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UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

JAIME ARNOLD, on behalf of herself and all others similarly situated, Plaintiff, v. I-HEALTH, INC. and DSM NUTRITIONAL PRODUCTS, INC, Defendants.	Case No. Pleading Type: Class Action **CLASS ACTION COMPLAINT FOR VIOLATIONS OF:** **THE UNFAIR COMPETITION LAW ANDTHE CONSUMER LEGAL REMEDIES ACT** **No Jury Demand**

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Plaintiff Jaime Arnold on behalf of herself, all others similarly situated, and the general public, by and through her undersigned counsel, hereby sues Defendants I-Health, Inc. and DSM Nutritional Products, Inc. (collectively "I-Health" or "Defendants") and upon information and belief and investigation of counsel, alleges as follows:

I. JURISDICTION AND VENUE

1. Jurisdiction is proper because Plaintiff Jaime Arnold is a citizen of California and because all claims are asserted under the laws of California and relate to a product that is sold in California and purchased by Plaintiff in California.

2. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Plaintiff Jaime Arnold and hundreds or thousands of class members reside in this District and suffered injuries as a result of Defendant's conduct in this District; many of the acts and transactions giving rise to this action occurred in this District; and Defendants (1) are authorized to conduct business in this District, and have intentionally availed themselves of the laws and markets of this District through the distribution and sale of their products in this District, and (2) are subject to personal jurisdiction in this District.

II. PARTIES

3. Plaintiff Jaime Arnold is a citizen and resident of Sacramento, California who purchased Mood Boost and Stress Relief during the class period for personal consumption.

4. Defendant I-Health, Inc. is a Delaware corporation with its principal place of business in Shelton, Connecticut. It is a wholly owned subsidiary of Defendant DSM Nutritional Products, Inc.

5. Defendant DSM Nutritional Products, Inc. ("DSM"), is a Delaware corporation with its principal place of business in Plainsboro, New Jersey.

6. During the class period, Defendants manufactured, marketed, distributed, and sold a line of purported menopause relief supplements under the Estroven brand name, including Estroven Mood Boost ("Mood Boost") and Estroven Stress Relief & Energy Boost ("Stress Relief") (collectively "Estroven").

7. At all times relevant, Defendant I-Health acted on behalf of, and as an agent for, Defendant DSM. At all times relevant Defendant DSM had the right to control its agent, I-Health.

III. SUMMARY OF CLAIMS

8. During the class period, Defendants marketed, distributed, and sold Estroven Mood Boost and Estroven Stress Relief. Defendants claim that Mood Boost "is formulated to provide relief from hot flashes and night sweats plus improve mood and support memory." Defendants similarly claimed that Stress Relief is "is formulated to provide relief from hot flashes and night sweats plus manage stress and fatigue."

9. These claims are misleading, as none of the "active ingredients" in Estroven—which include Soy Isoflavones, Black Cohosh Root Extract, Gingko Biloba Leaf Extract, and Magnolia Bark Extract, safely and effectively treat menopause symptoms such as "hot flashes," "night sweats," "sleeplessness," "low energy," "mood swings & more."

10. Further, I-Health markets Estroven with efficacy claims akin to prescription hormone replacement drugs.

11. Such claims are prohibited by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), unless they are approved by the FDA, and subject any individual manufacturing or selling Estroven to liability for the sale of an unapproved new drug.

12. Defendants' representations mislead consumers into believing that Estroven is legal, safe, and effective for its intended purposes.

13. Plaintiff Jaime Arnold purchased Estroven (1) in reliance on Defendants' deceptive drug claims, (2) with the belief that the product was safe, (3) was effective, and (4) was sold in compliance with state and federal law.

14. Plaintiff used Estroven as directed, but the product was not satisfactory because it was an

unlawful new drug, with an unlawful label, and because it does not effectively treat menopause symptoms.

15. This action is brought to remedy Defendants' fraudulent, unfair, and unlawful conduct. On behalf of the class defined herein, Plaintiff seeks an order compelling Defendants to, *inter alia*: (1) cease marketing and selling Estroven as an illegal unapproved new drug; (2) conduct a corrective advertising campaign; (3) destroy all unlawful products and labeling; (4) award Plaintiffs and the Class members restitution and damages; and (5) pay costs, expenses, and attorneys' fees.

IV. REGULATORY BACKGROUND

16. "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

17. A "new drug" is any drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1).

18. Pursuant to 21 U.S.C. § 355(a), "No person shall introduce or deliver for introduction into interstate commerce any new drug . . ." without approval by the FDA.

19. Further, 21 U.S.C. § 331(a) prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."

20. Under 21 U.S.C. § 352(f), drugs are required to have adequate instructions for safe use.

V. THE SALE OF UNAPPROVED DRUGS HARMS THE PUBLIC.

21. "Unapproved prescription drugs pose significant risks to patients because they have not been reviewed by FDA for safety, effectiveness or quality."[1]

22. "Without FDA review, there is no way to know if these drugs are safe and effective for their intended use, whether they are manufactured in a way that ensures consistent drug quality or whether their label is complete and accurate." *Id.*

[1]U.S. Food & Drug Admin., Unapproved Drugs (June 2, 2021), available at www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs.

23. "Unapproved drugs have resulted in patient harm, and the [FDA] works to protect patients from the risks posed by these drugs." *Id.*

24. Unapproved drugs lack "labels and prescribing information that has" "been reviewed by FDA for accuracy and completeness."[2]

25. Consumers using unapproved drugs run the risk of "unexpected and undocumented safety concerns due to lack of rigorous pre- and postmarket safety surveillance." *Id.*

26. Additionally, unapproved drugs lead consumers in need of medical treatment to forgo medically proven therapies.

VI. THE PURPORTED ACTIVE INGREDIENTS IN ESTROVEN ARE INEFFECTIVE.

27. The purported "active ingredients" in Mood Boost and Stress Relief include Soy Isoflavones, Black Cohosh Root Extract, Ginkgo Biloba Leaf Extract, and Magnolia Bark Extract.

28. None of these ingredients, either individually or in combination, safely and effectively relieves menopause symptoms.

A. Soy Isoflavones

29. One of the purported "active ingredients" in Mood Boost and Stress Relief is soy isoflavones.

30. However, studies demonstrate that soy isoflavones are not an effective treatment for menopause symptoms.

31. A 2024 "systematic review and meta-analysis" of 120 articles "aimed to examine the effect of soy isoflavones on menopausal symptoms and quality of life in climacteric women" found that "soy isoflavones had no effect on menopausal symptoms (vasomotor, psychosocial, physical, sexual, and urogenital complaints) and quality of life in climacteric women."[3]

32. Likewise, a 2014 double-blind, randomized, placebo-controlled trial of whole soy and soy isoflavone on menopausal symptoms concluded they "have no significant effect on alleviation of

[2] U.S. Food & Drug Admin., Unapproved Drugs and Patient Harm (June 2, 2021), www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs-and-patient-harm.

[3] Nuran Gençtürk et al., The effect of soy isoflavones given to women in the climacteric period on menopausal symptoms and quality of life: Systematic review and meta-analysis of randomized controlled trials, 20 Explore 103012 (2024), doi: 10.1016/j.explore.2024.05.010; PMID: 38825560.

menopausal symptoms."[4]

33. A 2011 "single-center, placebo-controlled, randomized, double-blind trial" sought to "determine the efficacy of soy isoflavone tablets in preventing bone loss and menopausal symptoms." A "total of 248 participants were randomly assigned 1:1 to receive tablets containing soy isoflavone, 200 mg daily (n = 122), or placebo (n = 126). Outcomes were measured at 2-year follow-up." "Compared with the control group, the soy group had a significantly larger proportion of women who reported hot flashes (48.4% vs 31.7%; *P* = .02) and a nonsignificantly larger proportion of women who reported constipation. Outcomes were otherwise similar in both groups."[5]

34. Further, a 2012 double-blind, placebo-controlled trial of 350 postmenopausal women found that "soy isoflavone supplementation in a dose comparable to that of traditional Asian diets has no effect on global cognition."[6]

B. Black Cohosh Root Extract

35. Another purported "active ingredient" in Mood Boost and Stress Relief is black cohosh root extract.

36. "Black cohosh is the underground stem of a plant that can be ingested directly in powdered form or extracted into tablet or liquid form. It should be standardized to contain certain triterpenes. Black cohosh contains no phytoestrogens that can account for its purported estrogen-like effects."

> Data from several randomized trials do not support the efficacy of black cohosh for reducing menopausal symptoms. For example, a systematic review including 16 randomized trials with 2027 perimenopausal or postmenopausal women found no significant difference in the frequency of hot flushes (3 trials; 393 women) or in menopausal symptom scores (4 trials; 357 women) when comparing oral preparations of black cohosh (average dose 40 mg) with placebo Another meta-analysis of randomized trials of botanical products that included black cohosh

[4] Zhao-Min Liu et al., Randomized controlled trial of whole soy and isoflavone daidzein on menopausal symptoms in equol-producing Chinese postmenopausal women, 21 Menopause 653, 653-60 (2014), doi: 10.1097/GME.0000000000000102; PMID: 24149925.

[5] Silvina Levis et al., Soy isoflavones in the prevention of menopausal bone loss and menopausal symptoms: A randomized, double-blind trial, 171 Archives of Internal Medicine 1363, 1363-69 (2011), doi: 10.1001/archinternmed.2011.330; PMID: 21824950.

[6] Victor W. Henderson et al., Long-term soy isoflavone supplementation and cognition in women: A randomized, controlled trial, 78 Neurology 1841, 1841-48 (2012), doi: 10.1212/WNL.0b013e318258f822; PMID: 22665144.

also found no benefit for menopausal symptoms.[7]

37. A Cochrane literature review evaluating "the clinical effectiveness and safety of black cohosh (Cimicifuga racemosa or Actaea racemosa) for treating menopausal symptoms in perimenopausal and postmenopausal women" that included "[s]ixteen randomised controlled trials, recruiting a total of 2027 perimenopausal or postmenopausal women" found "[t]here was no significant difference between black cohosh and placebo in the frequency of hot flushes . . . or in menopausal symptom scores . . .. Compared to black cohosh, hormone therapy significantly reduced daily hot flush frequency."[8]

C. Ginkgo Biloba

38. Another purported "active ingredient" in Mood Boost is Gingko Biloba.

39. A 2003 trial examining the effects of Gingko Biloba on mood and cognition in post-menopausal women found "[t]here were no significant effects of Gincosan treatment on ratings of mood, bodily symptoms of somatic anxiety, menopausal symptoms, or sleepiness or on any of the cognitive measures of attention, memory or frontal lobe function. Thus, after chronic administration," it "appeared to have no beneficial effects in post-menopausal women."[9]

D. Magnolia Bark

40. Magnolia Bark is another purported "active ingredient" in Mood Boost and Stress Relief.

41. A study examining Magnolia Bark Extract "on anxiety, stress and sleep in healthy premenopausal women" found it "was not effective in reducing long-standing feelings of anxiety or depression." Further, "[o]ther assessments conducted in this study including salivary cortisol and amylase levels, appetite, body morphology and sleep quality/latency were not significantly changed by [Magnolia

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[7] Laura Shane-McWhorter. *Black Cohosh*. Merk Manual Professional Version. (July 2025), available at merckmanuals.com/professional/special-subjects/dietary-supplements/black-cohosh.

[8] Matthew J. Leach & Vivienne Moore, Black cohosh (Cimicifuga spp.) for menopausal symptoms, 2012 Cochrane Database of Systematic Reviews, Issue 9, Art. No. CD007244, doi: 10.1002/14651858.CD007244.pub2; PMID: 22972105.

D. Hartley et al. *Gincosan (A Combination of Ginkgo biloba and Panax ginseng): The Effects on Mood and Cognition of 6 and 12 Weeks' Treatment in Postmenopausal Women*. Nutritional Neuroscience (2003) 7(5-6):325-33.

Bark] in comparison to placebo."[10]

VII. ESTROVEN'S DRUG CLAIMS.

42. During the class period, Defendants marketed Estroven with deceptive efficacy claims that suggest that the products can safely treat menopause symptoms including hot flashes, night sweats, sleeplessness, low energy, mood swings, and more.

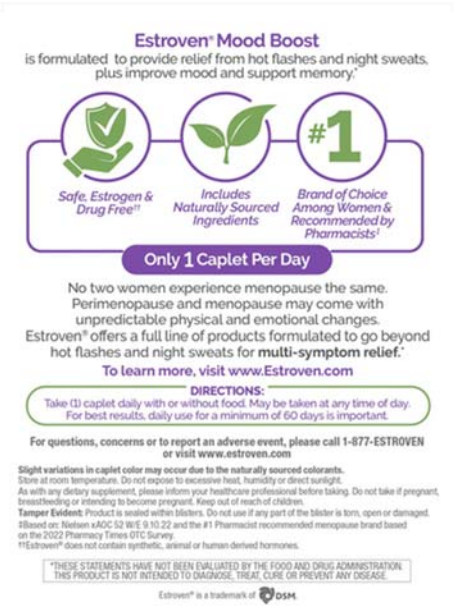
43. These claims are misleading, as none of the ingredients in Estroven safely treats menopause symptoms.

44. These claims also render Estroven a "drug" within the meaning of 21 U.S.C. § 321(g).

45. Defendants failed to obtain FDA approval to market Estroven in violation of 21 U.S.C. § 355 and Health & Safety Code § 111550.

