

November 16, 2001

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Facsimile
Certified Mail

Dr. Marilyn A. Coleman
President
OvImmune, Inc.
16475 Miller Road
Richwood, Ohio 43344

Dear Dr. Coleman:

This is in response to your letters of October 19, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that OvImmune, Inc. intends to market several products as dietary supplements that bear the statement "supports the immune system" in their labeling.

As you may know, FDA is under no statutory or other obligation to respond to your letters of October 19, 2001. Failure to respond to a notification submitted pursuant to 21 U.S.C. 343(r)(6) and the corresponding regulation, 21 CFR § 101.93, does not constitute approval of a product or claim, or agreement that the proposed claim is legal. Likewise, failure to respond does not serve as a bar to a subsequent enforcement action. This response is being provided solely as a courtesy to OvImmune, Inc., to inform it of the agency's position that the products it intends to market as dietary supplements are new drugs that may not be marketed without premarket approval from FDA.

Your notification does not provide FDA with enough information to determine whether OvImmune's products meet the statutory definition of a dietary supplement. However, even if the products were to meet the definition of a dietary supplement, they are still subject to regulation as drugs because they meet the definition of a drug. See United States v. Ten Cartons . . . Ener-B Vitamin B-12, 72 F.3d 285, 287 (2d Cir. 1995). 21 U.S.C. 321 (g)(1)(B) states that "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals" are drugs under the Act. These products are drugs because they are intended for use in the treatment, cure, prevention, or mitigation, of disease. The diseases that OvImmune, Inc. intends the products to treat, cure or prevent include candidiasis, candida vaginitis, inflammatory bowel disease, chronic fatigue, fibromyalgia, lupus and chlamydia pneumonia. See attachments A and B.

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Further, your products are new drugs under 21 U.S.C. 321(p) because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for their intended uses. New drugs may not be legally marketed in the United States without an approved new drug application from FDA. See 21 U.S.C. 355(a).

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Enclosure

As described above

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

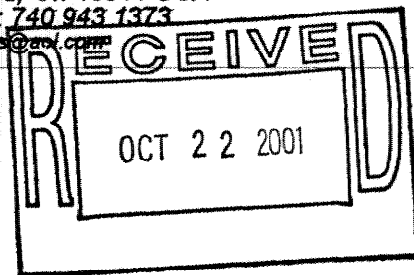
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Cincinnati District Office, Office of Compliance, HFR-MA440

Office of Nutritional Products, Labeling and
Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204



16475 Miller Rd Richwood, Oh 43344 USA
ph 740 943 1371 fax 740 943 1373
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October 19, 2001

RE: Notification of Dietary Supplement Marketing Claim

Dear Sir/Madam:

Pursuant to 21 CFR § 101.93 this is to notify you that OvImmune, Inc. will be marketing a dietary supplement containing the structure/function claim stated below:

1. Name and Address of Distributor:

OvImmune, Inc.
16475 Miller Road
Richwood, OH 43344

2. Text of Statement:

The following statement will be made in marketing the product:

“Supports the immune system.”

3. Name of Dietary Ingredient or Supplement:

The product is dried egg powder with a standardized level of Chlamydia.

4. Name of Dietary Supplement:

Dried Whole Egg Powder with the Special Immune Factor Chiamydia.

5. Certification of Accuracy:

I, Marilyn Coleman, Ph.D., OvImmune, Inc., do hereby certify that the information contained in this notice is complete and accurate and that OvImmune, Inc. has substantiation that the statement to be made is truthful and not misleading.

Sincerely,

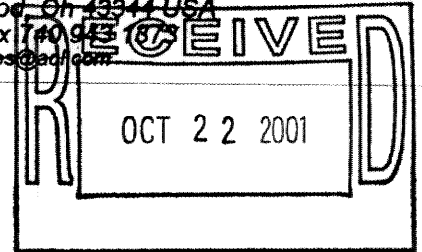
Dr. Marilyn A. Coleman

President

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
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Washington, DC 20204



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October 19, 2001

RE: Notification of Dietary Supplement Marketing Claim

Dear Sir/Madam:

Pursuant to 21 CFR § 101.93 this is to notify you that OvImmune, Inc. will be marketing a dietary supplement containing the structure/function claim stated below:

1. Name and Address of Distributor:

OvImmune, Inc.
16475 Miller Road
Richwood, OH 43344

2. Text of Statement:

The following statement will be made in marketing the product:

“Supports the immune system.”

3. Name of Dietary Ingredient or Supplement:

The product is dried egg powder with a standardized level of Mycoplasma.

4. Name of Dietary Supplement:

Dried Whole Egg Powder with the Special Immune Factor Mycoplasma.

5. Certification of Accuracy:

I, Marilyn Coleman, Ph.D., OvImmune, Inc., do hereby certify that the information contained in this notice is complete and accurate and that OvImmune, Inc. has substantiation that the statement to be made is truthful and not misleading.

Sincerely,

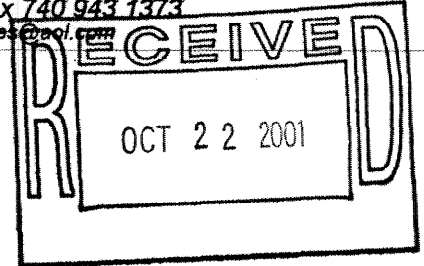
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1. Name and Address of Distributor:

OvImmune, Inc.
16475 Miller Road
Richwood, OH 43344

2. Text of Statement:

The following statement will be made in marketing the product:

“Supports the immune system.”

3. Name of Dietary Ingredient or Supplement:

The product is dried egg powder with a standardized level of Candida.

4. Name of Dietary Supplement:

Dried Whole Egg Powder with the Special Immune Factor Candida.

5. Certification of Accuracy:

I, Marilyn Coleman, Ph.D., OvImmune, Inc., do hereby certify that the information contained in this notice is complete and accurate and that OvImmune, Inc. has substantiation that the statement to be made is truthful and not misleading.

Sincerely,

Dr. Marilyn A. Coleman

President