Please name the "many other examples" mentioned. Was the FDA informed? When and how? Give name and title of drug specialists who discovered these problems?

(e) "We develop definitive product specifications which often exceed official or commercial standards."

Please name each product for which such specifications have been developed; the significance for each product of these extra requirements; and the medical purpose served by these extra requirements;

16. Please state deviations from FDA's good manufacturing practices regulations which the DOD considers significant, and which are not considered significant by the FDA? Please identify where there is a difference of opinion.

Who in DPSC makes the determination whether the raw observations are significant?

What criteria does DPSC use?

Does DPSC relate the violation to a particular product? In other words, does the violation, for example, contribute to the contamination of the product?

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