A. Mood Boost

46. During the Class Period, the Estroven Mood Boost label claimed that the product provides "menopause relief for" "hot flashes, night sweats," and "mood swings" and is "formulated to provide relief from hot flashes and night sweats." Further, Defendants claimed the product will "improve mood & support memory."



[10] Douglas S. Kalman et al., Effect of a proprietary Magnolia and Phellodendron extract on stress levels in healthy women: A pilot, double-blind, placebo-controlled clinical trial, 7 Nutrition Journal 11 (2008), doi: 10.1186/1475-2891-7-11; PMID: 18426577.

47. These claims were misleading, as Mood Boost does not deliver the advertised benefits as it is not a safe and effective treatment for menopause symptoms.

48. These efficacy claims, in addition to being misleading, render Mood Boost a "drug" as defined by 21 U.S.C. § 321(g).

49. Defendants also advertise Mood Boost with deceptive safety and efficacy claims online that suggest the product can provide prescription hormone replacement drug benefits.

50. The Mood Boost label, the Estroven website, estroven.com, and the Mood Boost Amazon page, which Defendants control, contained the following claims, which show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease, during the Class Period:

- "Mood Boost"
- "Menopause Relief for Hot Flashes, Night Sweats, Mood Swings"
- "formulated to provide relief from hot flashes & night sweats plus improve mood and support memory"
- "Improves mood and reduces menopausal anxiety"
- "Reduces hot flashes and night sweats"
- "Helps relieve hot flashes & night sweats"
- "MULTI SYMPTOM RELIEF: Estroven Mood Boost is a safe and effective dietary supplement with ingredients that provide relief from multiple menopause symptoms, including hot flashes, night sweats and irritability"
- "Estroven Mood and Memory with naturally sourced ingredients is a safe and effective dietary supplement that provides relief from multiple menopause symptoms"
- "reduce the frequency and severity of hot flashes and night sweats"

51. These claims suggest Mood Boost can safely and effectively treat menopause symptoms including hot flashes, night sweats, anxiety, and memory loss. However, Mood Boost fails to deliver the advertised benefits.

52. Further, these claims render Mood Boost a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

53. True and correct copies of screenshots of the Mood Boost page from Defendants' website, estroven.com, are attached hereto as **Exhibit 1.**

54. True and correct copies of screenshots of the Amazon page for Mood Boost, which Defendants control, are attached hereto as **Exhibit 2**.

55. Defendants failed to obtain FDA approval prior to marketing, distributing, and selling Mood Boost.

B. Stress Relief

56. During the Class Period, the Estroven Stress Relief label claimed that the product provides "menopause relief for" "hot flashes, night sweats, low energy, daily stress, and mood swings." Further, Defendants claimed the product is "formulated to provide relief for hot flashes and night sweats, plus manage stress and fatigue."

57. These claims were misleading, as Stress Relief fails to deliver the advertised benefits because it is not a safe and effective treatment for menopause symptoms.

58. These efficacy claims, in addition to being misleading, render Stress Relief a "drug" as defined by 21 U.S.C. § 321(g).

59. Defendants also advertise Stress Relief with deceptive safety and efficacy claims online that suggest the product can provide prescription hormone replacement drug benefits.

60. The Stress Relief label, the Estroven website, estroven.com, and the Stress Relief Amazon page, which Defendants control, contained the following claims, which show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease, during the Class Period:

- "Stress Relief & Energy Boost"
- "Menopause Relief for Hot Flashes, Night Sweats, Low Energy, Daily Stress, and Mood Swings"
- "formulated to provide relief from hot flashes & night sweats plus manage stress & fatigue"
- "Maximum strength for hot flashes and night sweats* "Reduces hot flashes and night sweats"
- "reduce stress, moodiness, and irritability"
- "help reduce the frequency and severity of hot flashes and night sweats"
- "safely reduce menopausal related anxiety and irritability"
- "Clinically Proven Ingredients Provide Stress & Energy Support + Night Sweats & Hot Flash Relief"
- "clinically proven to help reduce the frequency and severity of hot flashes and night sweats and magnolia bark to help manage daily menopausal stress"
- "SAFE AND EFFECTIVE: With an excellent safety history, the dietary ingredients in this supplement are drug-free, free of both estrogen and other hormones,"
- "reduce the frequency and severity of hot flashes and night sweats"

61. These claims suggest Stress Relief can safely and effectively treat menopause symptoms including hot flashes, night sweats, anxiety, and fatigue. However, Stress Relief fails to deliver the advertised benefits.

62. Further, these claims render Stress Relief a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

63. True and correct copies of screenshots of the Stress Relief page from Defendants' website, estroven.com, are attached hereto as **Exhibit 3.**

64. True and correct copies of screenshots of the Amazon page for Stress Relief, which Defendants control, are attached hereto as **Exhibit 4**.

65. Defendants failed to obtain FDA approval prior to marketing, distributing, and selling Stress Relief.

VIII. ESTROVEN IS AN UNAPPROVED NEW DRUG.

66. "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

67. Estroven is a "drug" because it is advertised as a product which will treat menopause symptoms and affect the structure and function of the human body by reducing hot flashes, night sweats, menopausal anxiety, and improve mood.

68. The claims on the packaging of Estroven, I-Health's website, and Defendants'Amazon page for Estroven render the product an unapproved new drug.

69. The FDA has determined that the following claims, which are similar to those Defendants make regarding Estroven, constitute "drug claims":

- "Relieves Menopause Symptoms" (**Exhibit 5**, FDA Warning Letter to AnuMed International, LLC);
- "may help with menopause symptoms" (**Exhibit 5**);
- "for Menopause Relief, Mood Swings, Hot Flashes" (**Exhibit 5**);
- "can relieve the symptoms of menopause" (**Exhibit 6**, FDA Warning Letter to Sambrosa Care Inc.);

70. A "new drug" is any drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1). Here, Estroven is a "new drug" within the meaning of the FDCA because it is not generally recognized as safe and effective for the intended uses. See Title 21 of the Code of Federal Regulations, Chapter I, Subchapter D; 21 C.F.R. § 330.1.

71. Defendants have not received approval from the FDA to sell Estroven.

72. The sale of unapproved new drugs is illegal and dangerous. First, consumers risk purchasing and using a product that will endanger their health. Second, consumers risk purchasing a product that will not effectively treat their condition, forgoing actual treatment of that condition in lieu of an unapproved new drug which may not treat their condition. The FDA's regulatory regimen helps ensure that such products are kept away from consumers.

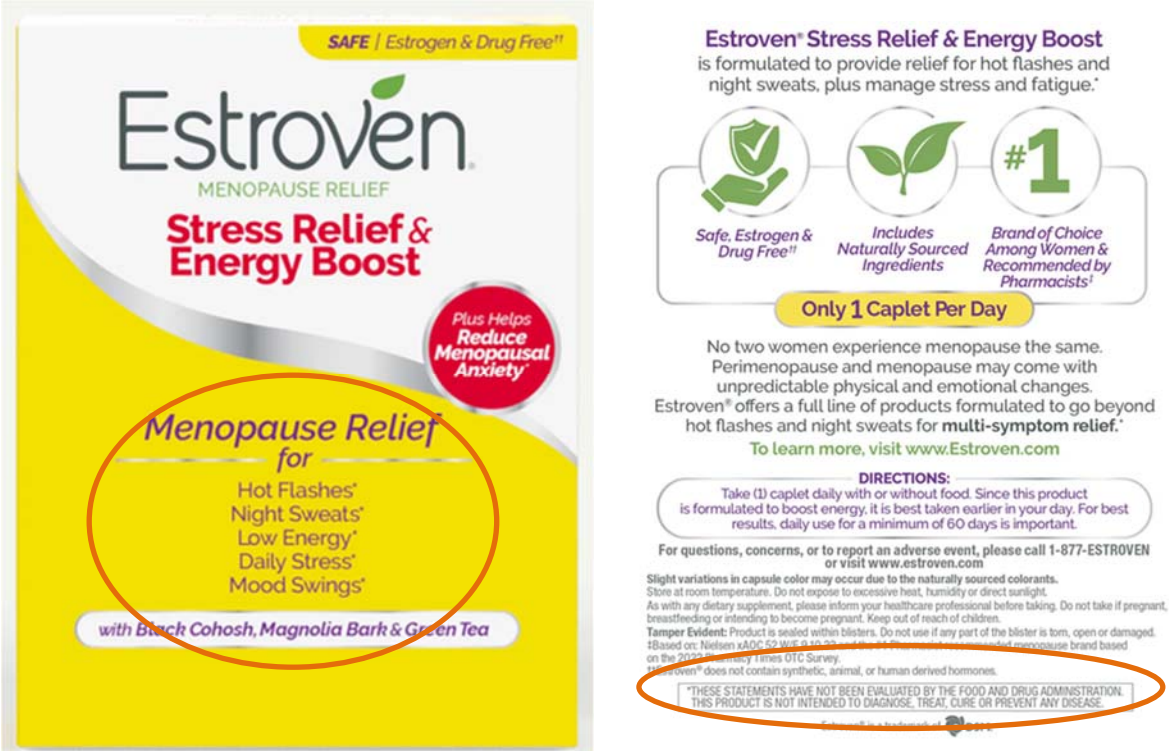
73. Defendants' failure to comply with these regulations puts consumers at risk and gives Defendants an unfair advantage over competitors that do commit the time and expense of complying with such necessary regulations.

74. Estroven does not qualify for the reduced level of regulation applicable to certain nutrition supplement products for several reasons. The Estroven label, Defendants' website, and Defendants' marketing materials neither describe the role of any nutrient or dietary ingredient intended to affect the structure or function in humans, characterize the documented mechanism by which any nutrient or dietary ingredient acts to maintain such structure or function, nor describe general well-being from consumption of any nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6)(A).

75. California similarly prohibits the sale of unapproved new drugs. Health & Safety Code § 111550.

IX. ESTROVEN'S LABELS VIOLATE 21 C.F.R. § 101.93(d).

76. The back panel of the packaging of Estroven contains a disclaimer which reads, "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."



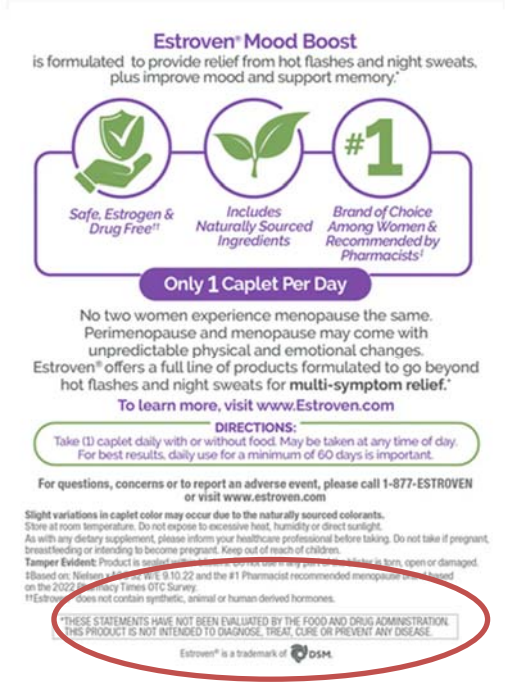
77. However, the disclaimer is improperly positioned in violation of 21 C.F.R. § 101.93(d) governing structure/function claims, which provides:

> The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

78. Here, on the front of the packaging of Estroven, Defendants make efficacy claims about the product and include asterisks next to these claims, linking them to the FDA's required disclaimer.

79. 21 C.F.R. § 101.93(d) requires that "the disclaimer shall appear on **each panel or page** where there such is a statement." (emphasis added)

80. Defendants make efficacy claims on the front of Estroven's packaging, also known as the principal display panel, but the disclaimer does not appear on this panel. Rather, the disclaimer only appears on the back of Estroven's packaging.



81. Thus, Defendants' placement of the disclaimer violates 21 C.F.R. § 101.93(d).

X. DEFENDANTS' PRACTICES WERE "UNFAIR" WITHIN THE MEANING OF THE UNFAIR COMPETITION LAW.

82. Defendants' practices as described herein are "unfair" within the meaning of the California Unfair Competition Law because Defendants' conduct is immoral, unethical, unscrupulous, and substantially injurious to consumers, and the utility of this conduct to Defendants does not outweigh the gravity of the harm to Defendants' victims.

83. In particular, while Defendants' marketing of Estroven with deceptive "drug" claims as defined by 21 U.S.C. § 321(g) and absent FDA approval to do so allowed Defendants to realize higher profit margins than if they did not use unlawful marketing tactics, this utility is small and far outweighed by the gravity of the economic harm and potential physical harm that Defendants inflict upon consumers. Further, the injury to consumers from Defendants' practices is substantial, not outweighed by benefits to consumers or competition, and not an injury that consumers themselves could reasonably have avoided.

XI. DEFENDANTS' PRACTICES WERE "UNLAWFUL" WITHIN THE MEANING OF THE CALIFORNIA UNFAIR COMPETITION LAW.

84. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "unlawful" business acts and practices in that Defendants' conduct violates the

California Consumer Legal Remedies Act, as alleged herein.

