to include substantial evidence of effectiveness and also required a review of the effectiveness of all drugs approved between 1938 and 1962.

The Food and Drug Administration contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to carry out a review of the pre-1962 drugs and we have used the results of the NAS/NRC advisory study in making our own final determinations of efficacy.

As a result of this program, some 5600 ineffective drug products have been removed from the market, ineffective indications for use have been deleted from drug labeling, and where drugs have been shown to be possibly or probably effective, manufacturers have been provided an opportunity to supply data that will establish their effectiveness.

In addition, manufacturers of many products not previously covered by new drug applications (NDA) have been required to submit abbreviated NDA's. Before such applications are approved, we require compliance with current good manufacturing practice regulations. As in the case of NDA submissions, this is determined by a plant inspection. This program has greatly increased our inspection activities in small and medium-size firms in the past and has resulted in substantial improvement in compliance