



FILE COPY

October 08, 2002

Richard A. Stolworthy
2303 Hurstbourne Village Drive
Suite 100
Louisville, KY 40299

Dear Mr. Stolworthy:

Your petition requesting the Food and Drug Administration to better protect patients & consumers in the U.S. by amending the FDA 510(k) policy to include discloser & labeling requirements, was received by this office on 10/08/02. It was assigned docket number 02P-0437/CP1 and it was filed on 10/08/02. 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,

Helen K. Harris
Dockets Management Branch

02P-0437

ACK1