The USAN Council, sponsored by the AMA, USP and APhA (publisher of the NF), negotiates with manufacturing firms in the selection of nonproprietary names for drugs which it is understood will be adopted as official names if the drugs are included in either compendia. On tentative selection by the Council of a nonproprietary name it is submitted for comment to collaborating organizations—FDA, WHO and the pharmacopeial commissions of the British, French and Nordic countries. By this procedure conflicts of the proposed names with existing nonproprietary names or trademarks may be revealed and avoided in the final selection. This collaboration, however, does not assure the selection of the same names by these organizations. Although the names adopted by the USAN Council do not have statutory recognition many of them eventually achieve this recognition by acceptance in official compendia and they have as a general rule been accepted as nonproprietary names in the approved labeling of drugs by FDA.

The 1962 drug amendments gave the Secretary authority to "designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity." FDA has initiated action to assure the selection of names which are in fact simple and useful and to designate them as official by publication in the *Federal Register*.

On April 20, 1967, official names for 28 drugs were published in the *Federal Register*, following publication for comment in August 1966. These were names originally selected by the USAN Council. The list would probably have included others if there had been no question of their usefulness and simplicity.

In the fall of 1966 FDA approached the USAN Council in the interests of promoting the selection of simpler names which would be more useful to the health professions, in order that the names selected by the Council could routinely receive official recognition by publication in the *Federal Register*. This led to two important developments. The first was a revision of the existing guiding principles of the Council for the selection of names. This was accomplished by incorporating into them a number of guidelines recommended by FDA. The resulting "Guiding Principles ***" are published in the current (number 5) edition of "United States Adopted Names," and in the 1967 edition of "New Drugs Evaluated by the AMA Council on Drugs."

A second development was an agreement between the sponsors of the USAN Council (AMA, USP and APhA) and FDA whereby the latter would appoint a member to the Council and agree to accept any name on which the Council is unanimous as the established or official name. In the event that the USAN Council cannot reach a unanimous agreement on a name the Commissioner of the Food and Drug Administration reserves the right to select the official name. For the latter purpose it is the intention of the Commissioner to appoint a committee, expert in this area, to advise him should the occasion arise. The program under this agreement has been operative since June 24 of this year with Dr. Ralph G. Smith as the FDA representative on the Council. An intramural Advisory Committee on Drug Nomenclature is being appointed to assist Dr. Smith on any special nomenclature problems encountered in relation to USAN activities or otherwise. The publication of additional official names is currently in process and it is intended that such publications will be a continuing operation.

This arrangement promises to have merit in that FDA obtains the services of an experienced organization with established procedures for the selection of appropriate and available names while retaining its legal authority to make its own selection in case of disagreement. It is also advantageous to the USAN Council to the extent that the names which it unanimously selects will be accepted as legally official names.

Through our policy of cooperation with the USAN Council will result in gradual, periodic designations of official names, it has the overriding merit of using a recognized organization with established procedures and expertise in this area.

The Food and Drug Administration budget allots some $50,000 per year for this activity which is carried forward by a medical officer and support staff, aided by expert consultants.

Senator NELSON. When did Congress take the power away from the companies to formulate the generic name for the drugs they develop?

Mr. GOODRICH. Congress did not take the authority from the companies to formulate names. What it did in 1962 was to provide that