



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

May 9, 2001

Mr. Terry S. Coleman  
Bennett, Turner & Coleman, LLP  
1900 K Street, N.W.  
Suite 750  
Washington, DC 20006

Dear Mr. Coleman:

Your petition requesting the Food and Drug Administration to initiate a rulemaking in which the last sentence of 21 C.F.R. 201.128 is deleted to make the regulation consistent with the concept of "intended use" embodied in the Act, the implementing regulations and decisions of the courts, was received by our office on 05/08/01. It was assigned docket number 01P-0228/CP 1 and it was filed on 05/09/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Dockets Management Branch

OIP-0228

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