ULLMAN, SHAPIRO & ULLMAN, LLP
COUNSELORS AT LAW
299 BROADWAY, SUITE 1700
NEW YORK, NY 10007
TEL. (212) 571-0068
FAX. (212) 571-9424
www.usulaw.com
usulaw@usulaw.com





June 25, 2009

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

**Re: Citizen Petition of OVOS Natural Health Inc. Seeking Promulgation of a Regulation Pursuant to §201(ff)(3)(B)(ii) of the Federal Food Drug and Cosmetic Act, or Alternatively Promulgation of a Regulation Pursuant to §301(ll)(2) of the Act**

Dear Sir or Madam:

The undersigned submits this citizen petition on behalf of OVOS Natural Health, Inc.,[1] ("OVOS") requesting the promulgation of a regulation (or other suitable action) permitting the marketing of a New Dietary Ingredient[2] for use in dietary supplements pursuant to §201(ff)(3)(B)(ii) of the Federal Food Drug and Cosmetic Act ("FDCA"). In the event that FDA has not yet determined the manner in which it will implement §301(ll) of the FDCA or if FDA determines that

[1] 275, Boulevard Armand-Frappier, Laval (Québec) H7V 4A7 CANADA. OVOS is a wholly owned subsidiary of BELLUS Health, Inc., formerly known as Neurochem, Inc. ("BELLUS"), also of the same address. OVOS was incorporated in Canada on February 28, 2008, as part of a corporate strategy to more accurately reflect BELLUS' expanded business strategy and core programs that encompass both therapeutics and branded nutraceutical products. OVOS was created for the purposes of carrying on the BELLUS group's new nutraceutical business, in distinction to the group's continuing work on the development and commercialization of pharmaceutical products.

[2] Simultaneously with the filing of this Citizen Petition, OVOS submitted a 75-day premarket notification pursuant to FDCA §413(a)(2) on June 25, 2009, advising the FDA of its intent to market homotaurine as a new dietary ingredient and the basis for its conclusion that there is a reasonable expectation of safety when used in accordance with the labeling thereof. This submission is incorporated herein by reference.

FDA-2009-P-0298-0001

CP

§301(ll) supersedes §201(ff)(3)(B)(ii), OVOS is alternatively requesting the promulgation of a regulation thereunder. The dietary ingredient which is the subject of this petition is homotaurine, an amino acid which was previously authorized for study pursuant to an Investigational New Drug Application ("IND") held by BELLUS, the direct parent of OVOS, holding 100% of its shares.

## A. Actions Requested

OVOS respectfully requests that the Secretary:

1. promulgate a regulation pursuant to FDCA §201(ff)(3)(B)(ii) acknowledging that the use of OVOS' homotaurine dietary ingredient in dietary supplements is legal under the FDCA; or

2. promulgate a regulation pursuant to FDCA §301(ll)(2) acknowledging that FDA approves of the use of OVOS' homotaurine as a dietary ingredient for use in dietary supplements.

## B. Statement of Grounds

### 1. Background

On August 23, 2002, BELLUS, the parent Company of OVOS, submitted an IND (No. 63,879) with the FDA for the study of homotaurine, an amino acid found in certain species of seaweed (kelp), for potential applications in the treatment of patients suffering from Alzheimer's disease. On May 22, 2008, BELLUS chose to voluntarily discontinue the pursuit of the IND following the completion of a 78-week Phase III North American study of homotaurine in 1,052 mild-to-moderate Alzheimer's disease patients 50 years and older.[3] While the results of that trial indicated that homotaurine was safe, issues relating to the ability to achieve statistically significant results acceptable to FDA for the primary efficacy study endpoints led the company to conclude that it was no longer economically feasible to complete the drug approval process. Nevertheless, post hoc analysis of the data collected demonstrated that homotaurine preserved hippocampus volume by 68% vs. placebo after 18 months and improved cognitive performance by 33% vs. placebo after one year.

[3] Letter of May 28, 2008, from Elizabeth Wishart, Director of Regulatory Affairs, Bellus Health, Inc., to Dr. Russell G. Katz, Director, Division of Neurology Products, CDER, FDA.

