

DEC 20 1976

Mr. Sherwin Gardner
Acting Commissioner of Food
and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Mr. Gardner:

In accordance with the commitment undertaken during the recently concluded hearings on safety and efficacy of the anti-obesity drugs before the Monopoly Subcommittee of the Senate Small Business Committee, Senator Gaylord Nelson, Chairman, I am forwarding this agency's findings reflective of the current abuse of amphetamines. These findings include field data i.e., amphetamine diversion, audit reports and field intelligence as well as DAWN data and recent production figures.

Collectively, these findings are indicative of an unacceptable level of abuse despite recently imposed Schedule II restrictions. The issue remains whether the risk to benefit ratio associated with the therapeutic use of amphetamines for obesity or any other disease is sufficiently low to justify their continued commercial availability.

Additional updating of field surveys and analysis of the level of abuse of phenmetrazine and the Schedule III and IV anorectics is underway. This task will require an additional two to three months and will be forwarded when completed.

Sincerely,

/s/ Donald H. Miller

Peter B. Bensinger
Administrator