

THE UPJOHN COMPANY

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*Office of
HARRY R. ALLEN, M.D.
Manager, FDA Liaison
Domestic Pharmaceutical
Medical Affairs*

May 20, 1976

Hearing Clerk
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

In compliance with the Federal Register Notice, Volume 40, Number 51, March 14, 1975, page 11865, titled "Asbestos-form Particles in Drugs for Parenteral Injection", we are supplying the attached memo as an updated report for replacement of asbestos filters.

Very truly yours,

THE UPJOHN COMPANY



Harry R. Allen, M.D.
Manager, FDA Liaison

HRA:pjc

Attachment

75P-0261

54P02

1. J. W. Parker completed a study which showed that the amount of non-volatile residue remaining after a one liter sample of chloroform was evaporated to dryness was comparable whether the chloroform was filtered through asbestos or the Scott BNR Filter (1).
2. A second 1/4 production size lot of S.A.S. Diurnal Penicillin Readimixed 500M has been manufactured and placed on stability.
 - a. Lot #1 was manufactured according to the current production procedure except for using the Scott BNR filter (contains Centrolex H and Centrolex P).
 - b. Lot #2 was manufactured according to the current production procedure except for substitution of Centrolex P for Centrolex H and for using the Scott BNR filter (contains all Centrolex P).