

NUTRITION FOR TWO™, LLC

5742 WEST HAROLD GATTY DRIVE
SALT LAKE CITY, UT 84116
Phone 801-517-7000 Fax 801-517-7003

November 2, 2004

VIA: Certified Mail

NOV 23 2004

Food and Drug Administration
200 C Street S.W.
Washington, DC 20204

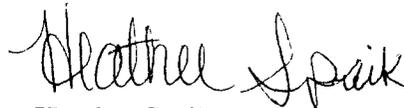
Re: Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93

Dear Sir or Madam:

Enclosed please find the Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93 for the dietary supplement product Vitrel-3™. This notification is on behalf of Nutrition for Two™, LLC.

Please review the information at your earliest convenience. Please contact me with any questions or if there is any further information I can provide regarding this matter.

Sincerely,



Heather Sprik
Legal Assistant

Enclosure

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**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR § 101.93**

This notification is being filed on behalf of Nutrition for Two™, LLC that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5742 W Harold Gatty Dr. Salt Lake City, Utah 84116. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is **Vitrel-3™**.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): "Helps Your Newborn Sleep Longer and Better."
- (Statement 2): "Natural Supplement You Take in the Third Trimester of Your Pregnancy Helps Stabilize Erratic Infant Sleep Patterns After Your Child Is born."
- (Statement 3): "A new government-funded study (by no less than the National Institutes of Health) conducted at the University of Connecticut and recently published in *The American Journal of Clinical Nutrition* found that newborns slept better and longer with fewer late-night interruptions if their mothers consumed adequate amounts of the active compound contain in Vitrel-3™ (from *Nutrition for Two*™) during the last trimester of pregnancy."
- (Statement 4): "Vitrel-3's™ active compound (an all-natural fatty acid derivative) stabilizes a newborn's erratic sleep patterns."
- (Statement 5): "And for mother's who decide to breast feed and maintain adequate levels of this all-natural, isolated nutrient, the benefits are even greater: enhanced neonatal development and more sleep for both mother and baby throughout the first six months of life."

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	Vitre-3™ - 60 Count Box
2	Vitre-3™ - 60 Count Box
3	Vitre-3™ - 60 Count Box
4	Vitre-3™ - 60 Count Box
5	Vitre-3™ - 60 Count Box

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Nutrition for Two™, LLC	both
2	Nutrition for Two™, LLC	both
3	Nutrition for Two™, LLC	both
4	Nutrition for Two™, LLC	both
5	Nutrition for Two™, LLC	both

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of Nutrition for Two™, LLC. I certify that the information presented and contained in this Notification is complete and accurate, and that Nutrition for Two™, LLC has substantiation that each structure-function statement is truthful and not misleading.

Dated this 2 day of November, 2004.

By: 
 Daniel B. Mowrey, Ph.D.
 Consultant for Nutrition for Two™, LLC



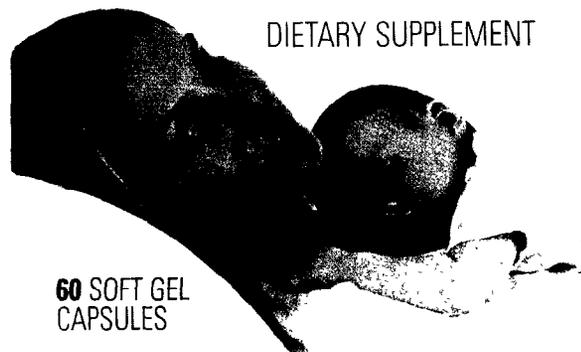
NBG-0076543-0065

VITREL-3™

Special Nutrition For Third Trimester Use

Helps Your Newborn Sleep Longer And Better*
(And That Means You Sleep Better Too!)

Natural Supplement You Take In The Third Trimester Of Your Pregnancy Helps Stabilize Erratic Infant Sleep Patterns After Your Child Is Born*



60 SOFT GEL CAPSULES

DIETARY SUPPLEMENT

Supplement Facts For Vitrel-3™		
Serving Size: 1 Capsule Servings Per Container: 60		
	Amount Per Serving	% Daily Value for Pregnant Women
Calories	5	
Calories from Fat	5	
Total Fat	0.5 g	†
Polyunsaturated Fat	0.5 g	†
Vitamin E	5 IU	17%
Vitamin B6	0.5 mg	23%
Folate	100 mcg	25%
Vitamin B12	0.5 mcg	19%
Magnesium	40 mg	10%
Vitrel-3™	276 mg	
A proprietary blend of the following		
Cervonic Acid		†
Leucine		†
Isoleucine		†
Valine		†
Proline		†
Methionine		†
Glutamine		†
Arginine		†

† Daily value not established

Ingredients: Specially processed polyunsaturated fatty acids, gelatin, glycerin, soybean oil, silicon dioxide, water and titanium dioxide (natural white color)

Note: Contains ingredients derived from marine sources

Nutrition For Two™ products are distributed throughout the USA exclusively by Basic Research®, LLC Salt Lake City, Utah 84116 Made in the U S A

Directions: Take 1 easy-to-swallow capsule twice a day with food. For example, one at breakfast and one at dinner

www.Vitrel3.com

www.NutritionForTwo.com
Call toll-free: 1-800-898-5153

Use only as directed. Store at controlled room temperature 15°-30°C/59°-86°F

*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.

Babies Slept Better And Longer, With Fewer Late-Night Interruptions... If Mom Consumed "Super Nutrient" During Third Trimester

A new government-funded study (by no less than the National Institutes of Health) conducted at the University of Connecticut and recently published in *The American Journal of Clinical Nutrition* found that newborns slept better and longer with fewer late-night interruptions if their mothers consumed adequate amounts of the active compound contained in Vitrel-3™ (from *Nutrition for Two*™) during the last trimester of pregnancy * Vitrel-3's™ active compound (an all-natural fatty acid derivative) stabilizes a newborn's erratic sleep patterns * And for mothers who decide to breast feed and maintain adequate levels of this all-natural, isolated nutrient, the benefits are even greater: enhanced neonatal development and more sleep for both mother and baby throughout the first six months of life *

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