

10558 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

usually do not pose a significant threat to the public health. HEW conceded that these firms should have been inspected in a more timely manner, but advised us that FDA's limited manpower precluded reaching this goal. HEW stated that the decision was made to use this manpower in inspecting those plants and those operations that do or could pose a significant health hazard to the consumer.

HEW advised us that instructions will be issued to the field to inspect newly registered drug producers as promptly as possible. The instructions will cover not only newly registered firms but new firms which have failed to register and which come to FDA's attention through other means. These firms will be required to register.

HEW also stated that it was unfortunate that the scope of our audit was not such that a number of approaches taken by FDA to protect the consumer were not commented on in the report. HEW cited FDA's new Quality Assurance Program which calls for large numbers of samples to be analyzed before inspection to detect specific flaws. HEW stated that under this approach, inspectors can focus on the conditions in a firm that led to these flaws.

The Quality Assurance Program was implemented subsequent to our review and is an attempt by FDA to make its drug inspections more efficient by obtaining preinspection information through product analysis. This program, if properly implemented and carried out, should assist FDA in improving the effectiveness of its inspection activities.