CENTER FOR Science IN THE Public Interest
The nonprofit publisher of Nutrition Action Healthletter

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Director, Center for Food Safety and Applied Nutrition
and
Dr. Patrizia Cavazzoni
Director, Center for Drug Evaluation and Research
and
Dr. Cara Welch
Acting Director, Office of Dietary Supplement Programs
and
Dr. Mark Moorman
Director, Office of Food Safety
and
Dr. Conrad Choiniere,
Director, Office of Analytics & Outreach

Food and Drug Administration
10001 New Hampshire Ave
Hillandale Bldg., 4th Floor
Silver Spring, MD 20993

Dear Director Susan Mayne, Director Patrizia Cavazzoni, Director Cara Welch, Director Mark Moorman, and Director Conrad Choiniere:

The Center for Science in the Public Interest (CSPI), the Alabama Association of Christian Recovery Ministries (ACCRM), and Dr. Pieter Cohen urge the U.S. Food and Drug Administration (FDA) to issue warning letters and pursue enforcement action against dietary supplement companies that illegally market phenibut products.

Phenibut is a potent psychoactive substance[1] used recreationally to achieve euphoria and other psychotropic effects.[2] It was developed in Russia for the treatment of anxiety and sleep disorders but has no approved use in the United States.[3] Phenibut use can result in adverse effects including sedation, respiratory depression, and reduced levels of consciousness.[4] Its withdrawal symptoms include anxiety, agitation, and acute psychosis.[5] From 2009-2019, US poison centers reported receiving 1,320 calls about phenibut exposure, of which about 12% were associated with major effects, including three deaths, and 80 reported comas.[6]

In the past three years, the agency has issued four warning letters against companies for illegally marketing phenibut products, detailed below.[7] Most recently, in July 20, 2021, FDA issued a warning letter to Chill6, which sells a variety of flavored beverages containing phenibut, on the grounds that it is an unapproved drug or, in the alternative, an adulterated and misbranded food

or dietary supplement.[8] Our enforcement request builds on these previous actions by identifying additional companies that continue to illegally market the substance and urging the agency to clarify to the public that the sale of phenibut products for consumption is illegal in the United States.

Specifically, we have identified 14 unique phenibut products that fit into three regulatory categories, which are determined based on how the products are marketed and their non-phenibut ingredients. (Broadly speaking, products that are marketed as dietary supplements and contain at least one dietary ingredient are regulated as dietary supplements, those without a dietary ingredient as foods, and those that claim to treat disease as drugs):

(a) Adulterated and Misbranded Dietary Supplements:
We found six dietary supplements that are adulterated with phenibut and misbranded because they represent phenibut (a non-dietary ingredient) as one of their dietary ingredients.
(b) Adulterated and Misbranded Foods:
We found one food product that is adulterated with phenibut and misleadingly marketed as a dietary supplement even though it contains no dietary ingredients.
(c) Unapproved Drugs:
We found seven products marketed with disease claims (*i.e.*, these products contained claims that the products can diagnose, cure, mitigate, treat, or prevent disease) even though they are not approved drugs.

As we explain below, the FDA has determined that incorporating phenibut into any of these products, whether they qualify as dietary supplements, foods, or drugs, is prohibited in the United States. This is because the FDA has banned phenibut as an unsafe additive in foods and dietary supplements, such that adding phenibut renders these products adulterated. Further, they may be misbranded as well if their labeling misrepresents what they are. Companies that market phenibut products to treat disease can also be prosecuted for selling their products as unapproved new drugs.

Our letter presents 14 different phenibut products being sold in the US that have not yet been targeted by the agency for enforcement action and explains how each runs afoul of FDA rules.

These 14 products are marketed by 19 different companies, which are also listed in Table 1. We request that the FDA send warning letters to these 19 entities, as well as any other parties involved in illegally manufacturing, distributing, and marketing products containing phenibut. We also request that the agency update its public facing web content[9] to inform consumers and industry that phenibut is an unsafe food additive and adulterant banned in foods and dietary supplements.

