



CENTER FOR  
Science IN THE  
Public Interest

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August 20, 2007

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FDA Center for Drug Evaluation and Research  
Office of Compliance  
MM2  
Room 323  
11919 Rockville Pike MD 20852

Robert E. Brackett, Ph.D.  
Director, FDA Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
College Park, Maryland 20740

Mary K. Engle  
Associate Director  
Division of Advertising Practices  
Federal Trade Commission  
600 Pennsylvania Avenue, N.W.,  
Washington, D.C. 20580

Dear Sir or Madam:

We would like to alert you to a dietary supplement that appears to be deceptively labeled and advertised and to contain a drug approved for sale only by prescription. The product has been called Encore Tabs and Zencore Tabs and is claimed to be a "powerful sexual performance supplement for men."

This dietary supplement containing a prescription drug is "adulterated" under sections 402 (f) and (g), 403 (a), 403 (s), and 503 of the Federal Food Drug and Cosmetic Act, 21 USC Sec. 342 (f),(g). And its advertising appears to violate section 5 of the Federal Trade Commission Act, 15 USC Sec. 45.

On June 25, 2007, Health Canada warned Canadian consumers not to use "Encore Tabs," manufactured by Bodee, LLC, of Los Angeles, California, because it contained an undeclared pharmaceutical ingredient similar to the approved erectile dysfunction drug tadalafil (brand name: Cialis).<sup>1</sup> "The use of Encore Tabs for Men could pose serious health risks, especially for patients with existing medical conditions such as heart problems, those taking heart medication, or those at risk of stroke," the agency warned.

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<sup>1</sup> [http://hc-sc.gc.ca/ahc-asc/media/advisories-avis/2007/2007\\_77\\_e.html](http://hc-sc.gc.ca/ahc-asc/media/advisories-avis/2007/2007_77_e.html) (accessed August 17, 2007)

According to Health Canada, the manufacturer no longer makes “Encore Tabs” and has replaced it with “Zencore Tabs.”<sup>2</sup> The ingredients in the two products are identical.

On July 20, 2007, less than a month after its warning about Encore Tabs, Health Canada advised Canadians not to use “Zencore Tabs,” because it contains the same undeclared pharmaceutical ingredient similar to tadalafil.<sup>3</sup> “The use of Zencore Tabs for Men could pose serious health risks, especially for patients with existing medical conditions such as heart problems, those taking heart medication, or those at risk of stroke,” the agency again warned.

“Zencore Tabs” consists of the amino acid arginine and a blend of 20 herbs that the company’s website claims will “boost your sex drive, energy, and sexual stamina” and has “no adverse side effects.”<sup>4</sup> Newspaper ads call it “the most powerful sexual performance supplement for men.”<sup>5</sup> (See Attachments 1 and 2.) The product’s label declares that “Zencore Tabs are an all-natural herbal supplement...Zencore Tabs contain a scientifically researched combination of powerful natural herbs that produce long lasting, hard erections and boost sexual stamina and energy. Potent and effective, Zencore Tabs have no adverse effects, and it works fast.” (See Attachments 3 and 4.)

An identical product with the same formulation of arginine and 20 herbs is marketed by Vitogen, Inc., of Palo Alto, California, as Axcil, “a scientifically formulated, breakthrough dietary supplement containing a proprietary standardized botanical extract that acts synergistically to promote erectile function and sexual desire in men.”<sup>6</sup>

The Zencore Tabs website claims, as evidence of the product’s efficacy, that “Zencore Tabs has conducted a randomized, double-blind, placebo-controlled clinical study led by a board-certified urologist on efficacy and safety of Zencore Tabs™ (GL49).”<sup>7</sup> The marketers of Axcil cite the same unpublished study as evidence for their product’s claims, as well.<sup>8</sup>

Although this study tested the effect of GL49 only on men suffering erectile dysfunction, the two companies do not limit their label and advertising claims to men with that condition.

The founder and president of Bodee, LLC, David Pourmand, told the publication AVN Novelty Business this spring that, “We currently advertise Zencore Tabs on the radio and newspapers nationwide. We plan to soon be on television nationwide this summer.”<sup>9</sup> Ads for Zencore Tabs are published frequently in the Washington Post and USA Today.

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<sup>2</sup> Email from Health Canada, August 2, 2007.

<sup>3</sup> [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2007/2007\\_90\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2007/2007_90_e.html) (accessed August 17, 2007)

<sup>4</sup> <http://www.zencoretabs.com/default.asp> (accessed August 17, 2007)

<sup>5</sup> Washington Post August 16, 2007, page E5; USA Today August 16, 2007, page 10C.

