video conferencing platform*); Anita Gupta, DO, MPP, GMP, PharmD, FASA (*via video conferencing platform*); Kathleen M. Gura, PharmD, BCNSP, FASHP, FASPEN; Linda F. McElhiney, PharmD, RPh, MSP, FAPC, FACA, FASHP, DPLA; Elizabeth Rebello, RPh, MD, FASA, CPPS, CMQ (*Acting Chairperson*); Brian Serumaga, PhD (*United States Pharmacopeia (USP) Representative*); Allen J. Vaida, BSc, PharmD, FASHP

Pharmacy Compounding Advisory Committee Members Not Present (Voting): Seemal R. Desai, MD, FAAD

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): Charles Billington, MD (*AOD-9604-related bulk drug substances (BDSs) Topic Only*); Kenneth D. Burman, MD (*CJC-1295-related BDSs Topic Only*); Nina Clark, MD (*Thymosin alpha-1-related BDSs Topic Only*); David W. Cooke, MD (*via video conferencing platform; CJC-1295-related BDSs Topic Only*); Amanda H. Corbett, PharmD (*via video conferencing platform; Thymosin alpha-1-related BDSs Topic Only*); Mark J. Czaja, MD, FAASLD (*Thymosin alpha-1-related BDSs Topic Only*); Todd Durham, PhD (*Acting Consumer Representative*); Hayley Gans, MD (*via video conferencing platform; Thymosin alpha-1-related BDSs Topic Only*); Marc Ghany, MD, MHSc (*Thymosin alpha-1-related BDSs Topic Only*); Kirk Jensen, MD, LtCol, USAF, MC (*CJC-1295-related BDSs Topic Only*); Mark G. Kris, MD (*Thymosin alpha-1-related BDSs Topic Only*); Brian P. Lee, MD, MAS (*via video conferencing platform; Thymosin alpha-1-related BDSs Topic Only*); Janet S. Lee, MD (*via video conferencing platform; Thymosin alpha-1-related BDSs Topic Only*); Cecilia Monge, MD, MPH, FACP (*Thymosin alpha-1-related BDSs Topic Only*); Alice K. Pau, PharmD (*Thymosin alpha-1-related BDSs Topic Only*); George K. Siberry, MD, MPH (*Thymosin alpha-1-related BDSs Topic Only*); Susan Z. Yanovski, MD (*via video conferencing platform; AOD-9604-related BDSs Topic only*)

FDA Participants (Non-Voting): Frances Gail Bormel, RPh, JD; Gabrielle Cosel, MSc (*via video conferencing platform*); Charles Ganley, MD (*via video conferencing platform*); Daiva Shetty, MD; Tracy Rupp, PharmD, MPH, BCPS, RD; Kemi Asante, PharmD, MPH, RAC; Russell Wesdyk, BS, MBA; Elizabeth Hankla, PharmD (*Thymosin alpha-1-related BDS Topic Only*); Emily Kneeream, PharmD (*AOD-9604-related BDSs Topic Only*); Jing Li, PhD (*Thymosin alpha-1-related BDSs Topic Only*); Bini Mathew, PhD (*AOD-9604-related BDSs Topic Only*); Marianne San Antonio, DO (*CJC-1295-related BDSs Topic Only*); Mai Tu, PhD (*CJC-1295-related BDSs Topic Only*)

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

Open Public Hearing Speakers Present:

- CJC-1295-related BDSs (Topic 1) – Dan DeNeui (Evexias Health Solutions); James Lavalley (Metabolic Code); Thomas Wynn (Farmakeio Pharmacy Network); Terri DeNeui, DNP, APRN, ACNP-BC; Lee Rosebush (BakerHostetler)
- AOD-9604-related BDSs (Topic 2) – Dan DeNeui (Evexias Health Solutions); James Lavalley (Metabolic Code); Thomas Wynn (Farmakeio Pharmacy Network); Edwin Lee, MD; Lee Rosebush (BakerHostetler); Brad Jordan (Eli Lilly & Co)
- Thymosin alpha-1-related BDSs (Topic 3) – Dan DeNeui (Evexias Health Solutions); James Lavalley (Metabolic Code); Thomas Wynn (Farmakeio Pharmacy Network); Edwin Lee, MD; Terri DeNeui, DNP, APRN, ACNP-BC; Lee Rosebush (BakerHostetler)