Based upon the potential health benefits relating to homotaurine's ability to preserve the volume of the hippocampus and to preserve memory functions, BELLUS, through its incorporation of OVOS, has elected to pursue an alternate pathway to market for homotaurine as an ingredient for use in dietary supplements and created its Natural Product division OVOS. BELLUS is the former holder of the IND and the owner of all relevant intellectual property associated with homotaurine, and OVOS was created specifically for the purposes of commercializing homotaurine as a dietary supplement. As such, FDA should recognize that the provisions of both § 201(ff) and § 301(ll) of the FDCA are designed to permit BELLUS, acting through its subsidiary, OVOS, and other similarly situated entities with a pathway to market for substances that, but for the existence of the IND, could otherwise legally be marketed for sale as an ingredient in dietary supplements.

The actions that OVOS requests are consistent with the intent and purposes of both sections 201(ff) and 301(ll) of the FDCA.

**2. FDA should promulgate a regulation pursuant to FDCA § 201(ff)(3)(B)(ii) acknowledging that the use of OVOS' homotaurine dietary ingredient in dietary supplements is legal under the FDCA**

§201(ff)(3)(B)(ii) provides, in pertinent part, that a substance cannot be legally marketed as a dietary supplement if it is

> an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Thus, the plain language of § 201(ff) indicates that this portion of the FDCA serves the public interest by protecting the incentive for pharmaceutical companies seeking to develop new ingredients with significant health benefits to conduct such investigations pursuant to an IND without concern that others will be able to market the identical substance as a dietary supplement. At the same

time, the investment that is made in research under an IND is further protected by providing an alternative pathway to market through the promulgation of a regulation permitting the marketing of the substance in question.

As a wholly owned subsidiary of the former holder of the IND for homotaurine and the owner of relevant intellectual property relating to the potential use of homotaurine (patents, trademarks, research, etc.) as a dietary supplement, and having been created specifically for the purposes of carrying on the BELLUS Health Group's new nutraceutical business, OVOS is precisely the type of company that § 201(ff)(3)(B)(ii) was written to protect. OVOS has submitted a premarket notification to FDA pursuant to FDCA § 413(a)(2) demonstrating a reasonable expectation of safety for homotaurine. Upon completion of the FDA's review of this submission, there can be no rational basis for failing to authorize OVOS' marketing of homotaurine as a dietary supplement.

**3. Alternatively FDA should promulgate a regulation pursuant to FDCA § 301(ll)(2) acknowledging that FDA approves of the use of OVOS' homotaurine as a dietary ingredient for use in dietary supplements**

§301(ll) was recently incorporated in the FDCA as part of the Food and Drug Administration Amendments Act of 2007. In pertinent part, it prohibits

> the introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505 [21 USC § 355], a biological product licensed under section 351 of the Public Health Service Act [42 USC § 262], or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public unless –
>
> *****
>
> (2) The Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food

In the event that at the time of the submission of this Petition, FDA has not yet determined the manner in which it will implement § 301(ll) of the FDCA or has

determined that § 301(ll) supersedes § 201(ff)(3)(B)(ii), OVOS is alternatively requesting the promulgation of a regulation thereunder.

As previously noted, OVOS has submitted a 75-day premarket notification to FDA pursuant to FDCA § 413(a)(2) and has incorporated the data contained therein by reference. That submission includes a report prepared by the Life Science Research Office ("LSRO") indicating that it has reviewed all data relevant to the safety assessment of OVOS' homotaurine and that it concurs in the conclusion that there is a reasonable expectation of safety for this ingredient when used as a dietary supplement. Based upon the data presented by OVOS in its 413(a)(2) submission as supported by LSRO's opinion, there can be no rational basis for refusing to approve the marketing of homotaurine as an ingredient for use in dietary supplements by OVOS.

## C. Environmental Impact

This petition qualifies under 21 C.F.R. § 25.30 for a categorical exemption from the need to prepare an environmental impact statement.

## D. Economic Impact

OVOS respectfully submits that granting its petition for the promulgation of a regulation permitting the marketing of homotaurine as an ingredient for use in dietary supplements will have a broadly positive economic impact.

