



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JAN 14 2000

7 9 8 1 '00 FEB -8 P1:59

Mr. Tim Thomas  
Vice-President, Marketing  
Immunotec Research Ltd.  
292 Adrien Patenaude  
Vaudreuil-Dorion, Quebec J7V 5V5  
Canada

Dear Mr. Thomas:

This is in response to your letter of January 10, 2000 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 Immunotec Research Ltd. is making the following claim, among others, for the product **Pure Milk Calcium containing XtraCal™**:

“Helps prevent Osteoporosis”

This statement is a claim of a relationship between calcium and osteoporosis. This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

978-0163

LET 329

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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

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett)

f/t:HFS-456:rjm:1/14/00:docname:68805.adv:disc43

Immunotec  
Research Ltd.

Recherche  
Immunotec Ltée.

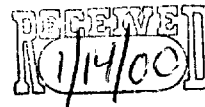
292 Adrien Patenaude Vaudreuil-Dorion (QC) Canada J7V 5V5

Tél.: (450) 424-9992 Fax: (450) 424-9993

Internet: www.immunocal.com

January 10, 2000

68805



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

Sirs:

Per FDA requirements, this is a request for use of specific wording on the labeling for a calcium supplement. Details follow:

Name and address of manufacturer

Immunotec Research Ltd.  
292 Adrien Patenaude  
Vaudreuil-Dorion, Quebec  
J7V 5V5

Text of statement being made

"Helps Build Strong Bones"  
or  
"Helps Prevent Osteoporosis"

Name of the dietary ingredient  
including the Brand Name

Pure Milk Calcium containing XtraCal™  
(see attached)

We await your decision on the use of either of these statements.

Sincerely,

Tim Thomas  
Vice-President, Marketing

/KS

Attach: Nutritional Information  
Label



# AVONMORE WATERFORD



## INGREDIENTS, INC.

523 - 6th Street, Monroe, WI USA 53566 (608) 329-2800 Fax: (608) 329-2828

Customer Service: (800) 336-2183



### Nutritional Information/100g

TOTAL FAT (g)	0.3
SATURATED FAT (g)	<0.3
POLYUNSATURATED FAT (g)	<0.3
MONOUNSATURATED FAT (g)	<0.3
CHOLESTEROL (mg)	15
SODIUM (mg)	600
POTASSIUM (mg)	830
TOTAL CARBOHYDRATE (g)	7
DIETARY FIBER (g)	N/a
LACTOSE (g)	6
PROTEIN (g)	5
VITAMIN A (µg RE)	<5
VITAMIN C (mg)	N/a
CALCIUM (mg)	24,000
MAGNESIUM (mg)	1,200
CHLORIDE (mg)	300
IRON (mg)	0.6
THIAMIN (mg)	N/a
RIBOFLAVIN (mg)	N/a
NIACIN (mg)	N/a

*Front Label  
(U.S.)*

***Real Calcium from Milk™***



Immunotec Research Ltd.

Pure  
**Milk Calcium**

*contains XtraCal™*

250mg Calcium

Dietary Supplement

***Helps Build Strong Bones  
Or  
Helps Prevent Osteoporosis***

***60 Tablets***

(Back Label)

**Contains XtraCal™ Milk Calcium Complex. Real calcium from milk™**

## Supplement Facts

Serving Size 2 tablets  
Servings Per Container 30

	Amount Per Serving	% Daily Value
Milk Calcium Complex (from XtraCal™)	500 mg	†
Vitamin D (as cholecalciferol)	200 IU	50%
† Daily value not established.		

Other ingredients: Acacia Gum, Magnesium Stearate

XtraCal™ and Real calcium from milk™ are  
registered trademarks of Glambia Ingredients.

Immunotec Research Ltd., Montreal, Canada, J7V 5V5

PRODUCT OF CANADA

Regular exercise and a healthy diet that includes enough calcium help teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life. While adequate calcium intake is important, daily intake above 2000 mg offers no added known benefit to bone health.

Suggested Use: Take two tablets one to two times a day, or as directed by your physician.

- No lead      -No Preservatives

**Store at room temperature. Keep out of reach of children. Do not use if imprinted seal under cap is broken or missing.**

Lot No.

Exp. Date