The agenda was as follows:

December 4, 2024, AM Session

Call to Order and Introduction of Committee	Elizabeth Rebello, RPh, MD, FASA, CPPS, CMQ Acting 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
FDA Immunogenicity Risk of Compounded Peptides Presentation	Daniela Verthelyi, MD, PhD Supervisory Senior Biomedical Research and Biomedical Product Assessment Service Expert Office of Pharmaceutical Quality (OPQ), CDER, FDA
FDA Bulk Drug Substance Discussion	Russell Wesdyk, BS, MBA Associate Director for Regulatory Affairs Office of Product Quality Assessment II (OPQAI) OPQ, CDER, FDA
Clarifying Questions from the Committee	

SECTION 503A BULK DRUG SUBSTANCES LIST – CJC-1295-RELATED BULK DRUG SUBSTANCES (CJC-1295 (FREE BASE), CJC-1295 ACETATE, CJC-1295 WITH DRUG AFFINITY COMPLEX (DAC) (FREE BASE), CJC-1295 DAC ACETATE, AND CJC-1295 DAC TRIFLUOROACETATE)

FDA PRESENTATION

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

And

Mai Tu, PhD
Senior Pharmaceutical Scientist
OPQAI, OPQ, CDER, FDA

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

BREAK

SECTION 503A BULK DRUG SUBSTANCES LIST – AOD-9604- RELATED BULK DRUG SUBSTANCES (AOD-9604 ACETATE, AND AOD-9604 (FREE BASE))

FDA PRESENTATION

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

And

Bini Mathew, PhD
Pharmaceutical Scientist
OPQAI, OPQ, CDER, FDA

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

LUNCH

December 4, 2024, PM Session

SECTION 503A BULK DRUG SUBSTANCES LIST – THYMOSIN ALPHA-1-RELATED BULK DRUG SUBSTANCES (THYMOSIN ALPHA-1 ACETATE, AND THYMOSIN ALPHA-1 (FREE BASE))

FDA PRESENTATION

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

And

Jing Li, PhD
Chemist
OPQAI, OPQ, CDER, FDA

Clarifying Questions from the Committee

BREAK

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

ADJOURNMENT

Questions to the Committee:

1. **VOTE:** Do committee members agree to use a single vote to address the group of CJC-1295-related bulk drug substances discussed today (CJC-1295 (free base), CJC-1295 acetate, CJC-1295 with drug affinity complex (DAC) (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate) (Yes or No)? If any member of the Committee votes no, FDA will take separate votes on each of these substances.

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

Question 1a was skipped based on the answer to Question 1.

If yes:

- a. **VOTE:** FDA is proposing that CJC-1295 (free base), CJC-1295 acetate, CJC-1295 DAC (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate NOT be included on the 503A Bulks List. Should CJC-1295 (free base), CJC-1295 acetate, CJC-1295 DAC (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate be placed on the list?

If no:

- b. **VOTE:** FDA is proposing that CJC-1295 (free base) NOT be included on the 503A Bulks List. Should CJC-1295 (free base) be placed on the list?

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

Committee Discussion: *The Committee unanimously agreed that CJC-1295 (free base) should not be included on the 503A Bulks List. One member commented on the lack of evidence for effectiveness. Please see the transcript for details of the Committee's discussion.*

- c. **VOTE:** FDA is proposing that CJC-1295 acetate NOT be included on the 503A Bulks List. Should CJC-1295 acetate be placed on the list?