<sup>6</sup> <http://www.axcil.com/Axcil.htm> (accessed August 17, 2007)

<sup>7</sup> <http://www.zencoretabs.com/ClinicalTrials.asp> (accessed August 17, 2007)

<sup>8</sup> <http://www.axcil.com/ClinicalTrials.htm> (accessed August 17, 2007)

<sup>9</sup> <http://www.nxtbook.com/syg/AVNANB/May2007/index.php?startpage=12> (accessed August 17, 2007)

The marketing of Zencore Tabs appears to violate laws and regulations prohibiting the deceptive labeling and advertising of dietary supplements and the marketing of prescription drugs in non-prescription products. We request that the FDA, in collaboration with the Federal Trade Commission:

- (1) immediately analyze the composition of Zencore Tabs and the Axcil supplement and, if either contains an unapproved prescription drug, order Bodee, LLC, and/or Vitogen, Inc., to implement an immediate recall of the products;
- (2) order Bodee, LLC, and Vitogen, Inc., not to sell or advertise Zencore Tabs, Axcil, or any similar product with a different name, until the companies can demonstrate that their products are free of adulteration and do not contain a drug approved only for sale by prescription;
- (3) prohibit Bodee, LLC, and Vitogen, Inc., from making claims of benefits for Zencore Tabs and Axcil, respectively, until the companies can demonstrate that such claims are based on reliable clinical tests of products that do not contain a prescription drug and in men who do not suffer from ED.

Please notify us of any actions that you take.

Sincerely,



David Schardt  
Senior Nutritionist

cc: Andrew C. von Eschenbach, M.D., Barbara Schneeman, Ph.D., FDA Dockets Management

Attachment 1: advertisement in Washington Post, August 16, 2007

Attachment 2: advertisement in USA Today, August 16, 2007

Attachment 3: label from package of Zencore Tabs

Attachment 4: label from package of Zencore Tabs

# FREE SAMPLE!



## Zencore<sup>®</sup> Tabs

### Tired of Sex Pills That Don't Work?

**Experience the Ultimate  
All-Natural Sexual Enhancement  
In as little as 45 minutes... Guaranteed!**

#### **Introducing Zencore Tabs: The most Powerful Sexual Performance Supplement for Men**

With Zencore Tabs, you can experience the ultimate sexual performance and take your partner to new levels of pleasure. Zencore's proprietary blend of all-natural herbs and ingredients produce maximum sexual performance results the first time and every time! Without side effects.

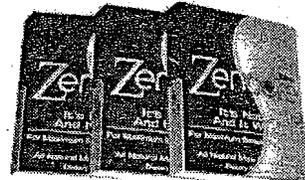
#### **Zencore Works Fast, The First Time and Every time**

Tired of all the other male pills and potions that make outrageous claims, and simply don't work? Zencore works, and works fast! Just take 2 capsules on an empty stomach 45 minutes before sexual activity. And you are ready to go, with hours and hours of sustained, sexual performance!

#### **Call Now for a FREE SAMPLE**

Don't miss out! Call the number below for your Free Sample of Zencore Tabs! Zencore is the one that Works! Satisfaction Guaranteed!

[www.ZencoreTabs.com](http://www.ZencoreTabs.com)