85. Defendants' practices as described herein are further "unlawful" within the meaning of the California Unfair Competition Law because the marketing, sale, and distribution of Estroven violate the California's Sherman Food, Drug, and Cosmetic Law, including federal provisions that have been adopted by California

- **Health & Safety Code § 110110**, which adopts all FDA regulations relating to new drugs and premarket approval;
- **Health & Safety Code § 110111**, which adopts all FDA nonprescription drug regulations;
- **Health & Safety Code § 111330**, "Any drug or device is misbranded if its labeling is false or misleading in any particular.";
- **Health & Safety Code § 110398**, "It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.";
- **Health & Safety Code § 111440**, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.";
- **Health & Safety Code § 111445**, "It is unlawful for any person to misbrand any drug or device.";
- **Health & Safety Code § 111450**, "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.";
- **Health & Safety Code § 111550**, prohibiting sale of new drugs unless approved under 21 U.S.C. § 355;
- **21 U.S.C. § 331(a)**, prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded";
- **21 U.S.C. § 331(b)**, prohibiting the "adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce";
- **21 U.S.C. § 352(f)(1)**, requiring drugs to have adequate directions for use; and
- **21 U.S.C. § 355(a)**, prohibiting the sale of unapproved new drugs; and
- **21 C.F.R. § 101.93(d)**, governing the placement of disclaimers in relation to structure/function claims.

86. The marketing and advertising of Estroven constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

87. Defendants' unlawful acts allowed them to sell more units of Estroven than they would have otherwise, and at a higher price and higher margin.

88. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and requiring Defendants to commence a corrective advertising campaign.

89. Plaintiff also seeks an order for the disgorgement and restitution of all revenue received by Defendants from the sale of Estroven and has no adequate remedy at law.

XII. PLAINTIFF'S PURCHASES OF ESTROVEN

90. Plaintiff Jaime Arnold repeatedly purchased Estroven during the class period. She purchased both Mood Boost and Stress Relief from Amazon. Her first purchase occurred in 2018, and her most recent purchase occurred in 2022. She purchased Estroven approximately 50 times during this period.

91. In deciding to purchase Estroven, Plaintiff relied on Defendants' deceptive safety, efficacy, and drug claims and fraudulent omissions described herein.

92. Because Estroven was both an unlawful new drug and ineffective, Plaintiff did not receive the benefit of her purchases.

XIII. RELIANCE AND INJURY

93. Plaintiff purchased and used Estroven in reliance on Defendants' deceptive safety, efficacy, and drug claims described herein and would not have purchased the product absent Defendants' advertising.

94. When Plaintiff purchased Estroven, she was seeking a lawful, safe, and effective product which would treat symptoms of menopause.

95. Plaintiff purchased Estroven with the natural assumption that products sold in stores and online by large companies would be safe and would be sold in compliance with applicable state and federal law.

96. Plaintiff suffered economic injury when she purchased Estroven because the product was not safe and effective for its intended purposes and was sold in violation of federal regulations and California law.

97. Plaintiff and class members would not have purchased Estroven had they known that it was not safe and effective for its intended purposes and was sold in violation of federal regulations and California law

98. Estroven was offered for sale in violation of California and federal law and had a value of $0 because it is illegal and ineffective.

99. Plaintiff would consider purchasing Estroven in the future if she could be assured that the product (1) would deliver the advertised benefits, (2) was safe and effective, and (3) was sold in compliance with all FDA regulations and California law.

XIV. CLASS ACTION ALLEGATIONS

100. Plaintiff brings this action on behalf of herself and all others similarly situated (the "Class"), excluding Defendants' officers, directors, and employees, and the Court, its officers and their families. The Class is defined as:

> All citizens and residents of California who purchased Estroven in California for their own personal or household use, and not for resale, from January 1, 2019 to the present.

101. Questions of law and fact common to Plaintiff and the Class include:

a. Whether Defendants' conduct constituted a violation of the unfair prong of California's Unfair Competition Law;

b. Whether Defendants' conduct constituted a violation of the unlawful prong of California's Unfair Competition Law;

c. Whether Defendants' conduct constituted a violation of the fraudulent prong of California's Unfair Competition Law;

d. Whether Defendants' conduct constituted a violation of the fraudulent prong of California's CLRA;

e. Whether I-Health communicated deceptive safety, efficacy and drug claims through Estroven's labeling, packaging, and website

f. Whether those messages were material, or likely to be material, to a reasonable consumer;

g. Whether those messages were false, at variance with the truth, misleading, likely to deceive, and/or had the capacity to deceive the public and/or a reasonable consumer;

h. Whether I-Health fraudulently omitted material information in advertising Estroven as safe and effective;

i. Whether Estroven is an unapproved new drug;

j. Whether Defendants' conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers;

k. Whether the slight utility Defendants realized as a result of their conduct outweighs the gravity of the harm the conduct caused to their victims;

l. Whether Defendants' conduct violated public policy as declared by specific constitutional, statutory, or regulatory provisions;

m. Whether the injury to consumers from Defendants' practices is substantial;

n. Whether the injury to consumers from Defendants' practices is outweighed by benefits to consumers or competition;

o. Whether Class members are entitled to restitution;

p. Whether Class members are entitled to damages;

q. Whether Class members are entitled to an injunction and, if so, its terms; and

r. Whether Class members are entitled to any further relief.

102. By purchasing Estroven, all Class members were subjected to the same wrongful conduct.

103. Plaintiff's claims are typical of the Class's claims because all Class members were subjected to the same economic harm when they purchased Estroven and suffered economic injury.

104. Plaintiff will fairly and adequately protect the interests of the Class, has no interests that are incompatible with the interests of the Class, and has retained counsel competent and experienced in class litigation.

105. The Class is sufficiently numerous, as it includes thousands of individuals who purchased Estroven during the Class Period.

106. Class representation is superior to other options for the resolution of the controversy. The relief sought for each Class member is small, as little as $10 for some Class members. Absent the availability of class action procedures, it would be infeasible for Class members to redress the wrongs done to them.

107. Questions of law and fact common to the Class predominate over any questions affecting only individual members.

CAUSES OF ACTION

First Cause of Action

Unfair Competition Law, Unlawful Prong

Bus. & Prof. Code §§ 17200, *et seq.*

108. In this and every cause of action, Plaintiff realleges and incorporates the preceding allegations as if fully set forth herein.

109. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as

alleged herein constitute "unlawful" business acts and practices in that Defendants' conduct violates the California Consumer Legal Remedies Act, as alleged herein.

110. Defendants' practices as described herein are "unlawful" within the meaning of the California Unfair Competition Law because the marketing, sale, and distribution of Estroven violate the California's Sherman Food, Drug, and Cosmetic Law, including federal provisions that have been adopted by California

- **Health & Safety Code § 110110**, which adopts all FDA regulations relating to new drugs and premarket approval;
- **Health & Safety Code § 110111**, which adopts all FDA nonprescription drug regulations;
- **Health & Safety Code § 111330**, "Any drug or device is misbranded if its labeling is false or misleading in any particular.";
- **Health & Safety Code § 110398**, "It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.";
- **Health & Safety Code § 111440**, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.";
- **Health & Safety Code § 111445**, "It is unlawful for any person to misbrand any drug or device.";
- **Health & Safety Code § 111450**, "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.";
- **Health & Safety Code § 111550**, prohibiting sale of new drugs unless approved under 21 U.S.C. § 355;
- **21 U.S.C. § 331(a)**, prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded";
- **21 U.S.C. § 331(b)**, prohibiting the "adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce";
- **21 U.S.C. § 352(f)(1)**, requiring drugs to have adequate directions for use;
- **21 U.S.C. § 355(a)**, prohibiting the sale of unapproved new drugs; and
- **21 C.F.R. § 101.93(d)**, governing the placement of disclaimers in relation to structure/function claims.

111. The marketing and advertising of Estroven constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

112. Defendants' unlawful acts allowed them to sell more units of Estroven than they would

have otherwise, and at a higher price and higher margin.

113. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendants to commence a corrective advertising campaign; and awarding the class restitution of all monies Defendants obtained from the sale of Estroven. Plaintiff has no adequate remedy at law.

Second Cause of Action

Unfair Competition Law, Unfair Prong

Bus. & Prof. Code §§ 17200, *et seq*.

114. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "unfair" business acts and practices because Defendants' conduct is:

- immoral, unethical, unscrupulous, and offends public policy;
- the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct; and
- the injury to consumers caused by Defendants' conduct is substantial, not outweighed by any countervailing benefits to consumers or competition, and not one that consumers themselves could reasonably have avoided.

115. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendants to commence a corrective advertising campaign; and awarding the class restitution of all monies Defendants obtained from the sale of Estroven. Plaintiff has no adequate remedy at law.

Third Cause of Action

Unfair Competition Law, Fraudulent Prong

Bus. & Prof. Code §§ 17200, *et seq*.

116. Cal. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."

117. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "fraudulent" business acts and practices in that Defendants' conduct has a likelihood, capacity or tendency to deceive Plaintiff, the Class, and the general public.

118. Defendants leveraged their deception to induce Plaintiff and members of the Class to

purchase products that were of lesser value and quality than advertised.

119. Plaintiff and class members suffered injury in fact and lost money or property as a result of Defendants' deceptive advertising: they were denied the benefit of the bargain when they decided to purchase Estroven over competing products, which are safe, legal, less expensive, and do not make misleading or false drug claims on their packaging and websites.

120. Had Plaintiff been aware of Defendants' false and misleading advertising tactics, she would not have purchased Estroven, and had Defendants not advertised it in a fraudulent manner, Plaintiff would have paid less for it.

121. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendants to commence a corrective advertising campaign; and awarding the class restitution of all monies Defendants obtained from the sale of Estroven. Plaintiff has no adequate remedy at law.

Fourth Cause of Action

Consumer Legal Remedies Act

Civil Code §§ 1750, *et seq.*

122. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

123. Defendants' policies, acts and practices were designed to, and did, result in the purchase and use of Estroven for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:

- **Civil Code § 1770(a)(5),** representing that goods have characteristics, uses, or benefits which they do not have;
- **Civil Code § 1770(a)(7),** representing that goods are of a particular standard, quality, or grade if they are of another;
- **Civil Code § 1770(a)(9)**, advertising goods with intent not to sell them as advertised; and
- **Civil Code § 1770(a)(16),** representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

124. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendants were

unjustly enriched.

125. As a further result, Plaintiff and the Class have suffered damages, and because the conduct was deliberate, immoral, oppressive, made with malice and contrary to public policy, they are entitled to punitive or exemplary damages.

126. Pursuant to section 1782 *et seq*. of the CLRA, Plaintiff notified Defendants in writing by certified mail of the particular violations of § 1770 of the Act as to Estroven and demanded that Defendants rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act.

127. Defendants received Plaintiff's written notice.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself, all others similarly situated, and the general public, pray for judgment against Defendants as follows:

a) An order confirming that this class action is properly maintainable as a class action as defined above, appointing Plaintiff Jaime Arnold and her undersigned counsel to represent the Class, and requiring Defendants to bear the cost of class notice;

b) An order requiring Defendants to pay $1,000 in restitution and interest to Plaintiff;

c) An order requiring Defendants to pay $10 million or a greater amount to be proven at trial in restitution to Class members, and $15,000 to Plaintiff as an incentive award, or such greater amount the Court deems fair and reasonable;

d) An order requiring Defendants to disgorge any benefits they received from Plaintiff and the Class and their unjust enrichment realized as a result of their improper and misleading advertising, marketing, sale, and distribution of Estroven;

e) An Order declaring the conduct complained of herein violates the Unfair Competition Law;

f) An order requiring Defendants to cease and desist their deceptive, unconscionable, fraudulent, and unlawful practices;

g) An order requiring Defendants to engage in a corrective advertising campaign;

h) A temporary and permanent injunction prohibiting the conduct described in the

Complaint;

i) An award of prejudgment and postjudgment interest;

j) An award of attorney fees and costs; and

k) Such other and further relief as this Court may deem just, equitable or proper.

l) Plaintiff intends to amend this complaint to add actual and punitive damages claims under the CLRA if Defendant does not desist from its behavior within the 30-day statutory notice period.

NO JURY DEMAND

Plaintiff does not demand a jury trial.

DATED: July 29, 2026

Respectfully Submitted,

s/ Gregory S. Weston
THE WESTON FIRM
GREGORY S. WESTON
Counsel for Plaintiff

EXHIBIT 1

Hover over image to zoom



MENOPAUSE

Estroven® Menopause Relief Mood Boost

★★★★½ (274) REVIEWS Write a review

- Improves mood and reduces menopausal anxiety with naturally sourced Magnolia Bark*
- Reduces hot flashes and night sweats*
- 30 or 60 Day Supply

PACK SIZE

30 Pack $0.47 /Count | 60 Pack $0.42 /Count

FREQUENCY

One-Time Purchase $13.99

Subscribe & Save 10% $12.59 ~~$13.99~~

- Save 10% on Every Order!
- Flexible Delivery, Skip or Cancel Anytime.
- Free Shipping. No Minimums!

Delivery every 30 days

1 ADD TO CART | $12.59 ~~$13.99~~

ALSO AVAILABLE AT 30 COUNT

Walmart Buy

amazon Buy

How It Works

GINKGO BILOBA

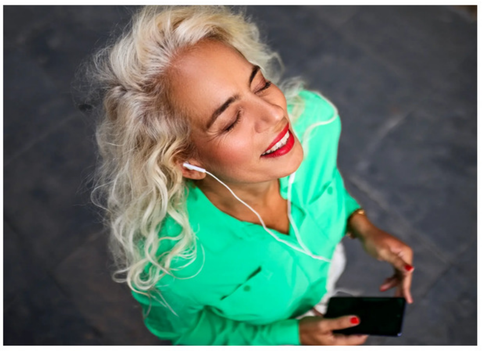
Supports healthy brain function, including mental sharpness and memory support*

BLACK COHOSH

To help reduce the frequency and severity of hot flashes and night sweats*

MAGNOLIA BARK

Helps safely improve mood and reduce menopause related anxiety*



Did You Know?

