

10550 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

letters will be issued after approval by headquarters and will request a response by the producer.

--Use of post inspection letters will be continued only as the findings relate to insanitary conditions which could lead to violations of the FD&C Act. (Insanitary conditions are associated primarily with the food industry.) The firm will be requested to reply within 10 days..

We discussed these changes with the Deputy Associate Commissioner for Compliance. He said the primary means of communication with drug producers regarding inspection findings would be the inspector's oral discussion with plant personnel and the list of inspectional observations. FDA district officials explained that, as a result of these changes, districts' top management are no longer authorized to notify producers' top management of significant adverse findings. Instead, they will recommend seizure or citation for prosecution to FDA headquarters.

In August 1972, subsequent to the completion of our fieldwork, FDA rescinded its policy statement of February 1972 and issued a new policy statement which (1) requires that post inspection letters be issued within 10 days of the completion of an inspection to all drug producers where critical deviations from GMP regulations are encountered and (2) allows the judicious use of regulatory letters in those cases where seizure actions are not practicable and injunctions or prosecutions are not warranted. The new policy statement also requires a response from the drug producers within 10 days, and prompt followup action by the District offices to insure that producers take corrective action. To maintain control, the Associate Commissioner for Compliance will receive copies of all regulatory letters issued and industry responses received.

However, the policy change does not provide instructions to insure that warning letters--unlike post inspection letters and regulatory letters--specify a time limit in which a drug producer must notify FDA of corrective actions planned or taken.