



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 30 2002

Food and Drug Administration
Rockville MD 20857

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Brian A. Green
Manager, Regulatory Affairs
ASTA Medica, Inc.
890 East Street
Tewksbury, MA 01876-1496

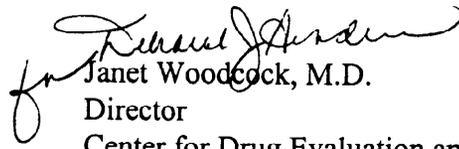
Re: Docket No. 01P-0333/CP1

Dear Mr. Green:

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 July 26, 2001. Your petition requests that FDA determine whether cyclophosphamide for injection USP (Cytosan), 2 gram vials (N12142 005), was voluntarily withdrawn or withheld from sale for reasons other than safety or effectiveness, and that an abbreviated new drug application may be submitted and approved under 21 CFR 314.122 and 314.161 using cyclophosphamide for injection as the reference listed drug.

FDA is in the process of drafting a notice to be published in the *Federal Register*. 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.

Sincerely yours,


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

01P-0333

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