



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

3751 '01 NOV 26 AM 11:32

November 16, 2001

Daniel J. Popeo, Esq.
Richard A. Samp, Esq.
Washington Legal Foundation
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036

Re: Docket No. 01P-0250

Dear Messrs. Popeo and Samp:

Your petition requesting the Food and Drug Administration to withdraw the Federal Register Notice of March 16, 2000 entitled, "Decision in Washington Legal Foundation v. Henney" and requesting related actions with regard to dissemination of non-misleading information concerning unapproved new uses of FDA-approved products was filed with the Agency on May 29, 2001. Pursuant to 21 C.F.R. § 10.30(e)(2), the Agency hereby provides you an interim response. Due to an internal miscommunication regarding staffing for consideration of your petition, the Agency has not yet prepared a final response to your petition. Having corrected this situation, the Agency anticipates that a final response will be forthcoming in mid-January 2002.

We regret the internal miscommunication and apologize for the resulting delay in issuing a final response.

Sincerely yours,

Margaret M. Dotzel
Associate Commissioner
for Policy

cc: Dockets Management Branch (HFA-305)

01P-0250

LETI