1. The literature covered by this survey ("item A") is sufficiently broad to indicate that it represents a reasonably comprehensive review of the subject field. It is rather unlikely that any significant areas have been overlooked in assembling this compilation.

2. The periodicals and journals which are cited as references constitute recognized and respected publications in the medical, pharmaceutical, and related professional or scientific fields. As such, they are appropriate sources for the collection of information on the subject topic of the compilation.

3. Of the 211 references, the first group of 102 references—according to the preface statement—pertain to *in vivo* clinical observations, which is the subject of greatest interest to the question that the compilation attemps to answer. *On this basis, the succeeding observations will be limited to references from this first group of 102.* However, it appears that this first group of references is quite analogous to the second group of references in all other respects, so that the same general observations could be validly drawn regarding the source of the information, the applicability of the studies, the scientific veracity of the conclusions, etc.

4. The absence of either abstracts or reprint copies of a substantial number of the references cited makes it difficult to evaluate the conclusions or pertinency of such articles without consulting the original literature. Certain of the articles listed by title only appear to be of questionable pertinency to the topic of this compilation; for example, references number 37 and 71.

5. A number of the references appear to pertain to isolated case histories or other types of casual observations which were not conducted in a scientific manner—nor were they intended to be. Such articles are equivalent to testimonials and while interesting, are usually regarded as almost meaningless by trained scientists and experienced clinical investigators. A few examples of this type include references number 13, 14, and 19.

6. A few of the references do not appear to be appropriate for inclusion in this listing since the titles and/or abstracts of the articles indicate that the study involved is concerned only with the pharmacology of the drug under examination and not in any way with dosage forms or matters of formulations; for example, reference number 35.

7. Somewhat along the same vein, certain references appear only to compare entirely different routes of administration of a drug rather than different dosage forms or formulations to be administered by the same route. It is obvious to all that a drug administered by injection will be physiologically available more promptly than virtually any oral dosage form. Examples in this category include references number 24, 25, and 97.

8. Many of the studies compare entirely different types of oral dosage forms—for example, a drug in the form of tablets or capsules in contrast to the drug substance in some liquid dosage form such as an elixir of suspension. Selection of the optimum dosage form is important and unquestionably can have an effect on the therapeutic effectiveness of the drug involved. However, I am unaware of any suggestion or claim that "therapeutic equivalency" exists between completely different types of dosage forms. This is quite another matter from comparing the tablets made by one firm with the tablets made by another firm. Therefore, references of this nature do not seem appropriate for inclusion in this compilation on "generic equivalency"; some examples include references number 7, 10, 12, 89, and 98.

9. By the same token, certain drugs are *purposely formulated* in a manner to provide slow or gradual release of the drug. Studies comparing such timed-release or sustained-release preparations with drug products intended for regular drug release should not be included in this listing. Since such products are purposely intended to have different properties or characteristics of drug release, it does not seem appropriate or valid to include such references in this listing. It is implied that the listing consists of references demonstrating differences observed in drug products where no such differences were intended. Examples of some of the references which should be excluded on this basis are numbers 4, 21, 32, 48, 70, 76, 84, 85, and 90.

10. Many of the articles cited appear only to compare completely different compounds. It is quite obvious that formation of a water-soluble salt of a water-insoluble organic compound will result in a new compound which is more