number of indications. In this process, we must also be sure that the new language is consistent with other labeling for the same product or closely related products that have been developed since 1962.

Despite these problems and others, we have developed procedures for implementing Academy reports which I believe are orderly, rational, and logical. These procedures have evolved from our experience in handling the reports and they are by no means static. Procedures will be changed as necessary to deal with any problems that may arise.

At the present time, our task force makes a preliminary screening of panel reports to determine the Division within the Bureau of Medicine which can best handle the drugs involved.

Parenthetically I would add that the divisional structure within the Bureau of Medicine is ordinarily by major categories of drug effect. For instance, cardiovascular renal is one, and endocrine metabolic is another one. The task force sets a deadline for completion of the evaluation and the preparation of labeling by the appropriate division. Priorities as to the order of evaluation are based upon—

1. Safety, direct or indirect.
2. Therapeutic significance of the drug (or class of drugs).
3. Volume of use of the product.

After we have determined the action necessary to carry out NAS recommendatinos, public notice is given in the Federal Register of FDA's conclusions and subsequent steps to be taken.

If a drug is found "effective," of course, no subsequent steps may be necessary.

For those drugs found "probably effective," we give the manufacturers 12 additional months to provide data to support their claims.

For those drugs found "possibly effective," and I might add that this was originally entitled "probably ineffective"—and then revised to the positive approach—we allow 6 months for the submission of such data (since there is a greater doubt as to efficacy).

For drugs ruled "ineffective," we allow 30 days for the submission of any evidence that may have been overlooked to support efficacy claims.

Senator NELSON. Would it not be correct to say, then, that in the standards established; that is, the probably effective and possibly effective, that you used what would be called a liberal interpretation of the statute in favor of companies rather than a strict interpretation of the statute against the companies; would that be correct?

Dr. LEY. I believe that is an appropriate way to summarize it, Mr. Chairman.

Mr. GORDON. May I ask a question here? On the probably effective and possibly effective drugs, after the time period is up and you find that you receive no evidence, will these drugs be taken off the market after a 30-day period?

Dr. LEY. We will get into great detail in this matter as we go through the statement. We initiate action if (after review of the evidence submitted), we find that there is not substantial evidence. We then initiate action to remove the product from the marketplace after the appropriate time period. The form of action we would take will vary depending upon the circumstances. We believe, for example, with the Panalba mixture, that there is a safety matter involved with the com-