> The Administrative Guideline concerning critical and significant GMP deviations must not be taken as hard and fast rules, but must be interpreted concerning relative significance in light of the firm's actual practices and operations.

They explained that supporting a seizure action based solely on not following GMPs must be more stringent; i.e., deviations must be of greater significance since the burden of proof of deficiency is on FDA.

FDA district officials took strong exception to the reasons for disapproval stating that deviations from GMPs when considered in a group support the recommended seizure. Specifically, the district was concerned with the Bureau's position interpreting it to mean that in similar future instances there would be a need for FDA laboratory analysis showing a violation to support a seizure action. District officials pointed out that the FD&C Act and GMPs permit seizure actions on the basis of inspectional evidence only, notwithstanding the need for or outcome of an FDA assay of the finished product.

Because of the confusion created by headquarters' disapproval, of this and other seizure recommendations, the district officials requested clarification in February 1972 of current FDA policy and guidelines for initiating legal action when inspections show firms are not complying with GMPs. The district officials told us that a headquarters' reply received in May 1972 did not provide the district with guidelines for future action. FDA advised us in October 1972 that the guidelines for implementing GMPs were being studied for improvement.

Therapeutic insignificance of nonprescription drugs

Neither the FD&C Act nor FDA guidelines preclude legal action against firms that deviate from GMPs when producing nonprescription drugs. FDA headquarter officials stated, however, that actions recommended and taken depended primarily on the demonstration of therapeutic significance or potential health hazard. Since nonprescription drugs usually do not pose a significant threat to the public health, FDA officials said they are reluctant to pursue legal actions for violations of GMPs on such drugs.