nent to an evaluation of the effectiveness of the drug. The submission of unpublished articles or other data appropriate for the same purpose was also invited from the firms. This procedure gave the sponsors the opportunity to identify the evidence which they believed supported claims made for the drugs. In October 1966, the same procedure was initiated to include in the drug efficacy study antibiotics which had been accepted for certification prior to 1962.

A small staff at FDA was responsible for the recording and transmission of these reports from the manufacturers to the Academy. This included the assignment of each drug to one or more therapeutic categories. These categories had been previously designated by an ad hoc committee appointed by NAS/NRC.

The staff at NAS/NRC and the PAC did a superb organizational job in preparation for the study. Twenty-seven panels, comprised of experts in medical centers throughout the country, were appointed to cover 21 therapeutic categories of drugs. In the course of the study it became necessary to increase the number of panels to 30 and the drug categories to 22.

Obviously, as already noted in the testimony here, many therapeutic categories were covered by more than one panel.

With the antibiotics, for example, it was five. With the chairman and five other members on each panel, plus consultants obtained for special problems, a body of approximately 200 experts conducted the reviews. FDA assigned 10 and later 11. Public Health Service medical officers to serve as executive secretaries for the 30 panels.

The magniture of this study and the complexity of the decisions involved can hardly be overestimated. Since October 1967, the panels have submitted to FDA 2,824 reports covering approximately 3,700 drug formulations manufactured by 237 companies. About two-thirds of the products could be handled by a single panel, but the remainder, because of the multiplicity of therapeutic indications or claims, had to be reviewed separately by two to 15 panels. The Academy has estimated that considering each claim made for the drug, 10,000 or more therapeutic judgments were required. Panelists spent about 10,000 man-hours in meetings, in addition to the time required for preparatory work.

The responsibility for evaluating and carrying out the Academy recommendations is, of course, FDA's. In January 1968, we established a special task force in the Bureau of Medicine to handle this difficult assignment. The procedures we had decided upon for implementing the recommendations were explained at a public meeting that same month.

We have encountered many complex and time-consuming problems in the process of translating Academy recommendations into agency actions. First, there is the sheer volume of handling more than 10,000 therapeutic judgments. Different panels that reviewed the same drug did not always use the same terms in describing its effects, and consultation with the various panel chairmen frequently was necessary.

The Academy panels considered only the medical aspects of the drugs reviewed, but FDA must consider regulatory responsibilities as well. For many products, this involved translating panel recommendations into completely new or revised labeling, frequently covering a