nation as well as the pharmacologic action and toxic potentials in laboratory animals. The biochemist, the pharmacologist, and the toxicologist must establish the basic data that warrants the first administration of the drug to man. It is unfortunate that in the present state of the art that this information gained from animal experimentation can only be considered an indicator of its potential action in man.

When the information that has been accumulated from the extensive animal research warrants the trial of the potential drug in man, a special form (FDA Form 1571)[1] is completed for submission to the Food and Drug Administration. A sample copy of a blank form is attached for your information. The assembly of the information required to complete this form may require as much as 2 months and constitutes a "Notice of Claimed Investigational Exemption for New Drug" (IND). The filing of this IND informs the FDA that the pharmaceutical company is prepared to initiate limited studies in man to determine whether or not the information gained from the animal studies can be confirmed.

The IND filed with the FDA represents a body of information gathered on a chemical entity or its combination products through animal experimentation. The cost involved in preparation and submission, however, reflects but a fraction of the total research expenditure to this point in the development of a marketable product. The man-hours of laboratory personnel, cost of animals, laboratory space, and equipment utilized in the screening of perhaps hundreds of compounds to discover a potentially safe and effective new drug product represents the hidden costs of drug research.

Prior to the 1962 amendments to the Food, Drug, and Cosmetic Act, it was the sole responsibility of the manufacturer to exercise his judgment in establishing the reasonableness and safety of first administering an entirely new drug product to man. Today, however, he shares that decision with the FDA which has the added responsibility of reviewing the information set forth on form 1571 and concurring in the decision to enter into phase I in the process of drug development. The IND is a total profile, containing all information that is known with respect to the chemical structure of active ingredients, biologic activity, pharmacologic action, dosage form, that is, tablet, capsule, or liquid, detailed process of manufacture and means of identifying ingredients both qualitively and quantitively, facilities for production, and a data sheet that provides all pertinent information for a prospective investigator.

The development of a drug product must necessarily be tailored to the chemical and physical nature of the active ingredients, anticipated therapeutic effects, the route of administration, the duration of action, and the ratio of pharmacologic and physiologic action to toxic potential. These developmental steps require an average of 12 months and are not instituted without the cautious control of persons experienced in the several disciplines that will influence the total procedure.

[1] See attachments for FDA Forms 1571, 1572, 1573, and FD356H, beginning at p. 2364, infra.