Hormonal fluctuations during menopause, combined with the stress of a difficult workday, anxiety about aging and unease with the menopausal transition itself, can all contribute to your irritability and mood swings.

The Basics

Estroven® Menopause Relief Mood Boost is made with naturally sourced ingredients such as Black Cohosh for hot flashes and night sweats, Ginkgo Biloba for mental sharpness and memory support, and Magnolia Bark for irritability and mood.*

Directions for Use +

Ingredients +

Supplement Facts +

Supplement Facts

Serving Size: One (1) Caplet

Amount Per Serving		%Daily Value
Total Carbohydrate	<1g	<1%++
Calcium (as dicalcium phosphate)	95mg	7%
Black Cohosh Root Extract	40mg	**
Soy Isoflavones	56mg	**

Amount Per Serving		%Daily Value
Ginkgo biloba Leaf Extract	120mg	**
Magnolia Bark Extract (*Magnolia officinalis*)	15mg	**

++Percent Daily Value based on a 2,000 calorie diet. **Daily Value not established.

Other Ingredients: microcrystalline cellulose, stearic acid, coating (hydroxypropyl methylcellulose, medium chain triglycerides (safflower oil), inulin, vegetable juice [color], titanium dioxide [color]), croscarmellose sodium, magnesium stearate.
Contains: Soy
Distributed by i-Health, Inc.
59 Sebethe Drive,
Cromwell, CT 06416
Made in the USA with US and imported materials.

The Basics

Estroven® Menopause Relief Mood Boost is made with naturally sourced ingredients such as Black Cohosh for hot flashes and night sweats, Ginkgo Biloba for mental sharpness and memory support, and Magnolia Bark for irritability and mood.*

Directions for Use +

Ingredients +

Black Cohosh and Soy Isoflavones, to help reduce the frequency and severity of hot flashes and night sweats.*

Magnolia Bark to safely improve mood and reduce menopausal related anxiety.*

Ginkgo Biloba for healthy brain function, including mental sharpness and memory support.*

Supplement Facts +

★★★★★

"Started having night sweating and sleepless nights. Been taking this for almost a year, everything is great and now I sleep like a baby."

Erika C
Verified Customer

Frequently Asked Questions

How does Estroven® Menopause Relief Mood Boost reduce hot flashes and night sweats?

Estroven® Menopause Relief Mood Boost is designed to address hot flashes and night sweats with the ingredients of naturally sourced Black Cohosh, plus clinically proven Soy Isoflavones (from soy beans).* Both ingredients have a relatively long safety profile history and demonstrated efficacy supporting their use to reduce hot flashes and night sweats.*

How does Estroven® Menopause Relief Mood Boost help daily stress plus mood and memory?

Estroven® Menopause Relief Mood Boost contains naturally sourced Magnolia Bark to safely help manage daily stress, irritability and menopausal anxiety.* It also contains naturally sourced Ginkgo Biloba that has been clinically studied for healthy brain function, including mental sharpness and memory support.*

Does Estroven® Menopause Relief Mood Boost contain soy?

Yes, Estroven® Menopause Relief Mood Boost contains soy. Soy Isoflavones have been clinically proven to reduce hot flashes and night sweats.*

Does Estroven® Menopause Relief Mood Boost contain the hormone estrogen?

No, Estroven® Menopause Relief Mood Boost does not contain synthetic, animal or human-derived hormones.

How long should I take Estroven® Menopause Relief Mood Boost before I start to see relief for my menopause symptoms?

Results vary based on each individual's symptoms and needs however, we recommend daily use for a minimum of 60 days for best results.

Can I take more than the recommended serving of Estroven® Menopause Relief Mood Boost?

No, Estroven® Menopause Relief Mood Boost should be taken as directed. It is formulated with amounts of active dietary ingredients to achieve the desired results.

Can I use Estroven® Menopause Relief Mood Boost with other dietary supplements or medications?

We recommend speaking with your healthcare professional to see if taking Estroven® Menopause Relief Mood Boost with other dietary supplements or medications is appropriate for your individual situation.

How should I store Estroven® Menopause Relief Mood Boost?

Please store Estroven® Menopause Relief Mood Boost at room temperature. Do not expose to excessive heat, humidity or direct sunlight.

Where can I manage my subscription?

You can access your subscription in our subscription portal by requesting an account invite. Please use the email address your order was place with and as always, please check your SPAM folder if you don't see an email.

EXHIBIT 2

Click to see full view

Ask Alexa

Can it help with sleep? | Does it contain any hormones? | Is it vegan friendly? | Why you might like this | Compare with similar | Ask something else

Estroven Mood Boost for Menopause Relief, Helps Reduce Hot Flashes & Night Sweats, Helps Manage Mood Swings, 30 Count

Visit the Estroven Store

4.4 ★★★★½ (8,118) | Search this page

Save $0.24

Overall Pick

4K+ bought in past month

$13.99 ($0.47 / count) Price history

Save 50% (up to $80) on eligible products when using Membership Rewards® points. Terms apply. Activate now.

prime Today

Size: **30 Count (Pack of 1)**

30 Count (Pack of 1)	30 Count (Pack of 2)
$13.99 ($0.47 / count) FREE Delivery **Today 2 PM - 6 PM**	$27.98 ($0.47 / count) FREE Delivery **Today 5 PM - 10 PM**

Top highlights

Brand	Estroven
Flavor	Unflavored
Primary Supplement Type	multivitamin
Unit Count	30 Count
Item Form	Capsule,Caplets
Item Weight	4.54 g

See more

About this item

- HELPS MANAGE MOOD, MEMORY and STRESS: Stress and irritability are common symptoms of menopause, but are very manageable; Mood Boost supports restful sleep, mental attention and focus
- MULTI SYMPTOM RELIEF: Estroven Mood Boost is a safe and effective dietary supplement with ingredients that provide relief from multiple menopause symptoms, including hot flashes, night sweats and irritability
- NATURALLY SOURCED INGREDIENTS: Contains naturally sourced black cohosh, soy isoflavones, and magnolia bark; proven to help reduce the frequency and severity of hot flashes and night sweats while managing daily menopausal stress
- SAFE AND EFFECTIVE: With an excellent safety history, the dietary ingredients in this supplement are drug-free, free of both estrogen and other hormones, vegan and gluten-free
- Estroven Mood and Memory with naturally sourced ingredients is a safe and effective dietary supplement that provides relief from multiple menopause symptoms
- Clinically proven Soy Isoflavones plus Black Cohosh help reduce the frequency and severity of hot flashes and night sweats
- For best results, daily use for a minimum of 60 days is important
- Estroven Mood & Memory with naturally-sourced ingredients is a safe and effective dietary supplement that provides relief from multiple menopause symptoms
- Clinically proven Soy Isoflavones plus Black Cohosh help reduce the frequency & severity of hot flashes and night sweats
- For best results, daily use for a minimum of 60 days is important

Show less

Item details

Measurements

See all product specifications

Report an issue with this product or seller

One-time purchase

$13.99 ($0.47 / count)

Price history

prime Today

FREE delivery **Today**
2 PM - 6 PM

Or $4.99 delivery **in 3 hours**

Shorter shipping distance

Deliver to Kari - West Des Moines 50266

In Stock

Quantity: 1

Add to cart

Buy Now

Shipper / Seller	Amazon.com
Returns	Non-returnable due to Food safety reasons
Gift options	Available at checkout

See more

Subscribe & Save

$13.29 ($0.44 / count)

prime

FREE delivery Today
2 PM - 6 PM

Shipper / Seller	Amazon.com

Add to Auto Buy

Add to List

Important information

Safety Information

Keep out of reach of children.

Ingredients

Black Cohosh and Soy Isoflavones, to help reduce the frequency and severity of hot flashes and night sweats.* Naturally sourced Magnolia Bark to safely improve mood and reduce menopause symptoms.* Ginkgo Biloba for healthy brain function, including mental sharpness and memory support.*

Directions

Use as directed on the packaging.

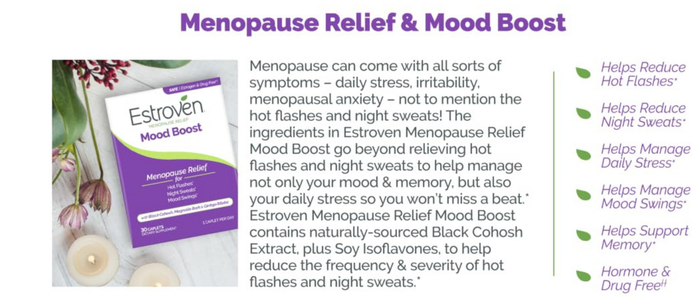
Legal Disclaimer

Statements regarding dietary supplements have not been evaluated by the FDA and are not intended to diagnose, treat, cure, or prevent any disease or health condition.

Product Description

No two women experience menopause the same way; that's why Estroven has a full line of products to help reduce not only hot flashes & night sweats, but also your most bothersome menopausal symptoms.* Every Estroven product contains both naturally sourced and clinically studied ingredients, so you can pick the the one that is right for you. Menopause can come with all sorts of symptoms – daily stress and irritability – not to mention the hot flashes and night sweats! The ingredients in Estroven Menopause Relief + Mood go beyond relieving hot flashes and night sweats to help manage not only your mood & memory, but also your daily stress so you won't miss a beat.* Estroven Menopause Relief + Mood also contains naturally-sourced Black Cohosh Extract, plus Soy Isoflavones, to help reduce the frequency & severity of hot flashes and night sweats.*; * These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease; **: Nielsen xAOC 52 W/E 12/03/2022 and #1 Pharmacist recommended menopause brand based on Pharmacy Times OTC Survey, 2022.

From the manufacturer



	Estroven Mood Boost For Menopause Relief, 30 Count	Estroven Pre-Menopause Relief, 30 Count	Estroven Weight Management for Menopause Relief, 30 Count	Estroven Sleep Cool for Menopause Relief for Women, 30 Count	Estroven Stress Relief & Energy Boost for Menopause Relief, 28 Count	Estroven Complete Multi-Symptom Menopause Relief Supplement, 28 Count
	Add to Cart	Add to Cart	Add to Cart	Add to Cart	Add to Cart	Add to Cart
Customer Reviews	4.5 out of 5 stars 8,118	4.5 out of 5 stars 4,468	4.5 out of 5 stars 16,583	4.5 out of 5 stars 7,131	4.5 out of 5 stars 6,000	4.5 out of 5 stars 19,111
Price	$13.99	$18.99	$18.12	$11.77	$18.68	$18.12
	Stress and irritability are common symptoms of menopause, but are very manageable; Mood Boost supports restful sleep, mental attention and focus	Perimenopause happens prior to a woman entering menopause, when the ovaries begin to produce less estrogen. Estroven Pre-Menopause provides hormone-free and drug-free support for when cycle changes begin with just one daily capsule*	During menopause, you may notice you are hungry more often and have a less efficient metabolism. Estroven Weight Management relieves hot flashes and night sweats and helps manage weight*	Take Estroven Sleep Cool as a part of your nightly regimen to help with occasional sleeplessness; formulated to promote restful sleep through safe ingredients	Our Stress Relief and Energy Boost formula provides night sweat and hot flash relief, while supporting energy levels and stress relief	Our menopause supplement is clinically shown to relieve all menopause symptoms tested*; all-in-one formula provides night sweat and hot flash relief, supports restful sleep, boosts energy and helps with stress relief & irritability*

From the brand


SAFE | Estrogen & Drug Free††
Estroven®
MENOPAUSE RELIEF
Mood Boost
Menopause Relief
for
Hot Flashes*
Night Sweats*
Mood Swings*
with Black Cohosh, Magnolia Bark & Ginkgo Biloba
30 CAPLETS
DIETARY SUPPLEMENT
1 CAPLET PER DAY


Menopause Relief
for:
Hot Flashes*
Night Sweats*
Mood Swings*

Black Cohosh

*Helps Relieve Hot Flashes & Night Sweats**

Safe, Estrogen & Drug Free‡‡

Supplement Facts

Serving Size: One (1) Caplet

	Amount Per Serving	%Daily Value
Total Carbohydrate	<1g	<1%++
Calcium (as dicalcium phosphate)	95mg	7%
Black Cohosh Root Extract	40mg	**
Soy Isoflavones	56mg	**
Ginkgo biloba Leaf Extract	120mg	**
Magnolia Bark Extract *(Magnolia officinalis)*	15mg	**

++Percent Daily Value based on a 2,000 calorie diet.
**Daily Value not established.

Other Ingredients: microcrystalline cellulose, stearic acid, coating (hydroxypropyl methylcellulose, medium chain triglycerides [safflower oil], inulin, vegetable juice [color], titanium dioxide [color]), croscarmellose sodium, magnesium stearate.

Magnolia Bark Extract

*For Mood Swings**

Ginkgo Biloba

*For Mental Sharpness & Memory Support**


Estroven®
#1
Brand of Choice
Among Women
& Pharmacists‡

EXHIBIT 3

Hover over image to zoom



MENOPAUSE

Estroven® Menopause Relief Stress Relief & Energy Boost

★★★★½ (831) REVIEWS Write a review

- Maximum strength for hot flashes and night sweats*
- Naturally sourced magnolia bark to reduce stress, moodiness, and irritability*
- Naturally sourced green tea and yerba mate to boost energy*
- 30 Day Supply

PACK SIZE

28 Pack
$0.68 /Count

FREQUENCY

One-Time Purchase $18.99

Subscribe & Save 10% $17.09 ~~$18.99~~

- Save 10% on Every Order!
- Flexible Delivery, Skip or Cancel Anytime.
- Free Shipping. No Minimums!

