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JUL 22 2002

Ms. Linda K. Craig, RN, BSN
Senior Vice President Clinical Resources
Immunity Today LLC
513A North Mur-Len
Olathe, Kansas 66062

Dear Ms. Craig:

This is in response to your letter of June 10, 2002 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 Immunity Today LLC is making the following claim, among others, for the product **Immune Care 64**:

“...helps to awaken and enhance the body’s own defenses against viruses including HHV-6, EBV and CMV.”

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 statement that you are making for this product suggests that it is intended to prevent virus-induced diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if you require further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is fluid and cursive, with a large initial "J" and "B".

John B. Foret

Director

Division of Compliance and Enforcement
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

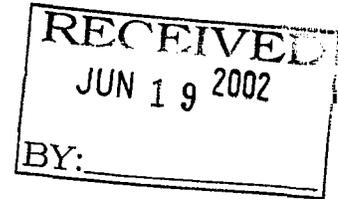
FDA, Kansas District Compliance, HFR-SW340

IMMUNITY TODAY LLC

513A North Mur-Len, Olathe, KS 66062

June 10, 2002

Office of Nutritional Products, Labeling and
Dietary Supplements (HFS-811)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, D.C. 20204



Section 404[r][6] Notification

Dear Sir or Madam:

In accordance with the requirements of section 403[r][6] of the Federal Food, Drug, and Cosmetic Act, Immunity Today, LLC notifies the FDA that it **has** begun using the following statement:

Immune Care 64 is a dietary supplement that enhances the immune system and energy level.

The product that bears the above statement is Immune Care 64 and the ingredients on which the above statement is based are a blend of transfer factors from bovine colostrums, Coenzyme Q-10, and Vitamin C.

I certify that the foregoing is complete and accurate, and that Immunity Today, LLC **has** substantiated that the above statement is truthful and not misleading.

Very Truly Yours,

A handwritten signature in cursive script that reads "Linda K. Craig".

Linda K. Craig, RN, BSN
Senior Vice ~~President~~ Clinical Resources

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