



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 21 2002

6046 '02 MAR 22 P1:16

John W. Herr, Esq.
2 N. Main Street, Suite 703
Middletown, OH 45042

Re: Docket No. 01P-0447/CP 1

Dear Mr. Herr:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on September 28, 2001. Your petition requests that the Agency determine whether ardeparin sodium (Normiflo) was withdrawn from sale for safety and efficacy reasons.

FDA has been unable to reach a decision on your petition due to the need to address other Agency 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 petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research

01P-0447

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