



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 2, 2006

FILE COPY

Daniel J. Popeo
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, D.C. 20036

Dear Mr. Popeo:

Your petition requesting the Food and Drug Administration to determine that the Food and Drug Administration would not regulate as medical devices any assays developed by clinical laboratories strictly for their in-house use, was received by this office on 10/02/2006. It was assigned docket number 2006P-0402/CP 1 and it was filed on 10/02/2006. 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 Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0402

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