



Office of Nutritional Products  
Labelling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740  
2<sup>nd</sup> December 2003

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Dear Sir or Madam,

This letter serves as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Boots Retail USA Inc. is using the following statements on the label or in the labelling of:-

**Boots Sleep Starter Pack**

(outer packaging, in reference to the Boots Sleep Herbal Tincture Dietary Supplement)

“Soothing extracts of chamomile, hops and lemon balm work together to relax your body and promote healthy and natural sleep”.

The pack contains the following dietary supplement and associated claims:-

**Boots Sleep Herbal Tincture Dietary Supplement,**

(dietary ingredients: Hops from Humulus lupulus flowers tincture, Chamomile from Chamomilla recutita flowers tincture, Lemon Balm from Melissa officinalis flowers extract).

“This will help to relax your mind and body to help you have a good night’s sleep”.

These statements are accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate and the company has substantiation that these statements are truthful and not misleading.

Sincerely,

Jane Burton  
International Regulatory Affairs

Boots Retail USA Inc.,  
Stamford,  
CT 06901.

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