Our request is particularly warranted in light of the increase in phenibut exposures reported to poison control centers, also detailed below.[10] Moreover, a study published on September 22, 2021 found that some phenibut products were found to contain as much as 450% more phenibut than a typical 250 mg pharmaceutical tablet.[11]

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government grants or corporate donations. A core part of CSPI's mission is providing consumers with current information relevant to their health and well-being. CSPI publishes Nutrition Action Healthletter, which provides science-based advice on health and nutrition to hundreds of thousands of readers. CSPI regularly advocates for greater transparency, disclosure, and the safety of food ingredients.

ACCRM is Alabama's largest residential recovery network, with the daily capacity to care for more than 3,000 persons. The members of AACRM's state-wide network personally observed the growing abuse of phenibut for its psychotropic effects and are concerned about how its widespread availability impacts addiction and recovery of their clients.

After ACCRM successfully advocated for tianeptine to be listed as a class two substance by the Alabama Department of Public Health,[12] its members and local police saw that tianeptine was quickly replaced by phenibut in Alabama stores, resulting in a rise in reported phenibut overdoses.[13] In response, the Alabama legislature quickly passed legislation classifying phenibut as a controlled substance.[14] Although phenibut is no longer commonly sold in Alabama's physical retail locations, ACCRM remains concerned that phenibut is readily available in neighboring states and online exposure is prevalent throughout the country. Without federal enforcement, phenibut will continue to be a public health threat.

I. Legal Background and History of FDA Enforcement Against Marketers of Phenibut Products

The FDA previously issued four warning letters against companies marketing phenibut products as dietary supplements, conventional foods, and unapproved drugs.[15] These letters demonstrate that the sale of phenibut for consumption is prohibited in the United States because the FDA has determined phenibut is not a dietary ingredient,[16] declared phenibut to be an unsafe food additive,[17] and has not approved phenibut as a drug for any use.

(a) Phenibut in Conventional Foods

The FDA has indicated that phenibut cannot be added as a food ingredient to conventional foods. In a July 2021 warning letter against to the maker of Chill6 beverages, the FDA determined that phenibut is an unsafe food additive, not a generally recognized as safe (GRAS) substance, and not a dietary ingredient.[18] Therefore, phenibut would be considered an adulterant if added to any food.[19]

(b) Phenibut in Dietary Supplements

Dietary supplements are a subset of foods that contain one or more dietary ingredients and are marketed as dietary supplements (among other requirements).[20] As such, the FDA indicated in its July 2021 warning letter that dietary supplements that contain phenibut are also adulterated, the same as conventional foods.[21]

In addition, supplements that contain phenibut can be misbranded if they misrepresent phenibut as a "dietary ingredient" in their labeling. In April 2019, the FDA issued warning letters to three companies—Atomixx; Evol Nutrition Associates, Inc. (Red Dawn Energy); and NeuroScience Solutions, Inc. (NeuroScience)—for illegally listing phenibut as a dietary ingredient in their supplements.[22] As the agency explained in these warning letters, phenibut cannot be sold as a dietary ingredient in dietary supplements because the Federal Food, Drug, and Cosmetic Act (FDCA) defines "dietary ingredient" as "a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances."[23] The agency stated in these April 2019 letters that "[b]ecause phenibut does not fit in any of the dietary ingredient categories under section 201(ff)(1) of the [FDCA], it is not a dietary ingredient as defined in the Act."[24] Therefore, declaring phenibut as a dietary ingredient causes a supplement to be misbranded because such labeling is "false or misleading."

(c) Phenibut Marketed as Drugs

Phenibut also cannot be legally marketed as a drug in the United States.[25] In its July 2021 letter to Chill6, the agency explained that to the extent those products are marketed for the intended use of treating disease, they are considered a "new drug" under section 201(p) of the FDCA, and cannot be introduced into commerce without prior FDA approval (which has not been granted).[26]

All of the April 2019 warning letter recipients have now responded by ceasing online marketing of products that listed phenibut as an ingredient. A review of the websites for each of the three companies shows that the products are either "temporarily unavailable online"[27] or are now marketed without listing phenibut.[28,29]

However, as of September 22, 2021, five flavors of Anti Anxiety & Vitality Formula made by Chill6, the most recent recipient of a warning letter, are still sold on its website.[30] The products' website bears a supplement facts panel that lists 628 mg of Phenibut HCL under the heading, "Nootropic Compound Facts."[31]

II. Companies Currently Marketing Phenibut in Violation of Federal Law

A search by CSPI and ACCRM found 19 companies marketing the 14 phenibut products illegally as dietary supplements, foods, or drugs. In September 2020, CSPI searched Google for companies involved in marketing phenibut. This search included the keywords "phenibut," "phenibut supplements," "phenibut capsules," and "phenibut powders."