1 ADD TO CART | $17.09 ~~$18.99~~

ALSO AVAILABLE AT 28 COUNT

Walmart Buy
amazon Buy
TARGET Buy
CVS pharmacy Buy
Walgreens Buy

How It Works

GREEN TEA & YERBA MATÉ

To help boost energy & manage fatigue with naturally sourced extracts.*

BLACK COHOSH

To help reduce the frequency and severity of hot flashes and night sweats.*

MAGNOLIA BARK

To safely reduce menopausal related anxiety and irritability.*

Did You Know?

Unpredictable symptoms can include stress and low energy, which increase menopausal anxiety and irritability.

The Basics

On top of hot flashes and night sweats, menopause can come with unpredictable symptoms like feeling more stressed and irritable. Estroven® Menopause Relief Stress Relief & Energy Boost is made with naturally sourced ingredients such as Black Cohosh to help with hot flashes and night sweats, Magnolia Bark for managing stress, and Green Tea and Yerba Maté extracts to boost energy and manage fatigue.*

Directions for Use +

Ingredients +

Soy Isoflavones plus TWICE the amount of naturally sourced Black Cohosh to help reduce the frequency and severity of hot flashes and night sweats*

Magnolia Bark to help safely reduce menopausal irritability and manage mood*

Green Tea and Yerba Maté extracts to help boost energy & manage fatigue*

Supplement Facts +

★★★★★

"I tried it and I love it. It really helps with all of my symptoms and helps me have more energy to get through the day to do the things that I need to do. I will be purchasing this product and recommending it to everyone I know."

Juju B
Verified Customer

Frequently Asked Questions

How does Estroven® Menopause Relief Stress Relief & Energy Boost reduce hot flashes and night sweats?

Estroven® Menopause Relief Stress Relief & Energy Boost is designed to address hot flashes and night sweats with the ingredients of naturally sourced Black Cohosh, plus clinically proven Soy Isoflavones (from soy beans).*
Estroven® Menopause Relief Stress Relief & Energy Boost contains twice as much naturally-sourced Black Cohosh as other leading brands to help reduce the frequency & severity of hot flashes and night sweats.* Both Black Cohosh and Soy Isoflavones have a relatively long safety profile history and demonstrated efficacy supporting their use to reduce hot flashes and night sweats.*

How does Estroven® Menopause Relief Stress Relief & Energy Boost help manage irritability and fatigue?

Estroven® Menopause Relief Stress Relief & Energy Boost contains naturally sourced Magnolia Bark to help safely reduce menopausal irritability and manage mood.* It also contains naturally sourced Green Tea and Yerba Maté extracts to help boost energy and manage fatigue.*

Does Estroven® Menopause Relief Stress Relief & Energy Boost contain caffeine?

Yes, it contains 52mg of naturally occurring caffeine (similar to an 8 oz. cup of black tea).

Does Estroven® Menopause Relief Stress Relief & Energy Boost contain soy?

Yes, Estroven® Menopause Relief Stress Relief & Energy Boost contains soy. Soy Isoflavones have been clinically proven to reduce hot flashes and night sweats.*

Does Estroven® Menopause Relief Stress Relief & Energy Boost contain the hormone estrogen?

No. Estroven® Menopause Relief Stress Relief & Energy Boost does not contain synthetic, animal or human-derived hormones.

How long should I take Estroven® Menopause Relief Stress Relief & Energy Boost before I start to see relief for my menopause symptoms?

Results vary based on each individual's symptoms and needs however, we recommend daily use for a minimum of 60 days for best results.

Can I take more than the recommended serving of Estroven® Menopause Relief Stress Relief & Energy Boost?

No, Estroven® Menopause Relief Stress Relief & Energy Boost should be taken as directed. It has been formulated with amounts of the active dietary ingredients to achieve the desired results.

Can I use Estroven® Menopause Relief Stress Relief & Energy Boost with other dietary supplements or medications?

We recommend speaking with your healthcare professional to see if taking Estroven® Menopause Relief Stress Relief & Energy Boost with other dietary supplements or medications is appropriate for your individual situation.

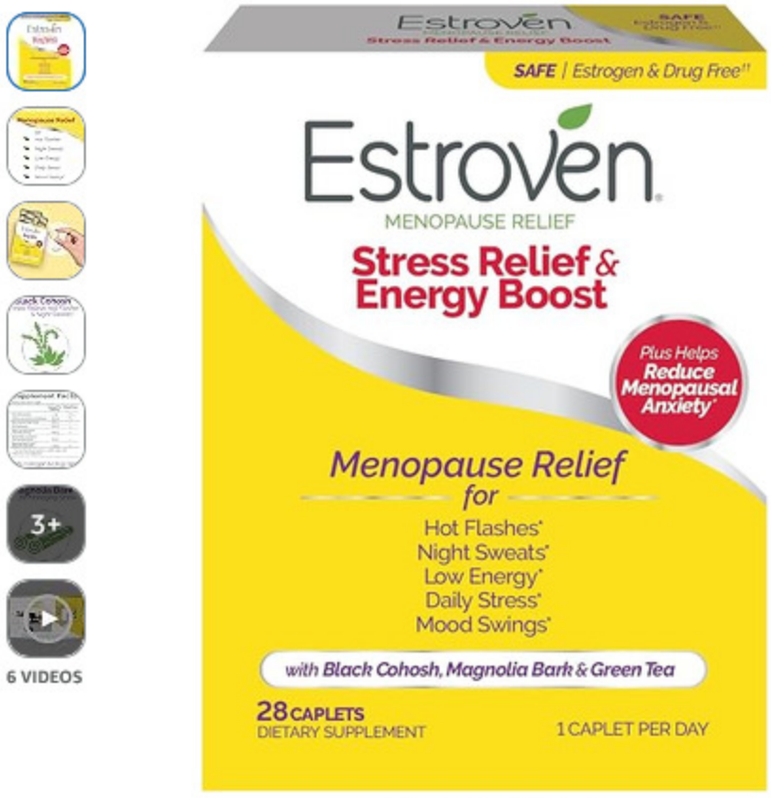
How should I store Estroven® Menopause Relief Stress Relief & Energy Boost?

Please store Estroven® Menopause Relief Stress Relief & Energy Boost at room temperature. Do not expose to excessive heat, humidity or direct sunlight.a

Where can I manage my subscription?

You can access your subscription in our subscription portal by requesting an account invite. Please use the email address your order was place with and as always, please check your SPAM folder if you don't see an email.

EXHIBIT 4



6 VIDEOS

Click to see full view

Ask Alexa

- Does it help with mood swings?
- Can it be taken with other supplements?
- Is this product vegan?
- Why you might like this
- Compare with similar
- Ask something else

Estroven Stress Relief & Energy Boost for Menopause Relief - 28 Ct. - Clinically Proven Ingredients Provide Stress & Energy Support + Night Sweats & Hot Flash Relief - Drug-Free and Gluten-Free

Visit the Estroven Store

4.5 ★★★★½ (6,000) | Search this page

Save $2

6K+ bought in past month

30-day low price

$18.68 ($0.67 / count) Price history

Save 50% (up to $80) on eligible products when using Membership Rewards® points. Terms apply. Activate now.

prime **Today**

Size: **28 Count (Pack of 1)**

Style: **Stress Relief & Enegy Boost**

Top highlights

Brand	Estroven
Flavor	Unflavored
Primary Supplement Type	Calcium
Unit Count	28 Count
Item Form	Capsule
Item dimensions L x	6 x 5 x 4 inches

See more

About this item

- DAILY RELIEF: Our Stress Relief and Energy Boost formula provides night sweat and hot flash relief, while supporting energy levels and stress relief
- ENERGY SOURCED FROM: Naturally sourced green tea and yerba mate to help boost energy levels and manage the fatigue that can be brought on by menopause
- NATURALLY SOURCED INGREDIENTS: Contains naturally sourced black cohosh and soy isoflavones clinically proven to help reduce the frequency and severity of hot flashes and night sweats and magnolia bark to help manage daily menopausal stress
- SAFE AND EFFECTIVE: With an excellent safety history, the dietary ingredients in this supplement are drug-free, free of both estrogen and other hormones, vegan and gluten-free
- MENOPAUSE BRAND: Estroven remains a top choice among women and comes recommended by pharmacists. Over a million women chose Estroven each year, more than any other brand

Item details

Measurements

See all product specifications

Report an issue with this product or seller

One-time purchase

$18.68 ($0.67 / count)

Price history

prime **Today**

FREE delivery **Today**
2 PM - 6 PM

Or $4.99 delivery **in 3 hours**

Shorter shipping distance

Deliver to Kari - West Des Moines 50266

In Stock

Quantity: 1

Add to cart

Buy Now

Shipper / Seller	Amazon.com
Returns	Non-returnable due to Food safety reasons
Gift options	Available at checkout

See more

Subscribe & Save

$17.75 ($0.63 / count)

prime

FREE delivery Today
2 PM - 6 PM

Shipper / Seller: Amazon.com

Add to Auto Buy

Add to List

Important information

Safety Information

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.Contains: Soy.As with any dietary supplement, please inform your healthcare professional before taking. Do not take if pregnant, breastfeeding or intending to become pregnant.Keep out of reach of children.Tamper evident: product is sealed within blisters. Do not use if any part of the blister is torn, open or damaged.This product is labelled to United States standards and may differ from similar products sold elsewhere in its ingredients, labeling and allergen warnings

Ingredients

Black Cohosh Root Extract, Soy Isoflavones, Green Tea Leaf Extract (Camellia sinensis), Yerba Mate' Leaf Extract (Ilex paraguariensis), microcrystalline cellulose, stearic acid, croscarmellose sodium, hydroxypropyl methylcellulose, silicon dioxide, titanium dioxide (color), polyethylene glycol, magnesium stearate, riboflavin (color)

Directions

Please follow label instructions.

Legal Disclaimer

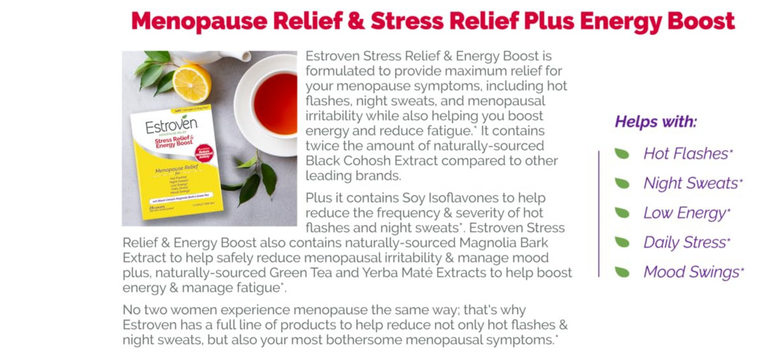
These statements have not yet been evaluated by the United States Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Statements regarding dietary supplements have not been evaluated by the FDA and are not intended to diagnose, treat, cure, or prevent any disease or health condition.

Product Description

No two women experience menopause the same way; that's why Estroven has a full line of products to help reduce not only hot flashes & night sweats, but also your most bothersome menopausal symptoms.* Estroven Stress Relief & Energy Boost for Menopause Relief can help you feel like yourself again. It's formulated to provide maximum relief for your most bothersome menopause symptoms, including: hot flashes, night sweats, and menopausal irritability.* Estroven Stress Relief & Energy Boost is also designed to help boost energy and reduce fatigue.* It contains twice the amount of naturally-sourced Black Cohosh Extract, plus Soy Isoflavones to help reduce the frequency & severity of hot flashes and night sweats.* Estroven Stress Relief & Energy Boost also contains naturally-sourced Magnolia Bark Extract to help safely reduce menopausal irritability & manage mood.* Plus, naturally-sourced Green Tea and Yerba Maté Extracts to help boost energy & manage fatigue.*; * These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease; **: Nielsen xAOC 52 W/E 12/03/2022 and #1 Pharmacist recommended menopause brand based on Pharmacy Times OTC Survey, 2022.

