



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20852-1448

JAN 31 2003

J. Barthelow Classen, M.D., M.B.A.
President and Chief Executive Officer
Classen Immunotherapies, Inc.
6517 Montrose Avenue
Baltimore, Maryland 21212

Re: Docket Number 02P-0349/CP1

Dear Dr. Classen:

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 submitted on August 5, 2002, and your two supplements to the petition. In your submissions, you raise safety and effectiveness issues related to the hemophilus vaccine and ask that FDA take a variety of actions to address these issues.

At this time, we are continuing to work on our response to your petition. Because of the numerous requests and complex issues raised, we have not been able to complete our final response at this time. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition 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)

02P-0349

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