This material was supplemented in September and November 2020, when Brandon Lackey, Executive Administrator of ACCRM, reported that the following retailers were recommended by users of a Facebook support group: rupharma.com, nootropicsdepot.com, liftmode.com, www.newmind.com. We searched each website for evidence of phenibut sales.

At that time, Brandon Lackey also forwarded pictures and addresses collected by ACCRM members of Za Za Silver products sold in convenience stores in Alabama.

The phenibut products found in our search are listed in Table 1, Appendix A, and Appendix B. As described in more detail in Table 1, these products are marketed on online stores, including at least one major grocery chain, Kroger.[32]

Although Chill6's beverages were still marketed with phenibut at the time of our market search, the beverages are not included in our list of additional phenibut products, as the products were already subject to the FDA's July 2021 warning letter.

(a) Adulterated and Misbranded Dietary Supplements:

We have identified the following six dietary supplements that contain phenibut and misleadingly list phenibut as a dietary ingredient, rendering them adulterated and misbranded dietary supplements:

- Za Za Silver (manufacturer not listed);[33]
- K Chill by K Chill;[34]
- Relax-All With Phenibut by Metabolic Relax Modifiers;[35]
- Phrenze White by MT Brands;[36]
- Phrenze Red by MT Brands;[37,38] and
- ZaZa Red Energy Shot by MT Brands[39]

Table 1 provides additional details for these products.

Because phenibut is an unsafe food additive and not a dietary ingredient, we urge the FDA to issue warning letters to these companies for including phenibut as an adulterant and misleadingly representing the substance as a dietary ingredient in their dietary supplements.

(b) Foods Adulterated with Phenibut and Misleadingly Marketed as Dietary Supplements

We have identified one food product that is adulterated with phenibut and marketed as a phenibut "supplement" without listing any substances that would qualify as dietary ingredients (as previously mentioned, the FDA has determined that phenibut itself is not a dietary ingredient):

- Phenibut by Repp Sports[40,41,42]

This product's details are listed in Table 1. Because this product lacks a dietary ingredient, it does not legally qualify as a dietary supplement under section 201(ff)(1) of the FDCA, which requires that a supplement "bears or contains one or more … dietary ingredients."[43]

Instead, the product is a misbranded food. As the FDA has explained previously,[44] dietary supplements are a subset of food products under the broader "umbrella" of foods, distinguished from conventional foods by meeting specific statutory requirements. Claiming that a food product is a dietary supplement when it does not qualify as such misbrands that food, because the claim is false or misleading.[45]

In addition to being misbranded, this food product is also adulterated because phenibut is an unsafe food additive.[46]

(c) Phenibut Products Marketed Illegally as Unapproved New Drugs

We identified the following seven phenibut products being marketed illegally as unapproved drugs with disease claims on either the label, the website, and/or other marketing materials:

- Phenibut by Absorb Health;[47]
- Phenibut by MT Brands;[48]
- Phenibut HCl (Fine Crystals) by Liftmode;[49]
- Phenibut HCL powder by Life Science Solutions, LLC;[50]
- PHENIBUT® (Fenibut, Phenybut) by Belmedpreparaty, RUE;[51]
- ANVIFEN® (Phenibut, Noofen, GABA) by Anvi Laboratory;[52] and
- NOOFEN® (Phenibut, GABA) by OlainFarm[53]

The above products are also listed in Table 1 with the disease claims that render the products unapproved drugs.

