FDA Briefing Document

Pharmacy Compounding Advisory Committee (PCAC) Meeting

July 23-24, 2026

The briefing packages for BPC-157-related bulk drug substances (BPC-157 (free base)/ BPC-157 acetate), KPV-related bulk drug substances (KPV (free base)/ KPV acetate), TB-500-related bulk drug substances (TB-500 (free base)/TB-500 acetate), MOTS-c-related bulk drug substances (MOTS-c (free base)/ MOTS-c acetate), Emideltide-related bulk drug substances (Emideltide (free base)/ Emideltide acetate), Epitalon-related bulk drug substances (Epitalon (free base)/Epitalon acetate), and Semax-related bulk drug substances (Semax (free base)/ Semax acetate) topics contain background information prepared by the Food and Drug Administration (FDA or Agency) for the panel members of the Pharmacy Compounding Advisory Committee (PCAC or advisory committee). We are bringing certain compounding issues to this advisory committee to obtain the advisory committee's advice. The briefing packages may not include all issues relevant to the final committee recommendation and instead are intended to focus on issues identified by the Agency for discussion by the advisory committee. The FDA does not intend to issue a final determination on the issues at hand until input from the advisory committee process has been considered and all reviews have been finalized. The final determination may be affected by issues not discussed at the advisory committee meeting.

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I. Introduction

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed Pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act: section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)); section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements).

A. Bulk Drug Substances That Can Be Used by Compounders under Section 503A

One of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A of the FD&C Act is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that:

(1) Comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;
(2) If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
(3) If such a monograph does not exist and the drug substances are not components of drugs approved by the Secretary, appear on a list developed by the Secretary through regulations issued by the Secretary under subsections (c) of section 503A (the 503A Bulks List).

(*See* section 503A(b)(1)(A)(i) of the FD&C Act.)

1. *Process for Evaluating Bulk Drug Substances Nominated for Inclusion on the 503A Bulks List*

FDA is considering substances for inclusion on the 503A Bulks List. In the *Federal Register* of February 19, 2019 (84 FR 4696), FDA published notice of a final rule establishing the criteria for evaluation of bulk drug substances for inclusion on the 503A Bulks List:

(1) The physical and chemical characterization of the substance;
(2) Any safety issues raised by the use of the substance in compounded drug products;
(3) The available evidence of the effectiveness or lack of effectiveness of a drug product compounded with the substance, if any such evidence exists; and
(4) Historical use of the substance in compounded drug products, including information about the medical condition(s) the substance has been used to treat and any references in peer-reviewed medical literature.

In evaluating bulk drug substances for the 503A Bulks List under these criteria, FDA will use a balancing test. Specifically, the Agency will consider each criterion in the context of the others

and balance them, on a substance-by-substance basis, to evaluate whether a particular substance is appropriate for inclusion on the list.

2. *Bulk Drug Substances Under Consideration for Inclusion on the 503A Bulks List*

On July 23, 2026, the Agency is considering BPC-157-related bulk drug substances (BPC-157 (free base)/BPC-157 acetate), KPV-related bulk drug substances (KPV (free base)/KPV acetate), TB-500-related bulk drug substances (TB-500 (free base)/TB-500 acetate), and MOTS-c-related bulk drug substances (MOTS-c (free base)/ MOTS-c acetate) for inclusion on the 503A Bulks List. See links provided for the background material that forms the basis for FDA's proposals regarding these bulk drug substances.

On July 24, 2026, the Agency is considering Emideltide-related bulk drug substances (Emideltide (free base)/ Emideltide acetate), Epitalon-related bulk drug substances (Epitalon (free base)/Epitalon acetate), and Semax-related bulk drug substances (Semax (free base)/ Semax acetate) for inclusion on the 503A Bulks List. See links provided for the background material that forms the basis for FDA's proposals regarding these bulk drug substances.

II. Substances Nominated for Inclusion on the 503A Bulks List (in order of discussion at the meeting)

July 23, 2026

A. BPC-157-related bulk drug substances (BPC-157 (free base) and BPC-157 acetate)

1. FDA Evaluation

2. Nominations
   a. LDT Health Solutions, Inc. on behalf of International Peptide Society[1]
   b. Wells Pharmacy Network[2]

B. KPV-related bulk drug substances (KPV (free base) and KPV acetate)

1. FDA Evaluation

[1] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0485/FDA-2015-N-3534-0487). However, FDA is electing to proceed with the presentation of BPC-157-related bulk drug substances (BPC-157 (free base) and BPC-157 acetate) to the PCAC.

[2] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0484). However, FDA is electing to proceed with the presentation of BPC-157-related bulk drug substances (BPC-157 (free base) and BPC-157 acetate) to the PCAC.