From the manufacturer



	Estroven Stress Relief & Energy Boost for Menopause Relief, 28 Count	Estroven Complete Multi-Symptom Menopause Relief Supplement, 28 Count	Estroven Sleep Cool for Menopause Relief for Women, 30 Count	Estroven Mood Boost For Menopause Relief, 30 Count	Estroven Pre-Menopause Relief, 30 Count	Estroven Weight Management for Menopause Relief, 30 Count
	Add to Cart	Add to Cart	Add to Cart	Add to Cart	Add to Cart	Add to Cart
Customer Reviews	6,000	19,111	7,131	8,118	4,468	16,583
Price	$18.68	$18.12	$11.77	$13.99	$18.99	$18.12
	Our Stress Relief and Energy Boost formula provides night sweat and hot flash relief, while supporting energy levels and stress relief	Our menopause supplement is clinically shown to relieve all menopause symptoms tested*; all-in-one formula provides night sweat and hot flash relief, supports restful sleep, boosts energy and helps with stress relief & irritability*	Take Estroven Sleep Cool as a part of your nightly regimen to help with occasional sleeplessness; formulated to promote restful sleep through safe ingredients	Stress and irritability are common symptoms of menopause, but are very manageable; Mood Boost supports restful sleep, mental attention and focus	Perimenopause happens prior to a woman entering menopause, when the ovaries begin to produce less estrogen. Estroven Pre-Menopause provides hormone-free and drug-free support for when cycle changes begin with just one daily capsule*	During menopause, you may notice you are hungry more often and have a less efficient metabolism. Estroven Weight Management relieves hot flashes and night sweats and helps manage weight*

From the brand


Estroven
MENOPAUSE RELIEF
Stress Relief & Energy Boost
SAFE
Estrogen & Drug Free††
SAFE | Estrogen & Drug Free††
Estroven®
MENOPAUSE RELIEF
Stress Relief & Energy Boost
Plus Helps Reduce Menopausal Anxiety*
Menopause Relief for
Hot Flashes*
Night Sweats*
Low Energy*
Daily Stress*
Mood Swings*
with Black Cohosh, Magnolia Bark & Green Tea
28 CAPLETS
DIETARY SUPPLEMENT
1 CAPLET PER DAY


Menopause Relief
for:
Hot Flashes*
Night Sweats*
Low Energy*
Daily Stress*
Mood Swings*

Black Cohosh

*Helps Relieve Hot Flashes & Night Sweats**

Supplement Facts

Serving Size: One (1) Caplet

	Amount Per Serving	%Daily Value
Total Carbohydrate	<1g	<1%++
Calcium (as dicalcium phosphate)	90mg	7%
Black Cohosh Root Extract	80mg	**
Soy Isoflavones	60mg	**
Green Tea Leaf Extract *(Camellia sinensis)*	100mg	**
Yerba Maté Leaf Extract *(Ilex paraguariensis)*	30mg	**
Magnolia Bark Extract *(Magnolia officinalis)*	15mg	**

++Percent Daily Value based on a 2,000 calorie diet.
**Daily Value not established.

Safe, Estrogen & Drug Free††

Magnolia Bark
*for Managing Stress**

Green Tea & Yerba Mate

*to Boost Energy & Manage Fatigue**


Estroven®
#1
Brand of Choice
Among Women
& Pharmacists‡

EXHIBIT 5

WARNING LETTER

AnuMed International, LLC

MARCS-CMS 674310 — AUGUST 20, 2024

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Julie R. Alcantar

Owner

AnuMed International, LLC

3908 E Broadway Rd, Suite 110

Phoenix, AZ 85040-2995

United States

julie@anumed-intl.com (mailto:julie@anumed-intl.com)

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

WARNING LETTER

August 20, 2024

RE: 674310

Dear Julie Alcantar:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, AnuMed International, LLC, FEI 3010164449, at 3908 E Broadway Rd, Suite 110, Phoenix, Arizona from November 1 to 7, 2023.

FDA also reviewed your website at the Internet address https://www.anumed-intl.com/ in February and April 2024 and has observed that your website offers “Semaglutide Homeopathic Formula,” “Magnesium 50 mg Body Cream,” “AnuMed™ 25mg Per Pump PROGESTERONE CREAM,” “AnuMed™ 75mg Per Pump PROGESTERONE CREAM,” “AnuMed™ BIO-IDENTICAL BIO-EST 2.5mg PER PUMP,” “AnuMed™ BIO-IDENTICAL BIO-EST 5mg Per Pump,” “AnuMed™ 2.5 All Natural ESTRIOL CREAM,” “AnuMed™ 5.0 All Natural ESTRIOL CREAM,” “AnuMed™ Bio-Identical DHEA 20 CREAM,”

Feedback

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"AnuMed™ Bio-Identical DHEA 50 CREAM," "50,000 IU Vitamin D3+K2 CREAM," "Travel Safe Drops: Advanced Intestinal Flora, Parasite Cleanser & Digestive Health Support," "Vitamin C Booster - 2000mg," "Immune Booster 90 Capsules," "Vegan Vitamin D3 K2 60ct Capsules," "B-12 – 1000 and Vitamin B12 5000mcg Drops (Methylcobalamin)," "2oz Vitamin C Booster Drops," "2oz Anumed Zinc Drops," and "Turmeric Curcumin Drops 775mg with Black Pepper Extract" products for sale in the United States. As described below, your above-mentioned products are unapproved new drugs introduced or delivered for introduction into interstate commerce in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, your "Magnesium 50 mg Body Cream," "AnuMed™ 25mg Per Pump PROGESTERONE CREAM," "AnuMed™ 2.5 All Natural ESTRIOL CREAM," "AnuMed™ 5.0 All Natural ESTRIOL CREAM," "AnuMed™ BIO-IDENTICAL BIO-EST 2.5mg PER PUMP," "AnuMed™ BIO-IDENTICAL BIO-EST 5mg Per Pump," "AnuMed™ Bio-Identical DHEA 50 CREAM" and "AnuMed™ Bio-Identical DHEA 20 CREAM," "Vitamin C Booster - 2000mg," "Immune Booster 90 Capsules," "Vegan Vitamin D3 K2 60ct Capsules," "B-12 – 1000 and Vitamin B12 5000mcg Drops (Methylcobalamin)" products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. 352, introduced or delivered for introduction into interstate commerce in violation of section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

In addition, because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B). We reviewed your November 28, 2023, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

Unapproved New Drugs

Based on a review of your product labeling obtained during FDA's inspection and on your website, your "Semaglutide Homeopathic Formula," "Magnesium 50 mg Body Cream," "AnuMed™ 25mg Per Pump PROGESTERONE CREAM," "AnuMed™ 75mg Per Pump PROGESTERONE CREAM," "AnuMed™ BIO-IDENTICAL BIO-EST 2.5mg PER PUMP," "AnuMed™ BIO-IDENTICAL BIO-EST 5mg Per Pump," "AnuMed™ 2.5 All Natural ESTRIOL CREAM," "AnuMed™ 5.0 All Natural ESTRIOL CREAM," "AnuMed™ Bio-Identical DHEA 20 CREAM," "AnuMed™ Bio-Identical DHEA 50 CREAM," "50,000 IU Vitamin D3+K2 CREAM," "Travel Safe Drops: Advanced Intestinal Flora, Parasite Cleanser & Digestive Health Support," "Vitamin C Booster - 2000mg," "Immune Booster 90 Capsules," "Vegan Vitamin D3 K2 60ct Capsules," "B-12 – 1000 and Vitamin B12 5000mcg Drops (Methylcobalamin)," "2oz Vitamin C Booster Drops," "2oz Anumed Zinc Drops," and "Turmeric Curcumin Drops 775mg with Black Pepper Extract" are drugs as defined by section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the body.

Examples of claims from your product labeling and website https://www.anumed-intl.com/ that provide evidence of the intended use of these products as drugs include, but may not be limited to, the following:

Semaglutide Homeopathic Formula
On the product label:
• "CRAVINGS
APPETITE
WEIGHT LOSS"

• "INDICATIONS:
It may help to temporarily reduce minor hunger pangs and control appetite to support weight loss efforts."

• "DIRECTIONS: . . . For maximum effectiveness repeat 2 to 3 times per day until desired weight or craving control is achieved. Continue as needed if cravings arise and to help avoid weight regain."

Magnesium 50 mg Body Cream
On the product webpage:

• “Highly Effective for Leg Cramps, Muscle Soreness, Nighttime Leg Discomfort, Inflammation Relief”

• “Magnesium is important for many processes in the body. It helps regulate muscle and nerve function, blood sugar levels, blood pressure, making protein, bone and DNA. Studies have shown that deficiency of Magnesium results in cramping and several muscular pain.”

• “Magnesium Chloride helps with the normal functioning of cells, nerves, bones, and the heart.”

• “Niacin (vitamin B3) helps support the cardiovascular system and the heart. It contributes to healthy metabolic function, supports the pancreas, and works to support brain & nerve function.”

AnuMed™ 25mg Per Pump PROGESTERONE CREAM and AnuMed™ 75mg Per Pump PROGESTERONE CREAM

On the product label:

• “75 mg Per Pump PROGESTERONE CREAM . . . Hormones / Mood / Sleep . . . Use 1 pump a day 1 to 3 minutes before a meal, or as recommended by your practitioner.”

On the product webpage:

• “**5 Benefits of Natural Progesterone Cream with ISO99:** . . . Relieves Menopause Symptoms . . . promote bone density . . . Boosts Fertility . . . preventing miscarriage. . . . Treats Fibroid Tumors . . . Helps Endometriosis . . . Balance Hormones and Relieve PMS Symptoms . . . Relieves Inflammation”

AnuMed™ BIO-IDENTICAL BIO-EST 2.5mg PER PUMP and AnuMed™ BIO-IDENTICAL BIO-EST 5mg Per Pump

On the product webpage:

• “**Natural Bio-Identical BIO-EST 2.5mg** may help with menopause symptoms. . . . **BENEFITS** . . . Lower the risk of urinary tract infections (UTIs) . . . Strengthen bones and prevent osteoporosis”

• “**Natural Bio-Identical Bio-EST 5mg** may help with menopause symptoms. . . . **BENEFITS** . . . Lower the risk of urinary tract infections (UTIs) . . . Strengthen bones and prevent osteoporosis”

AnuMed™ 2.5 All Natural ESTRIOL CREAM and AnuMed™ 5.0 All Natural ESTRIOL CREAM

On the product webpage:

• “**Natural Bioidentical Estriol Cream 2.5 with Hyaluronic Acid** . . . #1 Recommended Estriol Cream for Menopause Relief, Mood Swings, Hot Flashes, Breast soreness . . . Natural Hormone Balance”

• “**Natural Bioidentical Estriol Cream 5.0 with Hyaluronic Acid** . . . #1 Recommended Estriol Cream for Menopause Relief, Mood Swings, Hot Flashes, Breast soreness . . . Natural Hormone Balance”

AnuMed™ Bio-Identical DHEA 20 CREAM and AnuMed™ Bio-Identical DHEA 50 CREAM

From your storefront on Amazon’s webpage https://www.amazon.com/ANUMED-Bioidentical-Dehydroepiandrosterone-Hyaluronic-Essential/dp/B0BNHH4R8Q?th=1

• “ANUMED – All Natural Bioidentical DHEA 20mg Cream . . . for Hormone Balance, Mood, Immune System . . . Natural Balancing of Hormone Levels, Promotes Mood, Immune System, Anti-Aging, Energy, Metabolism.”

On the product webpage:

• “**All Natural Bioidentical DHEA 50mg Cream (Dehydroepiandrosterone) + Hyaluronic Acid . . . Hormone Balance, Mood, Energy, Immune System** . . . Natural Balancing of Hormone Levels. Promotes Mood, Immune System, Anti-Aging, Energy, Metabolism.”

50,000 IU Vitamin D3+K2 CREAM

On the product label:

• “With Hyaluronic Acid . . . May Increase Calcium Absorption . . . PSORIASIS & ECZEMA RELIEF . . . May help relieve skin flares caused by Psoriasis & Eczema. . . . Vitamin D is necessary for strong bones and teeth. . . . May Help muscle function & support immune system. . . . May help heal wounds faster such as fading bruising.”

On the product webpage:

• “Vitamin D3 50,000 IU cream is our most potent vitamin-based solution created with the intent of replenishing the lowest vitamin deficiencies and relieving the symptoms of various conditions such as psoriasis and eczema in a minimal time

frame. It can help with boosting immune system."

Travel Safe Drops: Advanced Intestinal Flora, Parasite Cleanser & Digestive Health Support

• In the name of the product – "Parasite Cleanser"

On the product webpage:

• "A proprietary blend of herbals along with zinc to help fight and eliminate parasites in the body"

• "Wormwood kills adult parasites and especially pinworms."

• "Black Walnut which has anti-fungal and antibacterial properties and can kill intestinal parasites like roundworm and tapeworm. It helps to clean out any toxins and dangerous pathogens."

• "Clove Bud kills the parasite eggs that may be lingering in the intestinal tract along with worms . . . Thus, helps relieve indigestion and constipation problems. . . . These compounds provide potent antiseptic and anti-inflammatory benefits."

• "Fennel is helpful in reducing diarrhea if it is caused by bacterial infection because some components of the essential oil in fennel such as anetol and cineole have disinfectant and antibacterial properties." • "Ginger is known as an anti-parasitic. Researchers show that it can inhibit a variety of worms and parasites.."

Vitamin C Booster - 2000mg

On the product webpage:

• "Best protection support from cold, flu [influenza], virus [viral infection]"

• "Zinc may help with wound healting [sic]"

• "L-Lysine . . . Also, may help people with the herpes simplex virus (HSV) [viral infection] and diabetes."

• "Ultimate Defense from cold, Flu [influenza], Virus [viral infection], allergy"

Immune Booster 90 Capsules

On the product webpage:

• "Has Zinc for which . . . may help combat colds, upper respiratory infections and viruses [viral infection]. . . . This product not only boosts immune system to help make body strong in order to combat most viruses [viral infection] and infections"

Vegan Vitamin D3 K2 60ct Capsules

On the product webpage:

• "Research studies have indicated that K2 intake can decrease bone loss among those with Osteoporosis."

• "Vitamin D deficiencies have been linked by researchers to . . . sleeping disorders."

• "Research has indicated that vitamin D, while in combination with other bodily properties, plays a pivotal role in fortifying the antibacterial potency of the essential immune cells."

B-12 – 1000 and Vitamin B12 5000mcg Drops (Methylcobalamin)

On the product webpage:

• "Heart Disease: Research has found that B-12 in combination with B-6 and folic acid may help regulate and decrease the levels of homocysteine in the blood system, which are known to increase the chances of cardiovascular disease."