Disease claims state or imply a product can diagnose, cure, mitigate, treat, or prevent disease.[54] Such claims render these products drugs under the FDCA, which defines the term "drug" by a product's intended use, as evidenced by disease claims.[55] When determining whether a product makes a disease claim, the FDA can consider statements on the product's label, the context in which the claim is presented, and marketing material.[56]

All seven products contain multiple claims to treat diseases. For example, our search found two products with claims related to hangovers, six products with claims related to anxiety, two products for post-traumatic stress disorder (PTSD), and two for depression. One product, *NOOFEN*® sold by RUPharma, claims that it can be used to "Eliminate Stuttering, Tics, and Enuresis in Children."[57] ANVIFEN®, also sold by RUpharma, even states "ANVIFEN (Phenibut, Noofen) is a nootropic drug" and that "[t]he drug is administered orally after meals."[58] Phenibut by Belmedpreparaty, RUE claims that phenibut can normalize sleep, reduce the effects of hangovers, help quit smoking, and treat vestibular disorders.[59] Details of these products, including the disease claims, can be found in Table 1 and Appendix B.

Phenibut has not been approved as a drug in the United States, and the interstate sale of these phenibut products as drugs making disease claims is therefore prohibited under the FDCA.[60]

Even if these marketing claims did not qualify as disease claims, or were removed from the products, these products still could not be legally marketed. This is because the inclusion of phenibut would render them adulterated foods or dietary supplements. In addition, the products would be misbranded to the extent that they misleadingly claim phenibut as a dietary ingredient, and/or claim to be dietary supplements without containing a dietary ingredient.

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Table 1:

Phenibut Products marketed online
as dietary supplements,[1] foods,[2] or drugs[3]

Brand Name & Manufacturer/ Distributors	Retailer(s)	Declared "Dietary Ingredient(s)"[4]	Disease Claims	Recommended Dosage
ZA ZA Silver by M&J Distribution[61]	Jack B Goods Outlet Store[62]	Proprietary Blend of Tianeptine, **Phenibut**, and Piper Methysticum	n/a	700mg of proprietary blend
K Chill by K Chill	Jack B Goods Outlet Store[63]	Kratom, White Willow, Passion Flower and California Poppy, Blend of Mitragyna Speciosa extract, Gamma Aminobutyric Acid, 4-isopropenyl-1-methylcyclohexene, Blue Lotus Extract, dimethylethanolamine, Kanna Extract, Tongkat Ali Extract, **β-phenyl-γ-aminobutyric acid**, Pikamilon, Passion Flower, and White Willow Bark[64,65,66]	n/a	1,115mg of proprietary blend
Relax-All With Phenibut by Metabolic Response Modifiers	Kroger[67]	Product Listing: Neuralcalm (Proprietary Blend) , L-Tryptophan (600mg), Gamma Aminobutyric Aciid (Gaba) (450 Mg), Jujube Extract (2 and [sic] Jujubosides), (400 Mg), Valerian Root Extract (.8 and [sic] Valeric Acid) (300 Mg), Inositol (250 mg), Ashwagandha (1 . 5 and [sic], with	n/a	2,400 mg of proprietary blend[71]

[1] Products that lack disease claims and list multiple Active/Dietary Ingredients are adulterated/misbranded supplements.
[2] Products that lack disease claims and list only phenibut as an active/dietary ingredient are misbranded/adulterated foods.
[3] Products with disease claims are unapproved drugs.
[4] Phenibut, as well as its other names, are bolded.

Brand Name & Manufacturer/ Distributors	Retailer(s)	Declared "Dietary Ingredient(s)"[4]	Disease Claims	Recommended Dosage
		: Anolides) (150 Mg), Chamomile Flowers (Matricaria Recutita) (100mg), Lemon Balm (Melissa Officinalis) (100mg), Venetron (Rafuma Leaf Extract) (50 mg), Rice Flour.[68] From Supplement Fact Panel*: Proprietary blend of L-Tryptophan **Beta-phenyl-gamma-aminobutyric acid (Phenibut 500 mg)**, Jujube Extract (2% Jujubosides), Valerian Root Extract (0.8% Valeric acid), Inositol Ashwagandha (1.5% withanolides), Chamomile Flower (Anthemis nobilis), Lemon Balm (Melissa officinalis)[69] *The supplement facts panel was not found on Kroger's website; however, these ingredients and images of the Relax-All's supplement facts panel were found on www.iherb.com.[70]		
Phrenze White by MT Brands[72]	n/a	**Phenibut**, Kava Extract, L-Theanine, Caffeine, Aloe Vera Powder, Noopept, and Vitamin B6	n/a	n/a
Phrenze Red by MT Brands[73]	Ark Smoke Shop[74]	**Phenibut**, Kava Extract, Aloe Vera Powder, Noopept, and Vitamin B6	n/a	n/a
Za Za Red Energy Shot	Jack B Goods Outlet Store[75]	**Phenibut**, Caffeine, GABA, 5-HTP	n/a	n/a
Phenibut by Repp Sports	Wilson Supplements,[76] My Supplement	**Phenibut**	n/a	250mg

