



AUG 01 2007

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Dr. Wulf Dröge
Senior Vice-President, Research
and Development, Immunotec, Inc.
300 Joseph Carrier
Vaudreuil-Dorion (Quebec)
Canada J7V 575

RE: Petition for a Health Claim Stating that Alkaline and Earth
Alkaline Citrates Minimize the Risk of Osteoporosis

Dear Dr. Dröge:

This letter is in reference to the subject health claim petition received by the Food and Drug Administration (FDA or the agency) on April 23, 2007, in which you requested that the agency authorize a health claim with respect to alkaline and earth alkaline citrates and osteoporosis. The petition was submitted pursuant to section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(5)(D)). On May 3, 2007, we informed you that the petition was undergoing initial FDA review.

We have completed our initial review of the petition and are filing it as specified in section 403(r)(4)(i) of the act (21 U.S.C. 343(r)(4)(i)), on August 1, 2007. Within 90 days of the filing date FDA will either publish a proposed regulation authorizing use of the health claim or deny the petition. We have calculated that date to be October 30, 2007. Denial may be made by FDA action or by lack of FDA action, in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

Please feel free to contact Dr. Jillonne Kevala at 301-436-1848 if you have questions concerning this petition.

Sincerely yours,

Barbara O. Schneeman, Ph.D.
Director
Office of Nutrition, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2007P-0361

Let 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

3561 7 AUG -9 P2:09 Food and Drug Administration
College Park, MD 20740

August 8, 2007

Ms. Gloria Ortega
Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Health Claim – Alkaline and Earth Alkaline Citrates and Osteoporosis (Docket Number 2007P-0301)

Dear Ms Ortega:

Will you please add the enclosed filing letter to Docket Number 2007P-0301, entitled “Alkaline and Earth Alkaline Citrates and Osteoporosis”? Thanks in advance for your time.

Sincerely,


Jillone Kevala, Ph.D.
Nutrition Programs Staff
Office on Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration

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College Park, MD 20740-3835
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Enclosures (1)

August 1, 2007 filing letter to Wulf Dröge, Ph.D, Immunotec, from Barbara Schneeman, Ph.D.,
Director Office on Nutrition, Labeling and Dietary Supplements, FDA, HFS-800.