



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

January 27, 2005

FILE COPY

Larry R. Pilot
McKenna Long & Aldridge
1900 K Street, NW
Washington, District of Columbia 20006

Dear Mr. Pilot:

Your petition requesting the Food and Drug Administration, to issue an advisory opinion with respect to agency limitations during inspection of or inquiries to device manufacturers whose facilities are located outside the jurisdiction of the United States government, was received by this office on 01/27/2005. It was assigned docket number 2005A-0039/AP1 and it was filed on 01/27/2005. 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,

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2005A-0039

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