• "Dementia and Cognitive Abilities: . . . Research has indicated an association between low levels of B-12 and cognitive decline. As a result, the B-12 . . . solution may help support and replace the lack of the nutrient while improving cognitive function."

• "When the body has a deficiency of the vitamin, harmful bacteria begins to grow. A consistent intake of B-12 has demonstrated that it can help remove bad bacteria . . . and potentially prevent gastrointestinal disorders."

2oz Vitamin C Booster Drops

On the product webpage:

• "Has been recommended to try and help ease cold and flu [influenza] symptoms."

• "Be prepared for fighting illness and germs."

2oz Anumed Zinc Drops

On the product webpage:

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• “Ultimate Defense from Cold, Flu [influenza], Virus [viral infection], Allergy”

Turmeric Curcumin Drops 775mg with Black Pepper Extract

On the product webpage:

• “Curcumin and other chemicals in turmeric might decrease swelling (inflammation). Because of this, turmeric might be beneficial for treating conditions that involve inflammation. Has been known to help with the reduction of inflammation, pain”

Your “Semaglutide Homeopathic Formula,” “Magnesium 50 mg Body Cream,” “AnuMed™ 25mg Per Pump PROGESTERONE CREAM,” “AnuMed™ 75mg Per Pump PROGESTERONE CREAM,” “AnuMed™ BIO-IDENTICAL BIO-EST 2.5mg PER PUMP,” “AnuMed™ BIO-IDENTICAL BIO-EST 5mg Per Pump,” “AnuMed™ 2.5 All Natural ESTRIOL CREAM,” “AnuMed™ 5.0 All Natural ESTRIOL CREAM,” “AnuMed™ Bio-Identical DHEA 20 CREAM,” “AnuMed™ Bio-Identical DHEA 50 CREAM,” and “50,000 IU Vitamin D3+K2 CREAM,” “Travel Safe Drops: Advanced Intestinal Flora, Parasite Cleanser & Digestive Health Support,” “Vitamin C Booster - 2000mg,” “Immune Booster 90 Capsules,” “Vegan Vitamin D3 K2 60ct Capsules,” “B-12 – 1000 and Vitamin B12 5000mcg Drops (Methylcobalamin),” “2oz Vitamin C Booster Drops,” “2oz Anumed Zinc Drops,” and “Turmeric Curcumin Drops 775mg with Black Pepper Extract” products are not generally recognized as safe and effective (GRASE) for their above referenced uses and, therefore, are “new drugs” under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). Subject to certain exceptions not applicable here[1], a new drug may not be introduced or delivered for introduction into interstate commerce without an approved application from FDA in effect, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). No approved applications pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, are in effect for these products.[2] Accordingly, the introduction or delivery for introduction into interstate commerce of these products violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

Misbranded Drugs

“Magnesium 50 mg Body Cream,” “AnuMed™ 25mg Per Pump PROGESTERONE CREAM,” “AnuMed™ 2.5 All Natural ESTRIOL CREAM,” “AnuMed™ 5.0 All Natural ESTRIOL CREAM,” “AnuMed™ BIO-IDENTICAL BIO-EST 2.5mg PER PUMP,” “AnuMed™ BIO-IDENTICAL BIO-EST 5mg Per Pump,” “AnuMed™ Bio-Identical DHEA 50 CREAM” and “AnuMed™ Bio-Identical DHEA 20 CREAM” are misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a), because the product labels and/or websites include statements that misleadingly suggest that the drug products are approved or endorsed by FDA in some way. For example, the website for Magnesium 50 mg Body Cream includes the image of a blue circle with the claim, “FDA * APPROVED * FACILITY.” Further, the product labels and/or websites for the other seven before-listed products include statements that these products are made or manufactured in an “FDA inspected and Certified Facility,” a “Certified FDA registered facility,” and/or a “FDA registered facility.” FDA’s regulations provide that “[r]egistration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or other drugs of the establishment, nor does it mean that a product may be legally marketed” (21 CFR 207.77(a)). However, the general public is not likely to be familiar with the details of FDA’s regulations. The above assertions misleadingly suggest that the above-mentioned drug products are approved or endorsed by FDA in some way. Your “Magnesium 50 mg Body Cream,” “AnuMed™ 25mg Per Pump PROGESTERONE CREAM,” “AnuMed™ 2.5 All Natural ESTRIOL CREAM,” “AnuMed™ 5.0 All Natural ESTRIOL CREAM,” “AnuMed™ BIO-IDENTICAL BIO-EST 2.5mg PER PUMP,” “AnuMed™ BIO-IDENTICAL BIO-EST 5mg Per Pump,” “AnuMed™ Bio-Identical DHEA 50 CREAM” and “AnuMed™ Bio-Identical DHEA 20 CREAM” products are not the subjects of an FDA-approved application. Therefore, these products are misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a), because their labeling is false or misleading. The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Additionally, a drug is misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1) if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can

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use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act, 21 U.S.C. 353(b)(1)(A), can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your “Vitamin C Booster - 2000mg,” “Immune Booster 90 Capsules,” “Vegan Vitamin D3 K2 60ct Capsules,” and “B-12 – 1000 and Vitamin B12 5000mcg Drops (Methylcobalamin)” are intended for prevention or treatment of one or more diseases that are not amenable to self-diagnosis, prevention, or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use these products safely for their intended purposes. Accordingly, your before-noted products fail to bear adequate directions for their intended uses and, therefore, are misbranded under section 502(f)(1) of the Act, 21 U.S.C. 352(f)(1). The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

CGMP Violations

During our inspection, our investigator observed specific violations including, but not limited to, the following:

1. Your firm failed to conduct at least one test to verify the identity of each component of a drug product (21 CFR 211.84(d)(1)).

You failed to perform adequate identity testing, including specific identity testing as appropriate, for each shipment of each lot of components, such as glycerin and ethyl alcohol (ethanol; alcohol), used in the manufacture of your drug products. During the inspection, you indicated that you were not aware testing was required and that you rely upon your supplier’s certificate of analysis (COA) for acceptance of incoming materials.

Alcohol (Ethanol)

Identity testing for pharmaceutical alcohol (ethanol and isopropyl alcohol) includes a limit test in the United States Pharmacopeia (USP) to ensure that the component meets the relevant safety limits for levels of methanol. The use of ethanol contaminated with methanol has resulted in various lethal poisoning incidents in humans worldwide. See FDA’s guidance document *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol* at: https://www.fda.gov/media/173005/download.

Glycerin

Identity testing for glycerin and certain other high-risk drug components[3] include a limit test in the United States Pharmacopeia (USP) to ensure that the component meets the relevant safety limits for levels of DEG or EG. Because you did not perform identity testing on each shipment of each lot using the USP identification test that detects these hazardous impurities, you failed to assure the acceptability of these components for use in manufacture of your drug products. The use of ingredients contaminated with DEG or EG has resulted in various lethal poisoning incidents in humans worldwide. See FDA’s guidance document *Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and Other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol* to help you meet the CGMP requirements when manufacturing drugs containing ingredients at risk for DEG or EG contamination, at https://www.fda.gov/media/167974/download.

In your response, you state that you are reviewing options for identity testing of raw materials. Your response is inadequate because you did not provide sufficient detail or evidence of corrective actions (e.g., assessing retain samples).

Without appropriate testing of components, you cannot ensure the quality and safety of your drug products.

In response to this letter, provide:

• A description of how you will test each component lot for conformity with all appropriate specifications for identity,

strength, quality, and purity. If you intend to accept any results from your supplier's COA instead of testing each component lot for strength, quality, and purity, specify how you will robustly establish the reliability of your supplier's results through initial validation as well as periodic re-validation. In addition, include a commitment to always conduct at least one specific identity test for each incoming component lot.

• The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing.

• A comprehensive, independent review of your material system to determine whether all suppliers of components, containers, and closures, are each qualified and the materials are assigned appropriate expiration or retest dates. The review should also determine whether incoming material controls are adequate to prevent use of unsuitable components, containers, and closures.

• A commitment to provide test results for components used in the manufacture of your drug products, no later than 30 calendar days from the date of this letter, including testing retains for all lots of drug components at high-risk for DEG and EG contamination, and pharmaceutical alcohol for methanol contamination. Alternatively, if a retain of a component lot is unavailable, perform retain sample testing of all implicated finished drug product batches for the presence of DEG, EG, and methanol.

• A full risk assessment for drug products that are within expiry which contain any ingredient at risk for DEG, EG, or methanol contamination (including, but not limited to, glycerin and ethyl alcohol). Take prompt and appropriate actions to determine the safety of all lots of the component(s) and any related drug product that could contain DEG, EG, or methanol including customer notifications and product recalls for any contaminated lots. Identify additional appropriate corrective action and preventive action (CAPA) that secure supply chains in the future including, but not limited to, ensuring that all incoming raw material lots are from fully qualified manufacturers and free from unsafe impurities. Detail these actions in your response to this letter.

2. Your firm failed to establish written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

Lack of Process Validation

You failed to adequately validate your processes used to manufacture your drug products and demonstrate that your processes are reproducible and controlled to consistently yield drugs of uniform character and quality.

In your response, you state that your process validation procedure will be reviewed and personnel trained. However, your response is inadequate as you did not provide sufficient detail or evidence of corrective actions.

Process validation evaluates the soundness of design and state of control of a process throughout its lifecycle. Each significant stage of a manufacturing process must be designed appropriately and assure the quality of raw material inputs, in-process materials, and finished drugs. Process qualification studies determine whether an initial state of control has been established. Successful process qualification studies are necessary before commercial distribution. Thereafter, ongoing vigilant oversight of process performance and product quality is necessary to ensure you maintain a stable manufacturing operation throughout the product lifecycle.

See FDA's guidance for industry, Process Validation: General Principles and Practices for general principles and approaches that FDA considers appropriate elements of process validation at https://www.fda.gov/media/71021/download.

Inadequate Water System

Your firm uses water as a component to manufacture your drug products. You failed to adequately qualify your purified water system. You also failed to show that your water system is adequately monitored to ensure it consistently produces water that meets appropriate microbial limits. Routine monitoring of microbial counts and identity of contamination in the

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system is integral to ensuring oversight of ongoing state of control and suitability of water for use in manufacturing operations.

In your response, you state that your quality unit will begin conducting regular inspections to ensure the water system is adequate. However, your response is inadequate as you did not provide sufficient detail or evidence of corrective actions.

Purified water must be suitable for its intended use and routinely tested to ensure ongoing conformance with appropriate chemical and microbiological attributes.

Furthermore, you manufacture drug products (including hormones) and non-pharmaceutical products (e.g., cosmetics) using shared equipment (e.g., **(b)(4)** tanks, **(b)(4)**, and filling lines). In your response, you state that your cleaning validation procedure will be reviewed and revised to include the necessary cleaning validation studies. Adequate cleaning procedures are required as chemical and microbial residues on equipment from previous manufacturing activities can adversely impact the purity, quality, and safety of drug products also manufactured on that equipment.

In response to this letter, provide:
• A detailed summary of your validation program for ensuring a state of control throughout the product lifecycle, along with associated procedures. Describe your program for process performance qualification (PPQ), and ongoing monitoring of both intra-batch and inter-batch variation to ensure a continuing state of control.
• A timeline for performing PPQ for each of your marketed drug products.
• Include your process performance protocol(s), and written procedures for qualification of equipment and facilities.
• A comprehensive, independent assessment of your water system design, control, and maintenance.
• A thorough remediation plan to assure you operate a suitable water system, including any redesign. Include a robust ongoing control, maintenance, and monitoring program to ensure the system consistently produces water adhering to Purified Water, USP monograph specifications and appropriate microbial limits.
• Regarding the latter, ensure that your total microbial count limit for water is appropriate in view of the intended use of the products produced by your firm.
• Appropriate improvements to your cleaning validation program, with special emphasis on incorporating conditions identified as worst case in your drug manufacturing operation. This should include, but not be limited to, identification and evaluation of all worst-case:
  o Drugs with higher toxicities
  o Drugs with higher drug potencies
  o Drugs of lower solubility in their cleaning solvents
  o Drugs with characteristics that make them difficult to clean
  o Swabbing locations for areas that are most difficult to clean
  o Maximum hold times before cleaning
In addition, describe the steps that must be taken in your change management system before introduction of new manufacturing equipment or a new product.
• A summary of updated SOPs that ensure an appropriate program is in place for verification and validation of cleaning procedures for products, processes, and equipment.

3. Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity (21 CFR 211.160(b)).

You failed to validate your non-compendial microbial methods used to test drug products and assure the methods were equivalent to or better than USP methods. For example, you use **(b)(4)** to analyze total count and yeast and mold in finished product. Additionally, you failed to follow the instructions for use and the investigator observed the use of expired **(b)(4)** test materials for finished product testing.

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In your response, you indicate that you ceased use of the **(b)(4)** non-compendial tests. Your response is inadequate as you did not provide sufficient detail or evidence of corrective actions, including validation or verification of appropriate microbial methods for drug product testing by your contract laboratory or your internal laboratory, and to demonstrate that the methods used are equivalent to or better than USP methods. You also did not commit to conducting retrospective review of products tested using your non-compendial, non-validated tests.

In response to this letter, provide:
• A comprehensive, independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system.
• A list of chemical and microbial specifications, including test methods, used to analyze each lot of your drug products before a lot disposition decision. Include specifications for drug products within expiration that are already distributed within the United States and specifications for future drug products.
  o An action plan and timelines for conducting full chemical and microbiological testing of retain samples to determine the quality of all batches of drug product distributed to the United States that are within expiry as of the date of this letter.
  o A summary of all results obtained from testing retain samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls.
• Chemical and microbial test method verification or validation reports and supporting data for internal and contracted testing of your components and drug products.

