

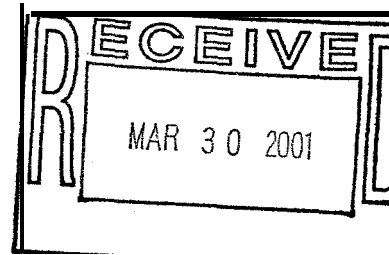
1824 South Robertson Blvd.
Los Angeles, CA 90035-4317
310/204-6936 • 800/726-0886

Fax Numbers
Orders 800/890-8955
General 310/204-2520
Administrative 310/204-5132

3940 01 MAY 10 2001

March 27, 2001

Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-810
200 C Street, S.W.
Washington, DC 20204
202-205-5229



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name of Address of distributor:
Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035
- (2) Text of the statement(s):
Pregnenolone has long been known as a precursor to a variety of compounds, including DHEA. Pregnenolone is derived from cholesterol with dihydroxy-cholesterol as an intermediary metabolite. Pregnenolone is metabolized in two directions: production of DHEA and its metabolites and production of progesterone and its metabolites.
- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:
Pregnenolone
- (4) Name of the dietary supplement(s)
Pregnenolone (10 mg, 100 capsules)
Pregnenolone (50 mg, 100 capsules)
- (5) The following disclaimer appears on the label in bold: 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.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

Siddharth Shastri, CCN

Vice President, Product Development
Licensed Dietitian/Clinical Nutritionist, #002378
(by the University of the State of New York, State Board of Education)

Preg strucfunc

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