



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20852-1448

MAY 29 2007

William L. Driscoll
Vaccine For All LLC
5107 25th Road North
Arlington, Virginia 22207

Re: Docket Number 2006P-0536/CP1

Dear Mr. Driscoll:

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 received on December 28, 2006. In your citizen petition, you request that FDA amend its regulation on promotion and charging for investigational new drugs (21 CFR 312.7) with respect to pre-pandemic and pandemic vaccine.

We have not been able to complete our response to your citizen petition due to the existence of other FDA priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your citizen petition as soon as we have reached a decision on your request.

Sincerely yours,

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

cc: Division of Dockets Management
(HFA-305)

2006P-0536

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