4. Your firm's quality control unit failed to exercise its responsibility to ensure drug products manufactured are in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity (21 CFR 211.22).

Your quality unit (QU) did not provide adequate oversight for the manufacture of your drug products. For example, your QU failed to ensure the following:
• An adequate system for retention of production, control, or distribution records associated for all batches of drug product (21 CFR 211.180(a)).
• Batch production and control records include documentation of the accomplishment of each significant step in the manufacture and processing for each batch of drug product (21 CFR 211.188(b)).
• Performance of periodic (i.e., at least annually) product reviews (21 CFR 211.180(e)).
• Adequate training for employees engaged in the manufacture, processing, packing, or holding of drug products (21 CFR 211.25(a)).

Significant findings in this letter demonstrate that your firm does not operate an effective quality system in accord with CGMP. The QU must be accountable for implementing all the controls and reviewing the results of manufacture to ensure that product quality standards have been met. In smaller firms, it is recommended that another qualified individual, not involved in the production operation, conduct an additional, periodic review of QU activities. See FDA's guidance document *Quality Systems Approach to Pharmaceutical CGMP Regulations* for help implementing quality systems and risk management approaches to meet the requirements of CGMP regulations 21 CFR, parts 210 and 211 at https://www.fda.gov/media/71023/download.

In response to this letter, provide:
• A comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to:
  o A determination of whether procedures used by your firm are robust and appropriate.
  o Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices.
  o A complete and final review of each batch and its related information before the QU disposition decision.
  o Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and

purity of all products.

Repeat Observations at Facility

In a previous inspection ending December 13, 2017, FDA cited similar CGMP observations. You proposed specific remediation for these observations in your response. Repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate.

CGMP Consultant Recommended

Based upon the nature of the violations we identified at your firm, you should engage a consultant qualified as set forth in 21 CFR 211.34 to evaluate your operations and to assist your firm in meeting CGMP requirements. The qualified consultant should also perform a comprehensive six-system audit of your entire operation for CGMP compliance and evaluate the completion and efficacy of your CAPA before you pursue resolution of your firm's compliance status with FDA.

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure, and injunction.

Please notify FDA in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction. Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance by email to FDAAdvisory@fda.hhs.gov and include your firm name in the subject line of your email.

Sincerely,
/S/

Jill Furman
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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1 Your AnuMed™ 25mg Per Pump PROGESTERONE CREAM," "AnuMed™ 75mg Per Pump PROGESTERONE CREAM," "AnuMed™ BIO-IDENTICAL BIO-EST 2.5mg PER PUMP," "AnuMed™ BIO-IDENTICAL BIO-EST 5mg Per Pump," "AnuMed™ 2.5 All Natural ESTRIOL CREAM," "AnuMed™ 5.0 All Natural ESTRIOL CREAM, "AnuMed™ Bio-Identical DHEA 20 CREAM" and "AnuMed™ Bio-Identical DHEA 50 CREAM" drugs are hormone containing products that are deemed to be new drugs under a final determination issued under 21 CFR part 330, as published in the Federal

Register on September 9, 1993 (see 58 FR 47610). There, the Agency has determined that any OTC drug product other than hydrocortisone that is labeled, represented, or promoted as a topically applied hormone-containing product for drug use are not generally recognized as safe and effective under section 201(p)(1) of the FD&C Act and that all such products are deemed to be new drugs and require an approved new drug application under section 505 of the FD&C Act to be lawfully marketed. 21 CFR 310.530.

Furthermore, as an OTC combination psoriasis/skin protectant drug products, your “50,000 IU Vitamin D3+K2 CREAM” must conform to the conditions of use set forth in the Over-the-Counter Monograph M032: Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for Over-the-Counter Human Use (henceforth “M032”), encompassed under the final administrative order OTC000021 and the Over-the-Counter Monograph M016: Skin Protectant Drug Products for Over-the-Counter Human Use (henceforth “M016”) encompassed under the final administrative order OTC000005. However, your “50,000 IU Vitamin D3+K2 CREAM” does not conform to conditions specified in either M032 or M016 because its labeling has intended uses such as, “PSORIASIS & ECZEMA RELIEF” and “help heal wounds” that go beyond the general intended uses described in M032 and M016. Neither final order allows for such a combination of a psoriasis and a skin protectant. There is no basis under the FD&C Act under which these products would be legally marketed without an approved application.

2 We recognize that the “Semaglutide Homeopathic Formula” labeling describes the products as being “homeopathic.”

First, we note that under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), the term “drug” includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drug products are subject to the same statutory requirements as other drugs; nothing in the FD&C Act exempts homeopathic drugs from any of the requirements related to adulteration, misbranding, or FDA approval.

In addition, FDA issued a guidance in December 2022 that describes how the Agency intends to prioritize enforcement and regulatory actions for homeopathic drug products marketed in the United States without the required FDA approval. (See Homeopathic Drug Products: Guidance for FDA Staff and Industry, available at https://www.fda.gov/media/163755/download). For purposes of this guidance, FDA defines a “homeopathic drug product” as “a drug product that is labeled as ‘homeopathic,’ and is labeled as containing only active ingredients and dilutions (e.g., 10X, 20X) listed for those active ingredients in the Homeopathic Pharmacopeia of the United States (HPUS).” Your product includes semaglutide, which is not listed in the HPUS; thus, this product falls outside the scope of products addressed in this guidance.

3 Components with higher risk of DEG or EG contamination compared to other drug components.

EXHIBIT 6

WARNING LETTER

Sambrosa Care Inc.

MARCS-CMS 673321 — JANUARY 24, 2024

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Product:

Drugs

Recipient:

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Issuing Office:

Center for Drug Evaluation and Research | CDER
United States

United States

WARNING LETTER

January 24, 2024

Re: FEI #3018095920

Dear Dr. de Wit:

This letter concerns your firm's distribution of the over-the-counter (OTC) combination antihistamine and nighttime sleep-aid drug product "Sambrosa sweet dreams Night Syrup." "Sambrosa sweet dreams Night Syrup" is an unapproved new drug introduced or delivered for introduction into interstate commerce in violation of section 505(a) of the Federal Food Drug & Cosmetic Act (FD&C Act), 21 U.S.C. 355(a), and is also misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). Introduction or delivery for introduction of such products into interstate commerce is prohibited under sections 301(d) and (a) of the FD&C Act, 21 U.S.C. 331(d) and (a). These violations are described in more detail below.

Unapproved New Drug and Misbranding Violations

"Sambrosa sweet dreams Night Syrup" is a drug as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)

(B), because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because it is intended to affect the structure or any function of the body. Specifically, this product is intended for use as a combination antihistamine and nighttime sleep-aid drug product.

Examples of the claims from the products' labeling, including your firm's product website https://www.sambrosa.com/ where the product is available for purchase, that provide evidence of the intended uses (as defined in 21 CFR 201.128) of the product as a drug include, but are not limited to, the following:

"**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itching of the nose or throat" [from your product label]

"Looking for the best OTC sleeping syrup? Sambrosa Sweet Dreams is specially formulated to promote a good night's rest. It combines the naturally-based ingredients of honey and 7 organic herbs with a small dose of doxylamine, which will help achieve both nighttime allergy relief and the quality rest you need..." [from your product website at https://www.sambrosa.com/product/sambrosa-300-ml/]

"Our Ingredients…Honey is quite amazing in its taste and in its countless health benefits; it is an antibacterial, anti-inflammatory, and contains antioxidants…California poppy extract is considered to be a nervine, which means that it may work to maintain a normal nervous system function, and it's often used as a sedative to induce sleep…Hawthorn species are shrubs or small trees. Hawthorn was already a staple in herbal medicine, said to strengthen cardiovascular function and stimulate blood circulation…Hops adds a bitter flavor and is a stability agent. In herbal medicine this plant is known to benefit conditions such as anxiety and insomnia, and it contains phyto-estrogen which can relieve the symptoms of menopause… Mistletoe is famous for adding a romantic touch to Christmas, but there's much more to it than just that—it's used in herbal medicine for headaches, dizziness, energy loss, irritability and exhaustion…Passion Flower Is a climbing vine with beautiful flowers, and is recommended as a sedative and antispasmodic agent. It's used for anxiety, insomnia and restlessness…Oats are very nutritious—they are a great source of dietary fiber, minerals, important vitamins and antioxidants. In herbal medicine, oats extract is used for anxiety and stress, and for its antimicrobial effects and sedative, soothing effects…White Chestnut is used as a reliever of repetitive thoughts and worrying." [from your product website at https://www.sambrosa.com/shop/]

Unapproved New Drug Violations

Based on the above labeling claims, "Sambrosa sweet dreams Night Syrup" is intended for use as a combination antihistamine and nighttime sleep-aid drug product. As described below, your drug product is an unapproved new drug marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d).

A drug product is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), if it is not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in its labeling; and in general, a new drug may not be introduced or delivered for introduction into interstate commerce without an approved application from FDA in effect, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless it is lawfully marketed under section 505G of the FD&C Act. No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for your drug product identified above.

Your "Sambrosa sweet dreams Night Syrup" is subject to section 505G of the FD&C Act, 21 U.S.C. 355h, which governs nonprescription drugs marketed without an approved application. Under section 505G of the FD&C Act, certain nonprescription drugs marketed without an approved application —commonly referred to as "OTC monograph drugs"— may be legally marketed if they meet applicable requirements. With respect to OTC antihistamine drug products, such products are deemed to be generally recognized as safe and effective (GRASE) and not new drugs if, among other things, they conform to the conditions of use set forth in the final administrative order, Over-the-Counter Monograph M012: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use (hereafter M012).[1]

However, your “Sambrosa sweet dreams Night Syrup” does not conform to conditions specified in M012.[2]

Specifically, your product contains 9.78 mg of doxylamine succinate per each 3 mL dose. The product's directions for use for “adults and children 6 years of age and over,” which read “take 3 mL every 4 to 6 hours. Do not exceed 35 mL in 24 hours." may result in a daily dose of 114.1 mg of doxylamine succinate, which is 76.6 mg of doxylamine succinate more than the daily maximum dose of 37.5 mg that is allowed for children between 6 and 12 years of age and 39.1 mg above the 75 mg daily maximum dose that is allowed for adults and children above 12 years of age under M012.72(d)(8). For your information, M012.72(d)(8) states “Adults and children 12 years of age and over: oral dosage is 7.5 to 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 3.75 to 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours, or as directed by a doctor.”

Additionally, your product is labeled to contain the combination of active ingredients that include honey, California poppy, hawthorn, hops, mistletoe, passion flower, oats, and white chestnut. However, none of these ingredients in combination or as sole ingredients are acceptable or recognized as an active ingredient in M012. Although the immediate product label does not specifically list these ingredients as active ingredients, the claims on the product website as listed above, demonstrate that they are each an “active ingredient” as defined in 21 CFR 201.66(b)(2) because they are intended to furnish pharmacological activity.[3] Furthermore, these intended use claims go beyond the general intended uses and do not comply with the applicable final order.[4]

Therefore, your “Sambrosa sweet dreams Night Syrup” drug product does not comply with the cold, cough monograph described above, and it is not otherwise marketed in accordance with section 505G. Thus, this product is a new drug within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p). Accordingly, this product is an unapproved new drug marketed in violation of section 505(a) of the FD&C Act, 21 U.S.C 355(a). Introduction or delivery for introduction of such a product into interstate commerce is prohibited under section and 301(d) of the FD&C Act, 21 U.S.C. 331(d).

Misbranding Violations

“Sambrosa sweet dreams Night Syrup” is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because it is a nonprescription drug subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but does not comply with the requirements for marketing under that section and is not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance by email to FDAAdvisory@fda.hhs.gov and include your firm name in the subject line of your email.

Sincerely,
/S/

CAPT Tina Smith
Office Director
Office of Unapproved Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

cc:

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1 Section 505G(a)(1) of the FD&C Act specifies criteria under which certain nonprescription drugs without an approved application are deemed GRASE and not "new drugs", notably conformance with conditions detailed in applicable OTC monograph documents issued by FDA under 21 C.F.R. part 330, prior to enactment of the CARES Act. In the case of OTC antihistamine drug products, relevant documents were deemed under section 505G to be a final administrative order, Over-the-Counter (OTC) Monograph M012: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use. (See Order ID OTC000026, available at FDA's website OTC Monographs@FDA, https://dps.fda.gov/omuf.)

2 We note that your "Sambrosa sweet dreams Night Syrup" also appears to be indicated for use as a nighttime sleep aid. OTC nighttime sleep aid drug products are deemed to be GRASE and not new drugs if, among other things, they conform to the conditions of use set forth in the final administrative order, Over-the-Counter Monograph M010: Nighttime Sleep Aid Drug Products for Over the Counter Human Use (M010). Your product does not conform to the conditions set forth in this monograph because, among other things, "Sambrosa sweet dreams Night Syrup" is formulated with the active ingredient, doxylamine succinate, which is not permitted under M010 for use as a nighttime sleep-aid. Furthermore, neither M012 nor M010 include provisions allowing for a combination antihistamine and nighttime sleep-aid product.

3 Under 21 CFR 201.66(b), an active ingredient is a component of a drug intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

4 FDA is not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that "Sambrosa sweet dreams Night Syrup" is GRASE for use under the conditions prescribed, recommended, or suggested in its labeling.

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No

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