

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 19, 2025

The Honorable Joseline A. Peña-Melnyk Chair, House Health and Government Operations Committee Room 241, House Office Building Annapolis, Maryland 21401

RE: House Bill (HB) 996 – Public Health - Phenibut Consumer Protection Act – Letter of Information

Dear Chair Peña-Melnyk and Committee members:

The Maryland Department of Health (the Department) respectfully submits this letter of information for House Bill (HB) 996 – Public Health - Phenibut Consumer Protection Act. This bill prohibits retailers from preparing, distributing, selling, or exposing for sale Phenibut products that have been adulterated or contaminated with dangerous substances other than Phenibut, which is defined as a product containing any level of beta–Phenyl–Gamma–Aminobutyric Acid 3 HCL. Additionally, this bill prevents the sale of Phenibut products to individuals under the age of 21 years, and requires a report from the Department and the Maryland Hospital Association on adverse events related to Phenibut.

The U.S. Food and Drug Administration (FDA) regulates food, drugs, and dietary supplements at the Federal level. The FDA has not approved any prescription or over-the-counter drug products containing Phenibut or its main chemical component, beta–Phenyl–Gamma–Aminobutyric Acid 3 HCL. There are no drug products containing Phenibut or its main chemical components that are legally on the market in the U.S., and the FDA has warned against the use of unapproved Phenibut products for medical treatment. In addition, the FDA has determined Phenibut is not appropriate for use as a dietary ingredient in dietary supplements, as there is insufficient evidence that it can be considered safe. Finally, for that same reason, the FDA has advised that Phenibut may not be used as a food ingredient.

The Department has the utmost interest in making sure Marylanders are not exposed (intentionally or otherwise) to potentially dangerous foods, dietary supplements, and unapproved medications. In the United States, Phenibut is legal to possess, but, as noted above, is not approved as a licensed pharmaceutical drug and does not meet the definition of a dietary ingredient in dietary supplements. In 2020, The Centers for Disease Control and Prevention (CDC) noted that Phenibut use and misuse can result in sedation, respiratory depression, and reduced levels of consciousness, as well as withdrawal symptoms including anxiety, agitation,

and acute psychosis. Regional poison center data suggested that adverse Phenibut exposures have increased in recent years, but is still limited in total number of cases.¹

Currently, medical harms related to consumer products like Phenibut are monitored through poison control services. Additionally, local and state entities can directly report the presence of Phenibut in their communities to the FDA through their telephone hotline or through their online portal. FDA has a history of enforcement around Phenibut labeled products including contacting manufacturers to withdraw their product and fines to companies selling the products.² Phenibut is not a substance detected on standard drug test,³ potentially limiting the capability of hospitals to provide surveillance and the Department would be unlikely to be able to identify Phenibut in current surveillance systems due its method of consumption.

If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs at sarah.case-herron@maryland.gov.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.

Secretary

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¹ Graves JM, Dilley J, Kubsad S, Liebelt E. Notes from the Field: Phenibut Exposures Reported to Poison Centers — United States, 2009–2019. MMWR Morb Mortal Wkly Rep 2020;69:1227–1228. DOI: http://dx.doi.org/10.15585/mmwr.mm6935a5.

²https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/arizona-company-and-ceo-plead-guilty-distribution-drugs-not-approved-fda-and-will-pay-24-million

³https://pmc.ncbi.nlm.nih.gov/articles/PMC11456982/#:~:text=However%2C%20phenibut%20does%20not%20show,disclose%20its%20use%20%5B8%5D.