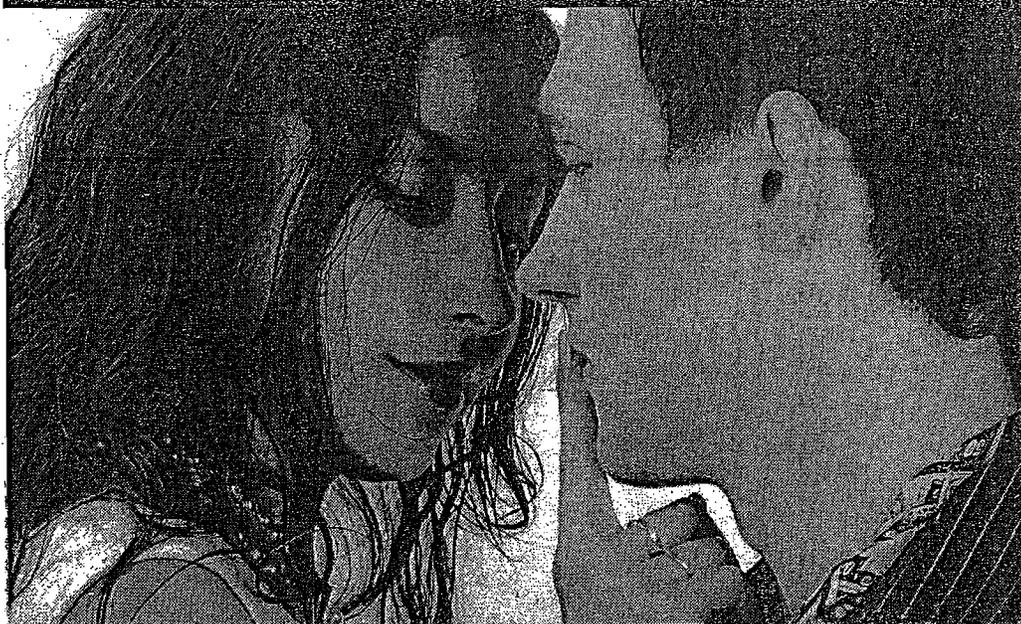


# 800-701-0322

Attachment 1: advertisement in Washington Post  
August 16, 2007

Washington Post 16 Aug 07 E5

# FREE SAMPLE!



## Zencore<sup>™</sup> Tabs

### Tired of Sex Pills That Don't Work?

**Experience the Ultimate  
All-Natural Sexual Enhancement  
In as little as 45 minutes... Guaranteed!**

#### **Introducing Zencore Tabs: The most Powerful Sexual Performance Supplement for Men**

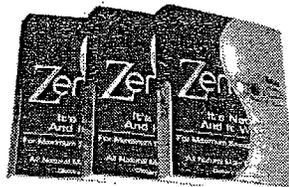
With Zencore Tabs, you can experience the ultimate sexual performance and take your partner to new levels of pleasure. Zencore's proprietary blend of all-natural herbs and ingredients produce maximum sexual performance results the first time and every time! Without side effects.

#### **Zencore Works Fast, The First Time and Every time**

Tired of all the other male pills and potions that make outrageous claims, and simply don't work? Zencore works, and works fast! Just take 2 capsules on an empty stomach 45 minutes before sexual activity. And you are ready to go, with hours and hours of sustained, sexual performance!

#### **Call Now for a FREE SAMPLE**

Don't miss out! Call the number below for your Free Sample of Zencore Tabs! Zencore is the one that Works! Satisfaction Guaranteed!



# 800-591-1896

Attachment 2: advertisement in USA Today  
August 16, 2007

USA Today 16 August 07 IDC

Attachment 3: label from package of Zencore Tabs

**Directions:**

For Adults: Take 2 capsules at least 45 minutes prior to sexual activity on an empty stomach. Zencore Tabs provides up to 24 hours of performance enhancement.

Distributed by Bodee LLC  
 Los Angeles, CA 90067  
[www.zencoretabs.com](http://www.zencoretabs.com)

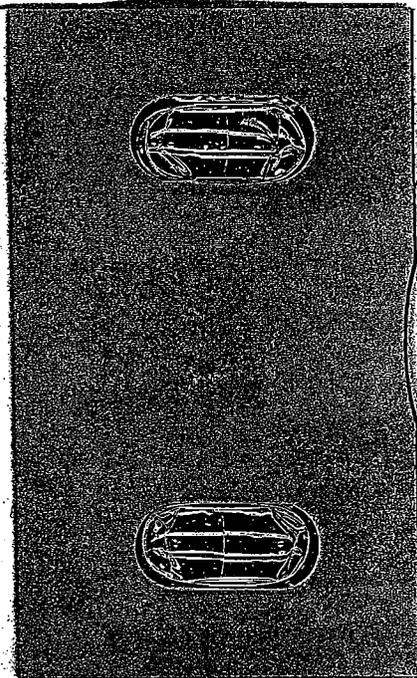
\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

**Warning:**

Do not exceed 2 capsules per 24 hour period. Do not take this product within 3 hours of taking any other medications. This product is not intended for use if taking prescription medications and those with a serious medical condition or pregnant or lactating women. Consult your physician before use.

This product is not intended for persons under the age of 18. This product is not intended for women who are pregnant or nursing a baby.

KEEP OUT OF REACH OF CHILDREN.



**Supplements**

Serving size 2 capsules:

L-Arginine 160 mg

Proprietary Blend 840 mg\*

- |                     |                  |
|---------------------|------------------|
| Tribulus            | Dong Quai        |
| Guava               | Indian Woodapple |
| Osage Broomrape     | Astragalus       |
| Cordyceps           | Rehmannia        |
| Maca                | Safflower        |
| Fo-ti               | Tenchi           |
| Epimedium           | Reishi           |
| Ginseng             | Eucommia         |
| Chinese Dodder Seed | Ginger           |
| Wild Yam            |                  |
| Morinda             |                  |

\* Daily Value Not Established

Other Ingredients: Gelatin, Silicon dioxide, Magnesium stearate, Maltodextrin.

Zencore Tabs are an all natural, potent supplement clinically tested for enhanced sexual performance. Zencore Tabs contain scientifically researched combination of powerful natural herbs that produce long lasting hard erections and boost sexual stamina and energy. Zencore Tabs have no adverse side effects. They are 100% safe for sexual intercourse and last up to 24 hours.

Zencore

Zencore  
 Tabs

It's Natural  
 And It Works

For Maximum Sexual Performance

All Natural Male Enhancement  
 Dietary Supplement

Lot code: ZTS100  
 Exp. date: 04/10



Attachment 4: label from package of Zencore Tabs

