

10036 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Information Required by Senator Nelson
from Department of Defense

15. ANSWER: (Cont'd)

(d) RE: Digoxin Tablets

Learned of problem - 1965.

Information to FDA - No record. This was before the Intra-Governmental Professional Advisory Council on Drugs and Devices (IPADD) was fully operational.

Drug Specialist - Cannot determine who became acquainted with problem first. The subject arose as a result of field complaints.

RE: Other examples

The other examples refer to information obtained through published literature, and complaint reports received by DPSC.

Such publications as The Bio-availability of Drug Products by the American Pharmaceutical Association and the Pharmacokinetics discuss equivalence and inequivalence of drug products.

Such drug products as Diphenylhydantoin Sodium Capsules, Nitrofurantoin Tablets, Prednisone Tablets, Nitroglycerin Tablets, Cortisone Tablets, and Thyroid Tablets were the subject of field complaints dealing with effectiveness. All field complaints are routinely forwarded to FDA as agreed upon via IPADD. The dates of complaint submittals are shown as follows:

<u>ITEM INEFFECTIVE</u>	<u>FDA ADVISED</u>
Diphenylhydantoin Sodium Capsules	4 December 1963 12 December 1963 15 April 1964 27 January 1966 2 May 1966
Nitrofurantoin Tablets	22 May 1961 16 June 1961 5 March 1962 11 April 1962 25 November 1969 (2 reports) 23 December 1969 2 January 1970 17 February 1970 15 May 1970 12 July 1971