Symposium on Chemical Information Utilization by FDA Bureau of Drugs Chemists

Introductory Remarks†

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This symposium was organized to acquaint the scientific community with the manner in which Bureau of Drugs chemists utilize available chemical information as it pertains to the various areas in which they are involved.

The Food and Drug Administration bears the prime responsibility for regulation of drugs in this country. The authority for FDA's activities is derived from the Federal Food, Drug, and Cosmetic Act. As enacted in 1938, the Act required premarket clearance of new drugs (via New Drug Applications (NDA)) based primarily on safety. In 1941 the requirement for batch certification of insulin was added. Two years later Congress amended the Act to require the batch certification of penicillin products. With the passage of the Kefauver–Harris amendments of 1962 the requirement for showing both safety and effectiveness of a new drug was made mandatory. The 1962 amendments for the first time also required the submission of a Notice of Claimed Investigational Exemption for a New Drug (IND) when human studies are first undertaken. Prior to this amendment an IND was not required to be submitted to the FDA when a new drug was investigated in humans. In regard to antibiotics, all human antibiotics became subject to batch testing and certification.

Chemists have a very responsible role in the review of applications, laboratory testing, and providing chemical information. The important role played by chemists, as well as other professionals, helps assure that drugs of highest quality are available to the public. The review and evaluation of chemical information and data, within a time constraint, requires the ready availability of adequate chemical information, usually from different sources, utilizing different retrieval systems. The Act requires that an evaluation and response be made to an applicant submitting an NDA within 180 days. This includes, in general, the review of the document, laboratory validation of methods, and inspection of the facilities involved in manufacturing the drug. In some instances decisions must be made based on data that do not *absolutely* ensure the validity of such decisions. Therefore, the more substantial data that are available to the chemist concerning the characteristics of a drug, the greater will be the assurance that an appropriate decision will be reached.

The symposium papers are from two viewpoints: the users of chemical information and the suppliers of chemical information. In the first paper, John Richman, Chemist, Division of Anti-Infective Drug Products, discusses the role of chemical information sources from a reviewing chemist's position. This reviewing function primarily is concerned with IND's and NDA's. The second is by Walter Benson, Acting Director, Division of Drug Chemistry, who discusses the role of laboratory chemists along with some other groups and the importance of chemical information utilization. M. L. Andrews, Assistant Branch Chief, Antibiotic Chemistry Branch, then discusses the role of laboratory chemists as it pertains to antibiotics and the certification procedures. The final paper by R. Solkot, Technical Information Specialist, Bureau of Drugs Medical Library, discusses the role of the Bureau of Drugs Library in supplying chemical information from outside sources.

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Chemical Information Sources: Aids in the Review of Drug Applications†

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Applications of computerized databases to the "Chemist's Review" of drug applications are presented with emphasis on the critical topics addressed in the controls review process and the time limitations imposed thereon.

The sustaining force of the drug industry lies in the research and development of novel compounds which demonstrate pharmaceutical activity and have market potential. The principal concern of the Food and Drug Administration is the demonstration of the safety and effectiveness of these new drugs.

A "new drug" is defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act as any drug whose composition is such that it is not yet generally recognized, among qualified

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