The April 2, 1969, announcement gave interested parties 30 days to submit any data relevant to the efficacy of the products listed. It is significant, Mr. Chairman, that only three of the 23 firms listed as marketing penicillin-sulfa and penicillin-streptomycin combinations responded to that invitation.

Wyeth and Pfizer submitted material on the pen-strep combinations, but no new clinical data were included. Squibb proposed labeling changes on its pen-sulfa preparations and also submitted data from a controlled study of this combination in pediatric use. After review of the study, we concluded that it did not provide substantial evidence of the effectiveness and safety of the penicillin-sulfa combination.

I have signed orders to end the marketing of both the penicillin-streptomycin and penicillin-sulfa preparations. Regulations under which these combinations were certified will be repealed. Outstanding stocks will be decertified. These orders will be published in the Federal Register later this week, or very early next week, if the holiday interferes, and will become effective 40 days later.

This will allow 30 days for the companies to file objections and to seek a hearing, 10 days for our review of the objections, and time for recalls to be completed.

Anyone who may be adversely affected by these actions may file objections within 30 days after publication and request a hearing. Such requests must state reasonable grounds for a hearing, identifying any claimed errors in the NAS/NRC evaluation or any adequate, well controlled investigations which may be offered as evidence of safety and effectiveness. As in the case of Panabla, however, we do not intend to permit the continued marketing of the pen-sulfa and pen-strep combinations during any hearing proceedings that may take place.

I also have signed an order to repeal the regulation and revoke certificates for Mysteclin–F, Squibb's combination of tetracycline and amphotericin–B. Since our announcement in December 1968 that this fixed combination is ineffective, we have received and reviewed additional data and have concluded that substantial evidence still is lacking to support claims in the labeling. The order regarding Mysteclin–F will take effect 40 days after publication in the Federal Register unless stayed by proper objections.

I can also report to the committee, Mr. Chairman, that we will be publishing shortly the academy's findings and FDA's proposals regarding sulfonamides, another widely used class of anti-infective drugs. Labeling revisions will be necessary to restrict markedly the indications for use, although the sulfonamides have been found effective for uncomplicated urinary tract infections and for prophylaxis in rheumatic fever. The industry, and any other interested parties, will be given an opportunity, of course, to react to these findings.

I hope that these examples have given the committee some indication of how we are proceeding with the challenging task of carrying out the NAS/NRC recommendations. Let me turn now, Mr. Chairman, to another challenge I believe is involved; namely, that of disseminating the information from the academy as widely as possible within the medical profession. We are using a variety of approaches to achieve this end.