Reasons for infrequent use of legal sanctions

The Director of the Office of Compliance, Bureau of Drugs, told us that in his opinion when FDA inspectors find major deviations from GMPs, in almost all cases they will find an adulterated product. The Deputy Director, Office of Compliance, said that in 1971 FDA had increased its effort to enforce compliance with GMPs.

The Deputy Director said that a producer manufacturing or marketing a prescription or nonprescription drug which constitutes a health hazard and which continually deviates from GMPs should be prosecuted and/or enjoined. He added that injunctions place a considerable burden on FDA's manpower since the producer's products must be continually monitored. He said that, because of this, few producers have been enjoined and FDA has been oriented toward approving only those cases which are health hazards.

FDA officials also described the following problems in effectively using legal sanctions to enforce compliance with GMPs:

--The lack of adequate guidelines for the use of seizure actions by the districts.

--The therapeutic insignificance of GMP violations by producers of nonprescription drugs.

--The need for embargo authority.

--The extremely slow judicial process.

Lack of adequate guidelines

According to the Director of the Office of Compliance, Bureau of Drugs, FDA has had difficulty providing guidelines to the field offices for implementing GMPs according to the law. He said GMPs require the user's interpretation. He acknowledged, however, that current guidelines for implementing GMPs should be revised and stated that staff resources limited this action.

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