Brand Name & Manufacturer/ Distributors	Retailer(s)	Declared "Dietary Ingredient(s)"[4]	Disease Claims	Recommended Dosage
	Store,[77] and Sports Nutrition Authority.[78]			
Phenibut by MT Brands[79]	Ark Smoke Shop[80]	**Phenibut**[81]	"The locals of Russia and Ukraine have extensively used Phenibut as a cognitive treatment for a variety of reasons. Users report that it promotes improved brain and cognitive-related functions and may even suppress symptoms of anxiety, especially social anxiety. Purchase Phenibut in capsules or powder."[82]	n/a
Phenibut HCL powder by Life Science Solutions, LLC	TheSmartShopOnline[83]	**Phenibut**[84]	• "Phenibut is primarily used to treat anxiety and stress. Aside from this, there are a lot more other uses for this nootropic drug, which includes [sic]: o Alcoholism o Fear and anxiety o Stress and fatigue o Depression and insomnia o Improving memory, learning, and thinking"[85] • "In Russia, where the drug was originally invented and produced, it is used as prescribed medication for treatment of large variety of psychological conditions including treatment of asthenia, depression, alcoholism, alcohol withdrawal syndrome, post-traumatic stress disorder, stuttering, tics, vestibular disorders, Meniere's disease, dizziness, for the prevention of motion sickness, and for the prevention of anxiety before or after surgical procedures or painful diagnostic tests."[86]	n/a
Phenibut by Absorb Health	Absorb Health[87]	**Phenibut**	"Phenibut has been shown to: protect against stress, reduce severity of brain injuries (Tiurenkenov, 2012); reduce anxiety (Tiurenkenov, 2011); and modulate the immune system (Samotrueva, 2010)"[88]	250mg
Phenibut HCl (Fine Crystals) by Liftmode	Liftmode[89]	**Phenibut**[90]	• Support relaxation, restful sleep, and positive mood.[91] • Product listing contains the following link, Can you use Phenibut to cure a hangover?,[92] which takes users to the a blog entry with the following claims:	500mg

Brand Name & Manufacturer/ Distributors	Retailer(s)	Declared "Dietary Ingredient(s)"[4]	Disease Claims	Recommended Dosage
			○ "Can you use Phenibut to cure a hangover? Phenibut is commonly used as an effective anti-stress product, and sometimes as a hangover cure."[93] ○ "Can Phenibut help with a hangover? Yes! Phenibut's main effects include reducing stress and promoting a feeling of calmness and serenity. Hangovers often leave you feeling low, depressed, and anxious, and this is exactly where Phenibut comes in. Another important factor is that Phenibut is able to reduce the sensations of pain, by targeting GABA-B receptors."[94]	
PHENIBUT ® (Fenibut, Phenybut) by Belmedpreparaty, RUE	RUPharma.com[95]	**Aminophenylbutyric Hydrochloride Acid** - 250 mg* *Listed as an "Active Ingredient"	• "Normalise [sic] Sleep" [96] • "Reduce the Effect of Hangovers (Reclaim Concentration Faster)" [97] • "Help in Quit Smoking" [98] • "Phenibut is used ti [sic] treat post-traumatic stress disorder, anxiety, depression, asthenia, insomnia, alcoholism, stuttering, and vestibular disorders." [99]	Maximum single dose: 750 mg, for patients over 60 years: 500 mg
ANVIFEN® (Phenibut, Noofen, GABA) by Anvi Laboratory	RUpharma.com[100]	**Phenibut**, Noofen, GABA*[101] *These ingredients are listed in the product's name	• ANVIFEN (Phenibut, Noofen) is a nootropic drug[102] • "Treat Asthenia (Loss of Energy and Strength)."[103] • "Reduce Anxiety and Tension."[104] • "Eradicate Sleep Disorders."[105] • "Reduce Alcohol Withdrawal Syndrome."[106] • "Remove Stammering and Tic Disorders in Children."[107] • "…reduces vazovegetative symptoms including headaches, feeling of heaviness in the head, sleep disturbances, irritability, emotional lability)."[108]	Adults and children over 14 years: 250-500 mg 3 times a day. Children aged 3 to 8 years old: 50-100 mg 3 times a day. 8 to 14 years old: 250 mg 3 times a day. Alcohol withdrawal syndrome: 250-500 mg 3 times a day. Vertigo vestibular

