



Food and Drug Administration
Rockville, MD 20857

June 18, 2003

FILE COPY

Mr. Robert A. Dormer
Hyman, Phelps & McNamara
700 13th Street, N.W.
Suite 1200
Washington, DC 20005-5929

Dear Mr. Dormer:

Your petition on behalf of Cape Cod, Inc. requesting the Food and Drug Administration to regulate recombinant and other previously unlicensed endotoxin detection tests for validation, in-process and finished product endotoxin testing of drugs, biological products and medical devices, was received by this office on 06/12/2003. It was assigned docket number 2003P-0278/CP 1 and it was filed on 06/18/2003. 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

2003 P-0278

ACK 1