hoped at the outset of this program to complete 250 Intensified Drug Inspections during the current fiscal year, and to cover the other 250 prescription drug manufacturers in fiscal 1970. It now appears that this schedule may have been overly ambitious, but we will move ahead as rapidly as possible. Obviously, this program will not eliminate the need for inspections in subsequent years. But I strongly believe it will achieve significantly higher standards of drug manufacturing on an industry-wide basis.

No single program, of course, can insure the American public of safe drugs that will do what they are intended to do. In addition to other enforcement and compliance activities, we plan to further expand the capabilities of our National Center for Drug Analysis at St. Louis. We are also moving ahead with the implementation of the recommendations of the National Academy of Sciences-National Research Council concerning the efficiency of pre-1962 new drugs. This will provide the prescriber, and the purchaser of the over-the-counter products, a more precise picture of what these medications will do. And we are continuing biologic availability studies to determine whether there are therapeutically significant differences between chemically equivalent drugs.

In this connection, I'm sure most of you will recall the performance differences among chloramphenicol capsules that required FDA action just about a year ago. That situation, unfortunately, became part of the socalled "generic-brandname" controversy. I say "unfortunately" because it seems to me that drug equivalency problems aren't necessarily related to the name by which a drug is sold. Just a few weeks ago, for example, Merck, Sharp & Dohme recalled from the market 15 lots of its hypertensive preparation, Aldomet tablets (or, generically speaking, methyldopa tablets). The recall was undertaken because disintegration rates were below the company's specification. The cause, apparently, was related to the particle size of a so-called inert ingredient. This is not dissimilar to the earliest problem with chloramphenicol capsules. The Merck management acted with commendable responsibility in catching the problem, confirming the deficiency through human blood level studies, and promptly initiating the recall. But it does illustrate that an equivalency problem can occur anywhere within the drug industry. We have to get at the basic causes o fthese problems; they can't be solved by comparing the names that appear on the product labels.

There is another problem area concerning drugs which also requires, I believe, renewed concentration on causes. During the last fiscal year, the FDA received 406 New Drug Applications. During the same 12 months, 59 NDAs were approved. These figures are not directly related, of course, since an application may not be acted upon in the same fiscal year that it is submitted. Nevertheless, I think it is significant that, for the year, the number of applications found incomplete, or returned as not approvable, outnumbered those approved by better than 5-to-1. More than 80 percent of the applications that were found not approvable lacked adequate information about manufacturing processes. More than half of these applications also suffered from deficiencies in clinical studies and inadequacies in efficacy data. The message, it seems to me, is clear: there is still a need for better data in industry's submissions to the Agency.

We are as interested as industry in getting to the market as swiftly as possible new drugs that can mean better health care for American citizens. But we cannot disregard our responsibility to determine that such drugs are safe and effective for their intended uses before they reach the market. By the same token, the manufacturer cannot disregard his responsibility to submit sound data that demonstrate safety and efficacy. I must tell you frankly that we have not seen the degree of improvement in the quality of clinical data from drug investigations that we would like. I intend to give this matter renewed attention in the weeks ahead, and possibly call upon experts outside the Agency as well to see if we cannot find the means to correct existing shortcomings.

As far as other priorities are concerned, the Agency as a whole will continue to give its most urgent attention to potential health hazards in every area of our responsibilities. Our concern with microbiological contamination of consumer commodities is, of course, part of this overall health-protection program.

Last September, as some of you know, a National Center for Microbiological Analysis went into operation on a pilot basis at our Minneapolis District laboratory. Samples of food products from around the Nation, starting with those classes of foods most susceptible to contamination by harmful bacteria, are being sent to the Minneapolis Center for analysis. This pilot operation should begin to give us a better grasp of the extent of the problem, and, more important, pinpoint the product classes where the hazard is greatest. The necessary next step,