Under your question 15(b) to DOD, you requested the names of the firms, the dates of the "gross violations," whether or not they were reported to FDA, etc., and the exact description of the violation. Further elaboration was requested under your question 15(c). Although DOD's response under 15(a) stated that during FY 1973 there were 97 rejections based upon plant inspections, DOD did not provide you with the specific information you requested relative to these 97 cases; instead, as stated on page 11 of their response, they simply provided "examples" without comment as to how these examples were chosen by them. Since there is no indication that DOD selected these examples purely at random, and since your request was couched in terms of the "gross violations," it is logical to assume that the examples they provided to you were actually the most extreme or serious violations among the 97 identified during FY 1973.

Turning to the list of violations supplied by DOD as "examples," it will be noted that there is a total of 12 entries for FY 1973. Certain comments can be made based upon inspection of the information provided relative to these 12 entries:

-- The nature of the violations is such that they are essentially technical in nature, and are minor and/or easily correctable. (Your hearing record indicates that an FDA spokesman has characterized them as "relatively trivial.")

-- Of the 12 entries, Zenith Laboratories of Northdale, New Jersey, is listed twice, thereby reducing the number of plants to a total of 11.

-- Of these 11 plants, 3 are located in Puerto Rico and one is located in England.

-- There appears to be no correlation between these 11 plants and the size or "reputation" of the company involved; 5 out of the 11 examples appear to be plants operated by member firms of the Pharmaceutical Manufacturers Association (the PMA has approximately 130 member firms) while 6 out of 11 are not PMA member firms. (There are probably several thousand drug companies operating in the United States which are not members of the PMA.)

b. Product Testing

The DOD answer to your question 3 reveals that it is their practice to make a preliminary determination of what drug products should be subjected to laboratory analysis in contrast to those which can be judged suitable without such