

MARCH 5, 1968.

Dr. EDWARD FELDMANN,
Director, National Formulary,
Washington, D.C.

DEAR DR. FELDMAN: During your testimony on June 8, 1967 before the Senate Small Business Committee's Monopoly Subcommittee you stated that you "would be hard pressed to name more than even a few—less than five—well-conducted clinically acceptable studies which have demonstrated significant differences between two or more products clinically where they have met all the chemical and physical standards as provided by the official compendia."

On November 29, 1967 Dr. A. E. Slesser of Smith, Kline and French submitted a notebook containing 211 references which, he stated, "are related to factors which can affect the therapeutic effectiveness and safety of products," and which show that there are many more than the small number of cases you, yourself, mentioned. Dr. Slesser, however, was unable to tell the Subcommittee how many different drugs were involved in the 211 references; whether they meet USP or NF standards; or to describe the scientific quality of studies which he was supplying.

To complete the record on this subject, I am taking the liberty of sending you the material which Dr. Slesser gave us, and I should be extremely grateful if you would examine its contents to ascertain how valid is the documentation for his position.¹

Your assistance is greatly appreciated.

Sincerely,

GAYLORD NELSON,
Chairman, Monopoly Subcommittee.

THE NATIONAL FORMULARY,
Washington, D.C., March 13, 1968.

HON. GAYLORD NELSON,
U.S. Senate, Washington, D.C.

DEAR SENATOR NELSON: This will reply to your letter dated March 5, 1968 relative to the notebook or compilation of 211 literature references and reprints entitled "A Measure of the Volume and Content of the Literature Pertinent to the pertinence of its content to its subject title."

In response to your request to me, I have examined this compilation and have evaluated it in a general way from the standpoint of its scientific character and the pertinence of its content to its subject title.

The preface statement in this compilation describes the division of the material contained therein into five sections identified as items A through E. From my examination of these five sections, it is my conclusion that items B, C, D, and E are largely supplemental to the information provided in item A. This conclusion can be drawn from the fact that item B principally draws upon many of the same references as those listed in item A. Item C is a chapter from a textbook, and as such is based principally upon information drawn from the literature—again largely information covered under item A. Item D is an annual review of all areas of research for a specific year in the broad field of the pharmaceutical sciences. As such, the articles in item D of pertinence to this compilation already have been listed under item A. Finally, item E is simply a listing of all periodicals and journals dealing with pharmacy which are published throughout the world.

On this basis then, it appears that greatest attention should be devoted to a consideration of the scientific aspects and pertinence of the material appearing under item A.

As noted in the preface to the compilation, item A consists of a listing of 211 articles (along with the abstracts relating to some of them, and along with photocopies of certain of the other articles). A detailed and thorough examination of these articles would constitute an enormous undertaking. My review of this material has been limited to a general examination of the material as presented in this listing. From this general review and survey, I believe that the following conclusions can be validly drawn:

¹ Retained in committee files.