CHAPTER 4

SOME DRUG PRODUCERS NOT INSPECTED AS OFTEN AS REQUIRED

The FD&C Act requires all drug producers to (1) register annually with FDA and (2) be inspected by FDA at least once in the 2-year period beginning with the date of registration and at least once every 2 years thereafter. FDA inspections are made to determine if GMPs are being followed in actual practice. FDA considers its inspections to be an integral part of its defense against adulterated drugs reaching the consumer.

However, FDA has not inspected some producers as often as required. At least 213--perhaps as many as 336[1]--of the 1,300 drug producers in the three districts included in our review had not been inspected during the 2-year period April 1969 through March 1971. FDA officials acknowledged during May 1971 hearings before the Subcommittee on Intergovernmental Relations, House Committee on Government Operations, that about 26 percent of the registered pharmaceutical manufacturers were not inspected during the 32-month period July 31, 1968, through March 31, 1971.

Failure to inspect some producers as often as required can be attributed to weaknesses in the inspection scheduling process, the priority given to reinspecting other producers that had a history of deviating from GMPs, diversion of manpower to crisis situations and headquarters-directed work, and the lack of available manpower.

FIRMS SUBJECT TO INSPECTION

FDA maintains a narrative inspection history, in the form of a computer printout, on all producers subject to inspection. For the three districts included in our review, the printout showed that 609 of the 1,539 firms classified as drug producers were not inspected during the 2-year period ended March 31, 1971.

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[1]See discussion on p. 31.