



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JUL 30 2003

Ms. Deborah Shur Trinker, Esq.  
Senior Vice President Regulatory Affairs  
Rexall, Inc.  
6111 Broken Sound Parkway, N.W.  
Boca Raton, Florida 33487-3613

Dear Ms. Trinker:

This is in response to your letters of June 13, 2003 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 submission states that Rexall, Inc. is making the following claims for the product Vuemax™ Intensive:

“As we age, the chances of developing age-related eye conditions increase.”  
“...based on the Age-Related Eye Disease Study (AREDS)...”  
“...patients who were at high risk for age-related eye conditons...”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, namely, macular degeneration. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written in a cursive style.

Susan J. Walker, M.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

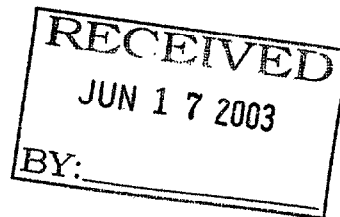
**Copies:**

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, Florida District Office, Office of Compliance, HFR-SE240

# Rexall®



June 13, 2003

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204

Dear Sirs:

Notice is hereby given that Rexall, Inc. ("Rexall") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Rexall brand name bearing the following statement(s) on the label and/or in the labeling:

**Vuemax™ Intensive: AREDS-Based Formula.** What can Vuemax™ Intensive do for you? As we age, the chances of developing age-related eye conditions increase. Vuemax Intensive is an eye care nutritional supplement that has been specifically formulated to help reduce some of the age-related declines in eye health. It's a combination of vitamins and minerals based on *the Age-Related Eye Disease Study (AREDS)*, conducted by the National Eye Institute (NEI). Plus, Vuemax Intensive contains the extra nutrients Lutein and Zeaxanthin. These nutrients are naturally occurring in the eye and provide protection by absorbing and filtering harmful light.

What is AREDS (Age-Related Eye Disease Study)? AREDS is a recently completed 10-year clinical study supported by the NEI (an agency within the Federal Government's National Institutes of Health). This study found that patients who were at high risk for age-related eye conditions benefited significantly when treated with a high potency combination of antioxidant vitamins, zinc and copper.

Why does Vuemax Intensive include Lutein and Zeaxanthin? Commonly found in dark leafy greens like kale and spinach, Lutein and Zeaxanthin are two beneficial carotenoids

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that have been shown to be important for eye health. These two nutrients are found in the retina, macula and lens of the eye. People with diets high in Lutein and Zeaxanthin may have a reduced risk of developing some age-related conditions. It is important to note that the levels of these carotenoids found in Vuemax Intensive generally can only be attained by supplementation and not through diet alone.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Cordially,



Deborah Shur Trinker, Esq.  
Senior Vice President  
Regulatory Affairs

Enclosures