1. There will be no cost increases to industry, government or consumers. Rather, OVOS believes that the introduction of homotaurine as an ingredient for use in dietary supplements has the potential to result in significant benefit to consumers by providing a unique new entrant into the cognitive support dietary supplement category that is backed by a significant body of scientific evidence. OVOS possesses substantiation to support structure/function claims that its patented homotaurine:

   a) Protects the brain structure associated with memory and learning;[4]

   b) Preserves memory;[5]

[4] Post-hoc analysis of a 78-week Phase III North American study of tramiprosate (homotaurine) in 1,052 mild-to-moderate Alzheimer's disease patients 50 years and older.
[5] *Id.*

c) Sustains brain cell health;[6]

d) Maintains verbal skills and comprehension ability;[7] and

e) Supports planning and execution skills.[8]

In addition, OVOS possesses substantiation demonstrating that in clinical trials its patented homotaurine:

a) Preserved hippocampus volume by 68% vs. placebo[9] at 18 months; and

b) Improved cognitive performance by 33% vs. placebo at 12 months.[10]

2. Action by FDA permitting OVOS to market homotaurine as an ingredient for use in dietary supplements will have no negative impact on issues relating to the productivity of wage earners, businesses or government.

3. Granting of OVOS' petition will have a positive effect on competition to the extent that it authorizes the entry into the market of an additional ingredient into the brain health/cognitive support category of dietary supplements with a unique mechanism of action and whose efficacy is supported with well documented trials.

4. This petition has no impact on suppliers of important materials, products or services.

5. Granting OVOS' petition would have a positive impact on employment, both direct and indirect. At the present time, OVOS' sister company, OVOS Natural Health US Limited[11], which is based in Salt Lake City, Utah, has a single employee. Upon FDA action authorizing the marketing of homotaurine by OVOS, the company anticipates expanding

---

[6] Gervais, F. *et al.* Targeting soluble Aβ peptide with Tramiprosate for the treatment of brain amyloidosis. *Neurobiology of Aging* 2007; (28):536-547.

[7] Post-hoc analysis of a 78-week Phase III North American study of tramiprosate (homotaurine) in 1,052 mild-to-moderate Alzheimer's disease patients 50 years and older.

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] 2150 South 1300 East, Suite 500, Salt Lake City, Utah 84106.

its US operations to at least 2 to 4 employees in the short term. In addition, OVOS will indirectly support employment in Utah and elsewhere in the United States through its use of third party providers such as printers (for labels, labeling, and marketing material), advertising/media placement firms, and professional advisors (regulatory and accounting experts).

6. This petition has no impact on energy supply or demand.

**E. Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Marc S. Ullman
Ullman, Shapiro & Ullman, LLP
299 Broadway, Suite 1700
New York, New York 10007

Counsel for:

OVOS Natural Health Inc.
275, Boulevard Armand-Frappier,
Laval (Québec) H7V 4A7
CANADA

OVOS is a wholly owned subsidiary of BELLUS Health Inc.

BELLUS Health Inc.
275, Boulevard Armand-Frappier,
Laval (Québec) H7V 4A7
CANADA

From: Origin ID: FIDA (212) 571-0068
Linda Dougherty
Ullman, Shapiro & Ullman, LLP
299 Broadway, Suite 1700

**New York, NY 10007**

FedEx Express

J0920000152823

Ship Date: 25JUN09
ActWgt: 1.0 LB
CAD: 5127758/INET9060
Account#: S *********

Delivery Address Bar Code

SHIP TO: (301) 827-6860 **BILL SENDER**

**Division of Dockets Management**
**FDA (HFA-305)**
**5630 FISHERS LN RM 1061**

**ROCKVILLE, MD 20857**

Ref # Ovos-CP
Invoice #
PO #
Dept #

TRK# 0201 7977 1323 0146

**FRI - 26JUN** **A2**
**STANDARD OVERNIGHT**
**ASR**

**ZD OBTA**

20857
**MD-US**
**IAD**

**After printing this label**:
1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning**: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com.FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery,misdelivery,or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim.Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic valueof the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental,consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss.Maximum for items of extraordinary value is $500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.