



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 24 2001

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Tom Stothoff
• 2152 West Potomac Avenue
Chicago, IL 60622

Re: Docket No.01P-0061/CP1

Dear Mr. Stothoff:

Pursuant to 21 CFR 10.30 (e)(2), this letter informs you that we are still considering the issue raised in your petition as to whether IFEX (ifosfamide for injection) was withdrawn from sale for reasons of safety or effectiveness.

We expect to conclude our evaluation shortly and will respond to your petition once that process is completed.

Sincerely yours,

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

01P-0061

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