nism for marketing new drugs for which only limited data, for example, bioavailability data are necessary to establish their safety and effectiveness. It will at the same time have the ancillary effect of providing a means by which competitive drugs can be marketed. This may have an advantageous effect on drug prices and will make available to the prescriber a wider selection of generic drugs.

I wish to emphasize that when a drug is classified and listed as "ineffective," it has been classified as "ineffective" for each indication.

Mr. GORDON. May I ask a question at this point?

Mr. SEGGEL. Yes.

Mr. GORDON. How many of these abbreviated NDA's have been approved up to now?

Dr. FINKEL. I will have to supply the figure for the record. But there have been over a hundred.

(The subsequent information was received and follows:)

There have been 267 abbreviated NDA's approved as of July 31, 1972.

Mr. SEGGEL. I would like to turn to policy implementation in procurement and reimbursement programs.

A notice was published in the Federal Register on October 8, 1971, stating that it is the policy of the Department that Federal funds will not be expended for purchasing drug products classified as "ineffective" and "possibly effective" for use in its direct care programs with two exceptions: (1) Funds may be expended to purchase "ineffective" and "possibly effective" drug products for use in approved clinical research projects, and (2) Federal funds may be expended to purchase a "possibly effective" drug product when no alternative means of therapy with drug products in the "probably effective" or "effective" classification are available.

Senator NELSON. Where would the ineffective drugs be purchased since they are supposed to have been removed from the market?

Mr. SEGGEL. That would be true of some. While they are in a transition status, presumably they would still be available.

Mr. Brands may wish to comment on it.

Mr. BRANDS. That is true. Before the final order is published in the Federal Register there is usually a 30-day period before the final order is published. During that time ineffective drugs would not be purchased unless it was for an approved research project to obtain additional evidence of effectiveness.

Mr. GORDON. Are you saying also that there are right now many ineffective drugs on the market?

Mr. BRANDS. No.

Dr. FINKEL. There are only about 60 prescription ineffective drugs that are still on the market. Of those, most of them are in the final stages before they will be removed. Some of them have been reformulated to remove an ineffective ingredient, and are going to be republished as possibly effective. Some are undergoing litigation.

Mr. GORDON. Is the public aware that they may be using ineffective drugs?

Dr. FINKEL. Yes. As of May 15 the firms were required to put a box on the package insert which gives the NAS/NRC ratings, and those which are ineffective must say that they have been considered ineffective by the NAS/NRC and the FDA.