Brand Name & Manufacturer/ Distributors	Retailer(s)	Declared "Dietary Ingredient(s)"[4]	Disease Claims	Recommended Dosage
				dysfunction and Meniere's disease: 250 mg 3 times a day for 14 days[109]
NOOFEN® (Phenibut, GABA) by OlainFarm	RUpharma.com[110]	**Aminophenylbutyric Hydrochloride Acid*** *Listed as an "Active Ingredient"	• "…reduces fatigue and vasovegetative symptoms, including headache..."[111] • "Treat Asthenic and Anxious-Neurotic Condition."[112] • "Eliminate Stuttering, Tics, and Enuresis in Children."[113] • "Remove Insomnia, Night Anxiety in the Elderly."[114] • "Treat Meniere's Disease, Vertigo."[115] • "Noofen increases dopamine level, thus providing anti-anxiety and antidepressant effects."[116]	The usual dose for adults is 250-500mg 3 times a day before meals. Maximum daily dose is 750mg[117]

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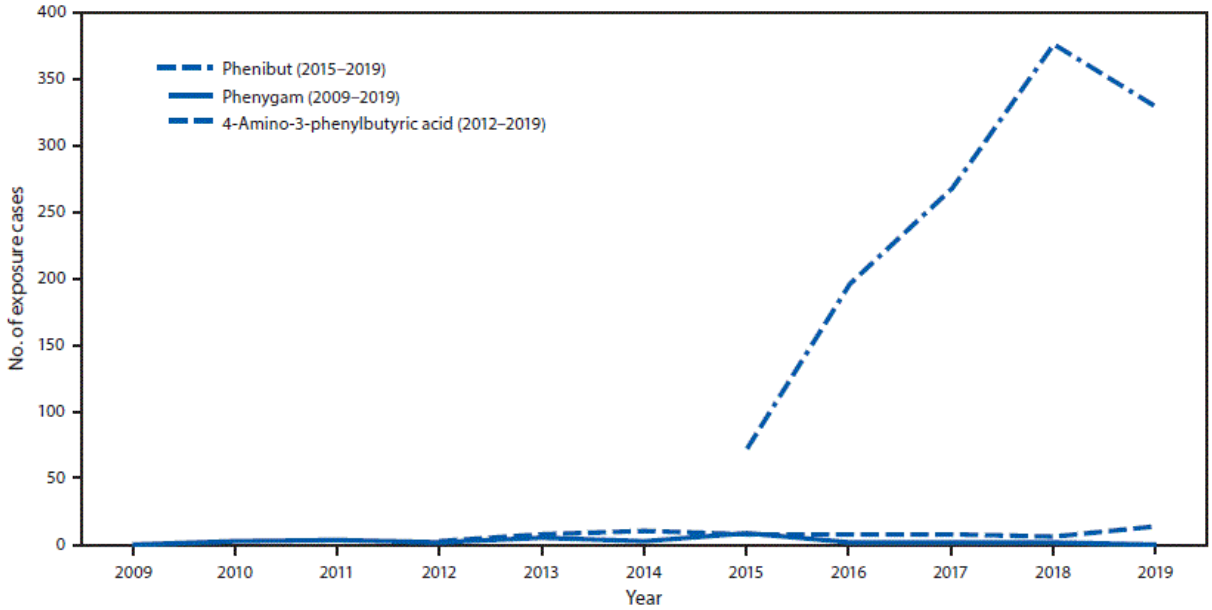
III. Public Health Need for Urgent Enforcement

Enforcement action against phenibut manufacturers, distributors and retailers is warranted because of the rising public health burden of phenibut products. As noted above, phenibut poses safety risks because its use can result in sedation, respiratory depression, and reduced levels of consciousness.[118] It also produces withdrawal symptoms that include anxiety, agitation, and acute psychosis.[119]

