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DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the General Counsel

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Office of the Chief Counsel  
Food and Drug Administration  
5600 Fishers Lane, GCF-1  
Rockville, MD 20857

February 13, 2002

Gary L. Yingling, Esq.  
Kirkpatrick & Lockhart, LLP  
1800 Massachusetts Avenue, NW  
Suite 200  
Washington, DC 20036-1221

Re: Digoxin (Docket No. 00N-1610)

Dear Mr. Yingling:

This is a response to your letter of January 8, 2002, pertaining to the status of digoxin products. As you know, on November 24, 2000, the agency published the following documents in the Federal Register: (1) a notice reaffirming that digoxin products for oral use are new drugs and requiring the submission of new drug applications for continued marketing (65 Fed. Reg. 70573); and (2) a proposed rule to revoke 21 C.F.R. § 310.500 (65 Fed. Reg. 70538). The comment period to the proposed rule closed on February 22, 2001. We are now in the process of responding to the comments (including yours) and drafting the final rule. We hope to complete this process soon.

I hope this information has been helpful.

Sincerely,

Daniel E. Troy  
Chief Counsel  
Food and Drug Administration

00N-1610

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