



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 31 2000

Food and Drug Administration
Rockville MD 20857

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Re: Docket No. 99P-5215/CP1

Dear Counsel:

Thank you for your July 14, 2000, letter regarding your citizen petition dated December 3, 1999. You state in that letter that you "will consider FDA's failure to respond substantively to [y]our Citizen Petition by Monday, July 31, 2000 as an effective denial of the Petition"

As we informed you by letter dated June 26, 2000, FDA has been unable to reach a decision on your 120+ page petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. In your petition, you request that the FDA revoke the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients (see 63 FR 66631; Dec. 2, 1998). Although the effective date for these regulations was April 1, 1999, no manufacturer is required to submit any required assessment of pediatric safety and effectiveness until December 2, 2000 (63 FR 66632). We will respond to your petition by November 1, 2000, assuming that you do not supplement your submission.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-5215

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