



FILE COPY

August 15, 2001

Sidney M. Wolfe, M.D.
Public Citizen's Health Research Group
1600 20th Street N.W.
Washington, D.C. 20009-1001

Dear Dr. Wolfe:

Your petition requesting the Food and Drug Administration to immediately ban as an unsafe medical device & recall all of dura mater derived from human cadavers, was received by this office on 08/15/01. It was assigned docket number 01P-0354/CP1 and it was filed on 08/15/01. 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,

Helen K. Harris
Dockets Management Branch

01P-0354

ACK1