

Chenland's Branded Ingredient

EuBone[®] has Received Confirmation of Filed NDI

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dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. § 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

Your notification will be kept confidential for 90 days after the filing date of September 30, 2022. After the 90-day date, the notification will be placed on public display at www.accessdata.fda.gov, as a new dietary ingredient notification report number 1262. Prior to that date, you may wish to identify in writing specifically what information you believe is trade secret.



December 1, 2022

Li Li
Product Manager
Chenland Nutritionals, Inc.
3 Park Plaza, Suite 410
Irvine, California 92614

Dear Li Li,

This letter is to inform you that the notification that you submitted, pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)), was received and filed by the Food and Drug Administration on September 30, 2022.

Additional information was received on October 18, 2022. Your notification concerns a new dietary ingredient (NDI) you call "EuBone", consisting of three traditional Chinese herbs: 1) Eucommia (Eucommia ulmoides Oliv.), 2) Drynaria (Drynaria fortunei [Kunze ex Mett.] J.Sm.), and 3) Chinese dodder (Cuscuta chinensis Lam.) that you intend to market as a bulk dietary ingredient in the dietary supplement under the trade name, "EuBone®".

According to your amended notification, the conditions of use are "Anytime". The serving size is "Once a day, 750 mg each time for 180 days". The maximum serving size of the NDI in the dietary supplement is "750 mg per serving". The target population description is "Adults only. If you are pregnant, nursing, taking medication or have a medical condition, please consult your healthcare professional before use".

Under 21 U.S.C. § 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. § 350b(a)(3), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. § 342(a)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification. Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new

U.S. Food and Drug Administration
8001 Campus Drive
College Park, MD 20740
www.fda.gov

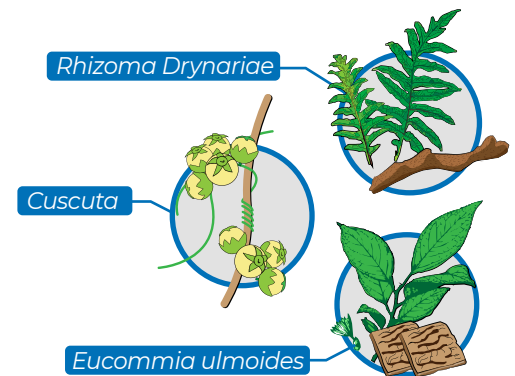


After two months of strict review by the US FDA, on December 1, 2022, Chenland's patented branded ingredient EuBone® received official confirmation that its NDI notification had been received (NDI number:



1262). This milestone not only represents the dedication of Chenland's scientific team to ensuring the safety and quality of EuBone®, but also shows that branded ingredients originating from traditional Chinese medicine have successfully gone abroad and been recognized internationally. International recognition of EuBone blazes a new path for Chinese branded ingredients. Both Chinese dietary supplements and health food products were poorly represented internationally. EuBone's foray into international markets has important practical significance and has created precedence for TCM (Traditional Chinese Medicine) products to enter international markets.

The patented branded ingredient EuBone® is composed of three classic herbs: *Eucommia ulmoides*, *Rhizoma Drynariae* and *Cuscuta*. It is a purely natural plant formula launched by Chenland to help guard estrogen levels and bone health in healthy individuals. EuBone® is based on a traditional Chinese medicine formula and has been verified by a number of experts in traditional Chinese medicine, nutrition, and health care. In addition to its historical substantiation and clinical research, EuBone's formulation has been analyzed by network pharmacology.



Unlike many current products that support bone and hormone health, EuBone® is an entirely plant-based ingredient with excellent tolerance and safety, which was shown through many preclinical and clinical studies to provide support to healthy hormone and bone systems. At the same time, it achieves multiple health guarantees to enhance bone density and bone strength.

In addition, EuBone® has filed 15 FDA structure/ function claims in support of bone health; additionally, 2 peer-reviewed SCI papers have been published, demonstrating that EuBone has a sufficiently high level of safety and efficacy.



"Based on biotechnology, benefiting human health." It is Chenland's desire to enhance the core competitiveness of enterprise through technological innovation. In the future, Chenland plans to increase investment in scientific research, unswervingly follow the road of scientific research, innovation, and development; and continue to make contributions to human health.



www.chenland.com (949) 308-2270
(949) 308-2276 info@chenland.com
3 Park Plaza, Suite 0410 Irvine, CA 92614, USA



Enriching Quality of Life

Chenland Nutritionals, Inc. is a leading supplier of natural branded ingredients. Our global headquarter is in Irvine, California. We select only globally certified GAP herbs and marine organisms to ensure our ingredients promote safety, quality, and sustainability. We specialize in TCM-based brand ingredients scientifically backed through in-vitro and in-vivo testing, alongside preclinical and clinical trials. We are committed to providing our customers with innovative solutions to health problems and meeting the world's growing natural nutritional needs.