



Food and Drug Administration  
Rockville MD 20857  
Re: Biofield Diagnostic System  
Docket No. 03E-0154

The Honorable Jon Dudas  
Acting Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

APR - 6 2004

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,328,809 filed by Barry Hirschowitz under 35 U.S.C. § 156. The medical device claimed by the patent is the Biofield Diagnostic System.

A review of the Food and Drug Administration's official records indicates that this product has not been approved by the Food and Drug Administration for commercial marketing or use, as required under 35 U.S.C. § 156(a)(4), and a marketing application for this product has not been filed.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Barry Hirschowitz  
1812 Burnett Way  
Sacramento, CA 95818

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