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

Committee Discussion: *There was no committee discussion regarding this question. Please see the transcript for details.*

- d. **VOTE:** FDA is proposing that CJC-1295 DAC (free base) NOT be included on the 503A Bulks List. Should CJC-1295 DAC (free base) be placed on the list?

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

Committee Discussion: *There was no committee discussion regarding this question. Please see the transcript for details.*

- e. **VOTE:** FDA is proposing that CJC-1295 DAC acetate NOT be included on the 503A Bulks List. Should CJC-1295 DAC acetate be placed on the list?

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

Committee Discussion: *There was no committee discussion regarding this question. Please see the transcript for details.*

- f. **VOTE:** FDA is proposing that CJC-1295 DAC trifluoroacetate NOT be included on the 503A Bulks List. Should CJC-1295 DAC trifluoroacetate be placed on the list?

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

Committee Discussion: *There was no committee discussion regarding this question. Please see the transcript for details.*

2. **VOTE:** Do committee members agree to use a single vote to address the group of AOD-9604-related bulk drug substances discussed today (AOD-9604 (free base) and AOD-9604

acetate) (Yes or No)? If any member of the Committee votes no, FDA will take separate votes on each of these substances.

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

Questions 2b and 2C were skipped based on the answer to Question 2.

If yes:

- a. **VOTE:** FDA is proposing that AOD-9604 (free base) and AOD-9604 acetate NOT be included on the 503A Bulks List. Should AOD-9604 (free base) and AOD-9604 acetate be placed on the list?

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

Committee Discussion: *There was no committee discussion regarding this question. Please see the transcript for details.*

If no:

- b. **VOTE:** FDA is proposing that AOD-9604 (free base) NOT be included on the 503A Bulks List. Should AOD-9604 (free base) be placed on the list?
 - c. **VOTE:** FDA is proposing that AOD-9604 acetate NOT be included on the 503A Bulks List. Should AOD-9604 acetate be placed on the list?
3. **VOTE:** Do committee members agree to use a single vote to address the group of Thymosin alpha-1-related bulk drug substances discussed today (Thymosin alpha-1 (free base) and Thymosin alpha-1 acetate) (Yes or No)? If any member of the Committee votes no, FDA will take separate votes on each of these substances.

Vote Result: Yes: 20 No: 1 Abstain: 0

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

If yes:

- a. **VOTE:** FDA is proposing that Thymosin alpha-1 (free base) and Thymosin alpha-1 acetate NOT be included on the 503A Bulks List. Should Thymosin alpha-1 (free base) and Thymosin alpha-1 acetate be placed on the list?

If no:

- b. **VOTE:** FDA is proposing that Thymosin alpha-1 (free base) NOT be included on the 503A Bulks List. Should Thymosin alpha-1 (free base) be placed on the list?

Vote Result: Yes: 4 No: 17 Abstain: 0

Committee Discussion: *The majority of the Committee members voted against placing Thymosin alpha-1 (free base) on the 503A Bulks List. Several Committee members who voted “No” agreed there was no compelling evidence demonstrating clinical effectiveness and safety in the uses of Thymosin alpha-1 (free base) under review. Some Committee members who voted in favor of placing Thymosin alpha-1 (free base) on the 503A Bulks List commented that this substance should be accessible to patients as an option for use. Please see the transcript for details of the Committee’s discussion.*

- c. **VOTE:** FDA is proposing that Thymosin alpha-1 acetate NOT be included on the 503A Bulks List. Should Thymosin alpha-1 acetate be placed on the list?

Vote Result: Yes: 4 No: 17 Abstain: 0

Committee Discussion: *The majority of the Committee members voted against placing Thymosin alpha-1 acetate on the 503A Bulks List due to the lack of convincing effectiveness data. Committee members who voted in favor of placing Thymosin alpha-1 acetate on the 503A Bulks List commented that this substance should also be accessible. Please see the transcript for details of the Committee’s discussion.*

The meeting was adjourned at approximately 3:35 pm ET.