Recently, the Centers for Disease Control and Prevention (CDC) identified a dramatic rise in phenibut exposure calls reported to U.S. Poison Control Centers in the last ten years (see Figure below).[120]

Over 1,300 reports of phenibut exposure were reported between 2009 and 2019, with over 600 reports in 2018-2019 alone.[121] Twelve percent of all reported cases were considered life-threatening or resulted in significant disability or disfigurement, including three deaths and more than 80 cases resulting in coma.[122]

FIGURE:
Number of exposure cases related to phenibut* use reported to poison centers, 2009-2019[123]



* The graph also depicts data for phenygam and 4-amino-3-phynylbutyric acid, which are synonyms for phenibut used before the database included a code for phenibut specifically.

In addition to posing inherent safety risks, supplements containing phenibut should also be given high enforcement priority because many of these products are being marketed in direct competition with FDA-approved anxiety and sleep disorder treatments and drugs, and some target vulnerable populations, such as children.[124] For example, *NOOFEN*®, which contains phenibut, is marketed by RUPharma as a treatment for stuttering, tics, and enuresis in children.[125]

Additional risks may arise from undeclared phenibut. One study tested a sample of ten cognitive enhancement supplements and detected one supplement containing about 15.4 milligrams of phenibut per serving.[126]

The products identified in this letter and evidence from the published literature demonstrate that the FDA actions to date have been insufficient to eliminate phenibut product sales and the associated public health risk. Therefore, the agency should continue to take additional enforcement action against supplements that contain this ingredient.

IV. FDA Should Update its Public Facing Content to Better Inform Consumers and Industry that Phenibut Is an Unsafe Food Additive and Adulterant

In its July 2021 warning letter to the maker of Chill6 beverages, the agency concluded that phenibut was an unsafe food additive, meaning the addition of phenibut to a food or dietary supplement renders that product adulterated.[127] However, FDA's consumer webpages on phenibut only state that the substance is not a dietary ingredient and declaring it as such would cause a dietary supplement to be misbranded.[128]

We request that the FDA update its consumer facing content to better inform consumers, public health advocates, and industry that phenibut is an unsafe food additive, an adulterant, and not allowed to be sold as a dietary supplement, food, or drug in the United States.

V. Conclusion

We respectfully urge FDA to take more decisive enforcement action against companies that continue to market, sell, and distribute products containing phenibut. Specifically, the FDA should work with federal, state, and local officials—including the state governors, health officers, and attorneys general—to remove the dangerous products listed in this letter from the market, as well as identify and take enforcement action against additional companies involved in the phenibut market. The agency should also take measures to better inform the public that phenibut is an adulterant. We thank you for your efforts in this matter.

Sincerely,

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[20] 21 U.S.C. § 321(ff). In addition to containing a dietary ingredient and being marketed as supplements, the products must be intended for ingestion (i.e. the supplements are marketed as dietary supplements and have no inhalation or injection instructions), have no representations for use as a conventional food or sole item of a meal, and not list any article approved or authorized for investigation as a new drug, antibiotic or biological.
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[44] *E.g.* FDA. *Questions and Answers on Dietary Supplements*. July 22, 2019. https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements. Accessed September 14, 2021. ("DSHEA places dietary supplements in a special category under the general umbrella of 'foods,' not drugs, and requires that every supplement be labeled a dietary supplement").
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[56] 21 C.F.R §101.93(g). FDA. *Questions and Answers on Dietary Supplements*. July 22, 2019. https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements. Accessed May 26, 2020. (Noting that a product sold as a dietary supplement that promotes on its labeling—which includes the label as well as accompanying material that is used by a manufacturer to promote and market a specific product—the treatment, prevention or cure for a specific disease or condition would be considered an unapproved and illegal drug.).
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[58] Product listing: *ANVIFEN® (Phenibut, Noofen, GABA) 250 mg/cap, 20 caps*. https://rupharma.com/anvifen/. Accessed November 6, 2020.
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[118] CDC. *Notes from the Field: Phenibut Exposures Reported to Poison Centers — United States, 2009–2019*. September 4, 2020. https://www.cdc.gov/mmwr/volumes/69/wr/mm6935a5.htm. Accessed September 18, 2020.

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