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Testimony Before the Food and Drug Administration's Pharmacy Compounding Advisory Committee (PCAC) Regarding Emideltide Free Base and Emideltide Acetate

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I'm Dr. Marie Ezran, a family medicine physician and a fellow with the nonprofit, consumer advocacy organization Public Citizen. I have no financial conflicts of interest related to today's topic.

Public Citizen strongly supports the assessment of the Food and Drug Administration (FDA) that emideltide, or Delta Sleep-Inducing Peptide, should not be included on the 503A Bulk Drug Substances List. The FDA assessed emideltide for the indications of chronic insomnia, narcolepsy, and opioid withdrawal. We share FDA's conclusions about the absence of convincing evidence on the efficacy of this peptide, safety concerns regarding the lack of chemical characterization, and the incomplete information on impurities.

Emideltide is a common name that includes multiple bulk drug substances with different active molecules. The lack of consistency in the nomenclature and chemical structure of this imprecise substance is a safety risk, since individuals may receive different emideltides with possible variable clinical effects.[1]

In addition, these peptides are sensitive to the environmental conditions in which they are produced and stored. There is a high risk of peptide aggregation and loss of biological activity. There is also a concern for immunogenicity for both emideltide free base and acetate due to incomplete information on their potential impurities. Emideltide free base is a powder with limited solubility in water, leading to potential issues with formulating the injection at a specified concentration.[2]

There is little evidence about the efficacy of emideltide in humans for the indications of chronic insomnia, narcolepsy, and opioid withdrawal. The clinical trials the FDA considered are limited by small sample size, lack of placebo-controlled methods, and short trial duration.[3]

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[1] Food and Drug Administration. FDA briefing document for Emideltide – related bulk drug substances (emideltide (free base) and emideltide acetate) prepared for the July 23-24, 2026, meeting of the Pharmacy Compounding Advisory Committee. May 11, 2026. https://www.fda.gov/media/193344/download. Accessed July 23, 2026.
[2] *Ibid.*
[3] *Ibid.*

For example, for the indication of chronic insomnia the FDA identified seven studies dating from 1981 to 1992 with fewer than 20 individuals per study. There were inconsistent findings for the endpoints of sleep latency, nocturnal awakening, and total sleep time.[4] One study from 1992, Bes et al., had 16 participants with chronic insomnia. Half of the participants received emideltide and half received glucose over three consecutive nights. The experimental group had weak improvements in sleep efficiency and sleep latency but no differences in additional objective measures of sleep.[5] It is concerning that there are no clinical trials more recent than 1992 about the efficacy of this peptide.

There are even less data for the other indications. The FDA identified one case report on the effect of emideltide in a patient with narcolepsy. For opioid withdrawal, there are two clinical trials. There is also an absence of research that demonstrates how this peptide could potentially treat opioid withdrawal. In fact, based on in-vitro and rat experiments, it is possible that emideltide stimulates the opioid system by releasing enkephalins that then bind to the opioid receptors.[6] In the midst of an opioid epidemic, the FDA should not make products with unknown addiction potential available to the public.[7]

To be clear, emideltide is not recommended in any clinical guideline for the conditions the FDA reviewed or other medical diagnoses.[8] I have never recommended emideltide to my patients. Although you may hear from individuals who have experienced positive results from taking this peptide, these testimonies are anecdotal. Without large, randomized clinical trials, it is impossible to know whether emideltide is in fact a safe and effective treatment for any disease or condition.

Finally, Public Citizen is concerned about the composition of the Pharmacy Compounding Advisory Committee and the conflicts of interest of some committee members who own or work at health companies that promote or sell peptides.

In summary, Public Citizen strongly supports the FDA's recommendation to reject the inclusion of emideltide on the 503A Bulk Drug Substances List. We therefore urge the committee to vote that the FDA should not include emideltide free base or emideltide acetate on the 503A Bulks List. Thank you.

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[4] *Ibid.*

[5] Bes F, Hofman W, Schuur J, Van Boxtel C. Effects of delta sleep-inducing peptide on sleep of chronic insomniac patients. A double-blind study. *Neuropsychobiology*. 1992;26(4):193-197.

[6] Food and Drug Administration. FDA briefing document for Emideltide – related bulk drug substances (emideltide (free base) and emideltide acetate) prepared for the July 23-24, 2026, meeting of the Pharmacy Compounding Advisory Committee. May 11, 2026. https://www.fda.gov/media/193344/download. Accessed July 23, 2026.

[7] Skolnick P. The opioid epidemic: crisis and solutions. *Annu Rev Pharmacol Toxicol*. 2018;58(January 6):143-159.

[8] Food and Drug Administration. FDA briefing document for Emideltide – related bulk drug substances (emideltide (free base) and emideltide acetate) prepared for the July 23-24, 2026, meeting of the Pharmacy Compounding Advisory Committee. May 11, 2026. https://www.fda.gov/media/193344/download. Accessed July 23, 2026.