

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10549

<u>Scheduled time interval</u>	<u>Number of reinspections scheduled</u>
Within 1 month	1
2- 3 months	1
4- 6 months	13
7- 9 months	6
10-12 months	7
13-15 months	3
16-18 months	2
19-21 months	8
22-24 months	<u>7</u>
	<u>48</u>

Of the 48 followup inspections scheduled, only 28 had been made as of December 31, 1971, and the average time before reinspection was 14 months. Fourteen reinspections were made within 12 months, 9 more within 24 months, and 5 more within 36 months. The remaining 20 had not been made at the end of 1971, although an average of 22 months had elapsed since the initial inspection.

FDA district officials stated that, although they attempt to make followup inspections of producers with significant deviations from GMPs, higher priority work many times precludes or delays the inspections. They said that there were no definitive guidelines for determining what work should be done first; priority was usually given to headquarters-directed programs and problem firms that produce drugs with significant health implications. Consequently, some producers are not given the attention that may be warranted because the annual volume or health implications of their drugs is insignificant compared with other producers.

Post inspection letters to drug producers eliminated by policy statement

In February 1972 FDA's Associate Commissioner for Compliance issued a policy statement which provided the following instructions to district offices:

- Use of warning letters will be continued in cases of minor violations (no impact on health or safety). The