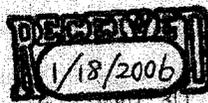


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January 13, 2006

VIA CERTIFIED MAIL

Kathleen C. Ellwood, Ph.D.  
Director, Division of Nutrition Programs and Labeling  
Office of Nutritional Products, Labeling and Dietary Supplements  
FDA/CFSAN  
HFS-830  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Ocean Nutrition Canada, Ltd: August 26, 2005 Nutrient Content Claim Notification

Dear Dr. Ellwood:

We write in response to a letter dated December 19, 2005, from the Office of Nutritional Products, Labeling and Dietary Supplements ("ONPLDS") acknowledging receipt of the above-reference nutrient content claim notification (the "Notification"). The letter was post-marked on December 28, 2005, and was received by our office on December 30, 2005.

We respectfully disagree with ONPLDS' conclusion that the nutrient content claims proposed in the Notification will not become effective until April 8, 2006 (assuming a lack of action by ONPLDS on the Notification prior to that date). As we explained in our letter of December 8, 2005, the Notification was filed with FDA's office at 5100 Paint Branch Parkway, College Park, MD on August 26, 2005. Prior to filing the Notification on August 26, we contacted FDA to confirm the address and procedures for hand delivery of the Notification. FDA informed us that hand delivery was acceptable and confirmed that the address for the submission was correct.

At the time of the delivery, the messenger service we tasked with delivery of the Notification was informed by FDA staff at the location that a date stamp was unavailable (we had charged the messenger service with obtaining such a date stamp on a copy of the Notification). In lieu of a date stamp, the FDA employee signed and dated the Notification, acknowledging receipt at 3:50 pm on August 26, 2005. As a result, we believe the nutrient content claims proposed in the Notification became legally effective on December 26, 2005. There is no reason to believe that the employee whose signature appears on the Notification (and the corresponding signature on the messenger service delivery manifest) was not authorized to accept such deliveries on behalf of FDA, particularly in light of the fact that we followed the instructions for hand delivery provided by FDA.

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Notably, when we hand-delivered a courtesy copy of the Notification to ONPLDS on December 9, 2005, we were confronted by the same situation. On that date, we again requested that the messenger service obtain a date-stamped copy of the Notification evidencing that it had been accepted by FDA. However, when the messenger service arrived at 5100 Paint Branch Parkway, an FDA employee agreed to accept the Notification, but was unable to produce a date stamp to verify the acceptance. Indeed, we understand that the employee was able to internally contact ONPLDS to inform the office of the delivery, but that a representative of ONPLDS failed (or refused) to appear to accept hand-delivery of the courtesy copy of the Notification. Ultimately, the FDA employee accepted the Notification and signed the messenger service's delivery manifest. The December 19, 2005 letter from FDA, post-marked December 28, 2005, acknowledges that the courtesy copy of the Notification was received by ONPLDS on December 9, 2005, the date of the hand delivery.

In light of these circumstances, we restate our position that the nutrient content claims proposed in the Notification became legally effective on December 26, 2005. As the facts clearly show that a representative of FDA accepted our hand delivery of the Notification on August 26, 2005, the failure to administratively process the Notification by ONPLDS must be due to an internal misrouting of the document once accepted. We recognize that, as a result of this misrouting, the ONPLDS had less than three weeks in which to review the Notification. We note, however, that the nutrient content claims proposed in the Notification are based on the same scientific data and authoritative source relied on in two previous nutrient content claim notifications reviewed by ONPLDS, both of which became legally effective without FDA objection.

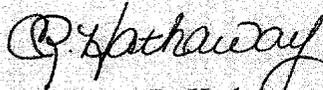
We also note that the use of the claims proposed in the Notification pose no threat to the public health, and indeed are designed to promote the use of ingredients that have been shown to benefit human health. Indeed, a large body of scientific evidence supports the health benefits of omega-3 fatty acids, specifically eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA"). Most significantly, the scientific literature supports the role of EPA/DHA in preventing coronary heart disease. Unfortunately, there is a huge gap between the intake of EPA/DHA recommended by the American Heart Association (and others), and the amount Americans actually consume. FDA's authorization of the nutrient content claims proposed in the Notification will provide clear direction for manufacturers to communicate to consumers which products they can consume to increase their consumption of EPA/DHA. This could have a significant beneficial impact on public health and, consequently, the consumption of both EPA and DHA should be encouraged by FDA. The fact that FDA has permitted a qualified health claim for reduced risk of coronary heart disease for foods that contain EPA and DHA is evidence that the Agency sees the value of assisting consumers in identifying foods that contain both of these crucial fatty acids. The delay in processing ONC's application was unexpected and has placed an unforeseen burden on ONC and its customers who were expecting to be able to commercialize products bearing this claim from the beginning of 2006. This hardship has delayed product launches and negatively impacted cash flows.

In light of these circumstances, we believe the most appropriate resolution to this matter is for FDA to authorize use of the nutrient content claims retroactive to December 26, 2005, unless and until such time as FDA promulgates a regulation clarifying the nutrient content

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claims that can be made for these important ingredients. We appreciate your continued attention to this matter. If you have any questions or would like to discuss these issues in more detail, please do not hesitate to contact the undersigned at (202) 637-2200 or [carolyne.hathaway@lw.com](mailto:carolyne.hathaway@lw.com).

Respectfully,



Carolyn R. Hathaway  
John R. Manthei  
of LATHAM & WATKINS LLP