HEW concurred in our recommendation and advised us that the Bureau of Drugs is studying administrative guidelines for GMPs as well as the current good manufacturing practice regulations with assistance from a drug quality control expert consultant with extensive industry experience. HEW stated that the guidelines will be rewritten to more clearly delineate and define actions to be taken. In addition, training programs for field and headquarters officials will be intensified and will continue to insure that everyone making regulatory decisions has written guidelines to the fullest extent possible or has the experience to make judgments where guidelines are not possible.

HEW stated that the use of the term "critical deviations" throughout the report in referring to inspections of drug firms was unfortunate and possibly misleading. HEW explained that in the administrative guidelines for GMPs, there is a list of critical areas with instructions on when to recommend regulatory actions where critical deviations are found and that these guidelines stress the importance of judgment in determining whether a situation exists that requires regulatory action. HEW stated that wherever truly critical deviations from GMPs are found it always acts to correct the situation.

We agree that certain types of deviations from GMPs are more significant than others and that judgment must be exercised in determining when regulatory actions should be taken. It should be noted, however, that the report shows the total number of deviations noted during the inspections of 73 drug producers. To show the extent to which serious deviations occurred, the report also identifies the number of deviations which were critical--according to FDA guidelines. This was done because FDA identifies critical deviations from GMPs as those deviations having the greatest probability of creating adulterated products.