



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

MAY 04 2000  
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Thomas Scarlett, Esq.  
Hyman, Phelps & McNamara, P.C.  
700 Thirteenth Street, N.W.  
Suite 1200  
Washington, D.C. 20005-5929

Re: Docket No. 99P-4932/CP1& SUP1

Dear Mr. Scarlett:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on November 12, 1999, and supplement submitted on March 31, 2000. In those submissions, you request that the Agency clarify its policy of requiring suitability petitions for parenteral drugs where the change from the listed drug is in the size of the container. You ask that the clarification include (1) a statement that a suitability petition is required only for changes in single-dose liquid parenteral drug container sizes and (2) a statement that different multiple-dose container sizes of parenteral drugs are not different "strengths" for purposes of 180-day generic drug exclusivity.

The Agency is still evaluating the requests made in your petition, and we will respond to your petition once this process is completed. 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 request.

Sincerely yours,

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

99P-4932

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