

July 8, 1999

VIA AIRBORNE EXPRESS #8410153861
& Regular Mail

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals, HITS-450
200 C. Street S.W.
Washington, District of Columbia 20204

Re: Natrol, Inc.

Dear Sir or Madam:

I am the General Counsel of Natrol, Inc., Chatsworth, California, a manufacturer of dietary supplement products (hereafter "Natrol").

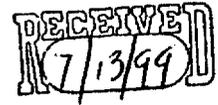
On behalf of Natrol, and pursuant to the requirement of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. 5343 (c) (6), your Agency is hereby notified that Natrol proposes to make statements of "nutritional support", as described in 21 U.S.C. §343(1)(6)(a), for its dietary supplements as follows:

- (1) **Gugulipid:** **Commiphora mukul** has been used for centuries in traditional Ayurvedic medicine (Asiatic Indian plant medicine). Natrol introduces Gugulipid featuring a standardized extract of **guggulsterones**, the active ingredient in the plant. Helps to maintain **healthy** cholesterol levels.
- (2) **ENADA:** As a coenzyme, NADH plays a key role in the energy production of our cells and **neurotransmitter** processes.
- (3) **GoldenSeal:** **GoldenSeal** (*Hydrastis canadensis*) originated in North America and was used for a wide range of ailments. The active ingredients of **GoldenSeal** include a group of alkaloids, **hydrastine** and berberine.
- (4) **CoEnzyme Q-10:** CoEnzyme Q-10 also known as Ubiquinone, is an essential component of our cells which promotes energy production. Numerous studies have shown CoEnzyme Q-10 plays a key role in promoting cardiovascular health.
- (5) **Beta Sitosterol:** Plant **sterols** are a desirable part of a healthy diet to assist in fat and cholesterol metabolism. As our intake of vegetable oils is not usually in appreciable amounts, Beta Sitosterol... a key plant **sterol**... may help supplement the diet.

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U.S. Food and Drug Administration

Re: Natrol, Inc.

July 8, 1999

Page 2 of 2

(6) Omega-3: Increasing research reveals the health-promoting properties of Omega-3 polyunsaturated fatty acids – EPA and DHA in promoting a healthy vascular system.

Please **be** advised that the label of each of the above dietary supplement products includes the statement that “**The** FDA has not evaluated these statements. This product is not intended to diagnose, treat, cure or prevent disease.”

If you have any questions regarding the foregoing, do not hesitate to contact the undersigned at **your** convenience.

Sincerely,

NATROL, INC.



Eve D. Mendoza
General Counsel

EDM/abs
LTR-035

cc: Elliott Balbert
Cheryl Richitt