

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10543

--In those instances where critical deviations are noted, seizure or citation will be recommended to headquarters.

This policy change indicates FDA's intention to enforce compliance with GMPs more aggressively since, before this instruction, recommendations to headquarters for seizure or citation were not mandatory.

CONCLUSION

FDA has not always aggressively enforced drug producers' compliance with GMPs, as indicated by the large number of producers in our samples with continuing deviations on successive inspections. As a result, many firms have continued to produce and market adulterated drug products. The non-aggressive enforcement appears to have stemmed primarily from a lack of guidance on when legal actions should be taken and what should be documented and the resultant confusion between FDA personnel responsible for recommending legal action and those responsible for approving such action. In our opinion, FDA has not provided sufficient incentive to producers chronically deviating from GMPs to correct their practices.

FDA's recent policy changes indicate a step toward more aggressive enforcement of GMPs. FDA district offices have been directed to submit to headquarters, recommendations of citation for prosecution or of seizure in all cases of critical deviations. However, we believe the effectiveness of this change will be hampered by the lack of guidance available to district offices, the confusion surrounding the criteria for legal action, and the needed documentation to support a case in court.

RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to establish more definitive guidelines to be followed by headquarters and district office personnel, specifying (1) when products should be seized--especially those posing a questionable health hazard, (2) the amount and type of documentation needed to adequately support the seizure action, and (3) when firms should be cited for prosecution.