CHAPTER 2

LIMITED AUTHORITY FOR ACCESS TO RECORDS

Accomplishment of FDA's consumer protection responsibilities is largely dependent upon FDA's ability to identify and remove products suspected or known to be violative from the market. To carry out this responsibility, FDA must obtain information from the manufacturers' records that will assist in identifying violative products and shipping destinations. Except for prescription drugs, present law does not require firms to provide FDA access to this information and, although most firms cooperate with FDA in this regard, many firms have been unwilling to voluntarily allow FDA such access. Consequently FDA may be unable to obtain needed information and may be prevented from identifying and removing violative products from the market.

During fiscal years 1969 through 1971, 3,300 firms refused to cooperate with requests by FDA inspectors on over 10,000 occasions, including about 7,900 denials of recorded information. The types of records refused and the number of refusals during this period are shown in the following table.

Records refused	Number	Percent
Formula data	4,575	46
Production and quality control records	1,508	15
Shipping records	1,257	13
Complaint files	589	6
Total	7,929	80
Other refusals (primarily taking of pictures)	2,080	20
Total	10,009	100

These statistics represent only part of the problem. In addition to outright refusals, FDA officials have informed us that some firms provide only partial data or delay providing the requested data to FDA inspectors. The officials informed us also that as a consequence of repeated refusals of data, some FDA inspectors have stopped asking for access to needed information.

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