In 1969 the inspector noted that for the previous several years management had a less than acceptable attitude toward compliance. He stated, "Specifically, the producer refuses or is incapable of complying with good manufacturing practices." Although the management had continually promised to comply with GMPs, according to the June 1971 inspection report, there was no evidence that its intent was sincere. Because of the lack of FDA action, this producer has been permitted to manufacture and market drugs which are considered adulterated under the FD&C Act.

Firm B is a producer with estimated annual sales of $30 million consisting primarily of medicated or extra relief cough drops. FDA inspected the producer's manufacturing practices twice during the 2-year period ended March 1971, each time concluding that the firm was not complying with GMPs. In its previous inspection, October 1968, FDA found that the producer failed to manufacture cough drops in compliance with GMPs. FDA had observed that no tests were performed on components or finished drugs and batch production records were not maintained.

In an April 1970 inspection, FDA observed that the producer continued to manufacture without batch production records, testing of components and finished products, as well as other critical deviations from GMP requirements. FDA, relying on the producer to voluntarily correct the deviations, scheduled the firm for reinspection in 5 months.

In September 1970 FDA reinspected the producer and again concluded that it was not in compliance with GMPs. The inspection showed that the producer initiated a components testing system that did not insure conformity to appropriate standards of identity and strength. Furthermore the producer continued to manufacture without subjecting finished drugs to testing (i.e., identity and strength of active ingredients). In addition, distribution records were not maintained to determine the disposition of drugs manufactured. FDA, relying on the producer to voluntarily correct deviations, scheduled the firm for reinspection in 10 months, July 1971.

In April 1971 FDA visited the producer to follow up on a consumer complaint of a bristle-like object in cough drops. In reviewing the producer's complaint file, FDA noted at least eight other complaints on cough drops. The firm refused further review of its complaint file and FDA terminated its review without taking any action.