2. Nomination
   a. Wells Pharmacy Network[3]

C. TB-500-related bulk drug substances (TB-500 (free base) and TB-500 acetate)

1. FDA Evaluation

2. Nomination
   a. Wells Pharmacy Network[4]

D. MOTS-c-related bulk drug substances (MOTS-c (free base) and MOTS-c acetate)

1. FDA Evaluation

2. Nominations
   a. Wells Pharmacy Network[5]

July 24, 2026

A. Emideltide-related bulk drug substances (Emideltide (free base) and Emideltide acetate)

1. FDA Evaluation

2. Nomination
   a. LDT Health Solutions, Inc. on behalf of International Peptide Society[6]
   b. Wells Pharmacy Network[7]

[3] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0484). However, FDA is electing to proceed with the presentation of KPV-related bulk drug substances (KPV (free base) and KPV acetate) to the PCAC.
[4] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0484). However, FDA is electing to proceed with the presentation of TB-500-related bulk drug substances (TB-500 (free base) and TB-500 acetate) to the PCAC.
[5] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0484). However, FDA is electing to proceed with the presentation of MOTS-c-related bulk drug substances (MOTS-c (free base) and MOTS-c acetate) to the PCAC.
[6] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0485/ FDA-2015-N-3534-0487). However, FDA is electing to proceed with the presentation of Emideltide-related bulk drug substances (Emideltide (free base) and Emideltide acetate) to the PCAC.
[7] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0484). However, FDA is electing to proceed with the presentation of Emideltide-related bulk drug substances (Emideltide (free base) and Emideltide acetate) to the PCAC.

B. Epitalon-related bulk drug substances (Epitalon (free base) and Epitalon acetate)

1. FDA Evaluation

2. Nominations
   a. LDT Health Solutions, Inc. on behalf of International Peptide Society[8]
   b. Wells Pharmacy Network[9]

C. Semax-related bulk drug substances (Semax (free base) and Semax acetate)

1. FDA Evaluation

2. Nominations
   a. LDT Health Solutions, Inc. on behalf of International Peptide Society[10]
   b. Wells Pharmacy Network[11]

III. Points to Consider

A. July 23, 2026, morning session

Points for the PCAC to Consider Regarding Whether FDA should Include Certain Bulk Drug Substances on the 503A Bulks List

1. FDA is proposing that BPC-157 (free base) NOT be included on the 503A Bulks List.

2. FDA is proposing that BPC-157 acetate NOT be included on the 503A Bulks List.

3. FDA is proposing that KPV (free base) NOT be included on the

[8] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0485/ FDA-2015-N-3534-0487). However, FDA is electing to proceed with the presentation of Semax-related bulk drug substances (Semax (free base) and Semax acetate) to the PCAC.
[9] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0484). However, FDA is electing to proceed with the presentation of Semax-related bulk drug substances (Semax (free base) and Semax acetate) to the PCAC.
[10] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0485/ FDA-2015-N-3534-0487). However, FDA is electing to proceed with the presentation of Epitalon-related bulk drug substances (Epitalon (free base) and Epitalon acetate) to the PCAC
[11] This nomination was withdrawn by the nominator (FDA-2015-N-3534-0484). However, FDA is electing to proceed with the presentation of Epitalon-related bulk drug substances (Epitalon (free base) and Epitalon acetate) to the PCAC

503A Bulks List.

4. FDA is proposing that KPV acetate NOT be included on the 503A Bulks List.

B. July 23, 2026, afternoon session

Points for the PCAC to Consider Regarding Whether FDA should Include Certain Bulk Drug Substances on the 503A Bulks List

5. FDA is proposing that TB-500 (free base) NOT be included on the 503A Bulks List.

6. FDA is proposing that TB-500 acetate NOT be included on the 503A Bulks List.

7. FDA is proposing that MOTS-c (free base) NOT be included on the 503A Bulks List.

8. FDA is proposing that MOTS-c acetate NOT be included on the 503A Bulks List.

C. July 24, 2026, morning session

Points for the PCAC to Consider Regarding Whether FDA should Include Certain Bulk Drug Substances on the 503A Bulks List

9. FDA is proposing that Emideltide (free base) NOT be included on the 503A Bulks List.

10. FDA is proposing that Emideltide acetate NOT be included on the 503A Bulks List.

11. FDA is proposing that Epitalon (free base) NOT be included on the 503A Bulks List.

12. FDA is proposing that Epitalon acetate NOT be included on the 503A Bulks List.

D. July 24, 2026, afternoon session

Points for the PCAC to Consider Regarding Whether FDA should Include Certain Bulk Drug Substances on the 503A Bulks List

13. FDA is proposing that Semax (free base) NOT be included on the 503A Bulks List.

14. FDA is proposing that Semax acetate NOT be included on the 503A Bulks List