DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Resear
1401 Rockville Pike
Rockville MD 20852-1448

DEC - 8 2003

Robert A. Dormer
Jennifer B. Davis
Counsel for Associates of Cape Cod, Inc.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Re: Docket Numbers 03-0278/CP1 and
03-0280/PSA1

Dear Mr. Dormer and Ms. Davis:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet completed its response to the issues raised in your citizen petition and petition for stay of action submitted on June 12, 2003, on behalf of Associates of Cape Cod, Inc. In your citizen petition, you request that the Commissioner of Food and Drugs direct the FDA to regulate recombinant and any other previously unlicensed endotoxin detection tests for validation, in-process and finished product endotoxin testing of drugs, biological products and medical devices in accordance with the same requirements that have been applied to Limulus Amebocyte Lysate (LAL) endotoxin detection tests for the past 30 years.

We are still considering your requests and supporting information stated in your citizen petition and petition for stay. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petitions as soon as we have reached a decision on your requests.

Sincerely yours,

Jesse L. Goodman, M.D., M.P.H.
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Branch
(HFA-305)

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