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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 10, 1997

Ryan McInstry
Washington Legal Foundation
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036

Re: Citizen Petition, Docket No. 96P-0001/CP1

Dear Mr. McInstry,

In response to your request, this letter is to confirm our telephone conversation of October 1997, in which we discussed the above referenced petition.

You had called me regarding the status of the agency's response to this petition, which requested a change in the regulations at 21 CFR 312.7(a) on the grounds that public companies should be allowed to disclose the results of studies relating to investigational new drugs in reports with the SEC and in press releases and informational statements directed to the investment community. I said that the petition had been reviewed and preparation of a response had been initiated, but formal processing of the response had been accorded a relatively low priority. The petition was given a low priority because it does not raise a genuine issue: the regulations do not operate as a bar to such disclosures and public companies make such disclosures on a routine basis. I asked if the WLF would consider withdrawing the petition. You said that Mr. Kamenar would have to make that decision.

You also requested that I copy Mr. Kamenar on this letter, which I have done.

Sincerely yours,

Dave Read

Dave Read
Acting Director, Regulatory Policy Staff (HFD-7)
Center for Drug Evaluation and Research

cc:
Paul D. Kamenar, Esq.
Washington Legal Foundation
2009 Massachusetts Avenue, N.W.
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