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Commentary

A Short Note on Food and Drug Administration

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DESCRIPTION

The US Food and drug administration's 21st century initiative has resulted in numerous key changes in how it will conduct business in the future. This includes the office of new drug chemistry's risk-based quality systems and the risk-based Good Manufacturing Practices initiative. Bioequivalence testing of multisource drug products occupies a significant portion of abbreviated new drug application filings and the US. The Food and Drug Administration recently announced numerous measures aimed at streamlining bioequivalence studies, including "Waivers of In Vivo Demonstration of Bioequivalence" and the "Biopharmaceutics Classification System."

However, the entire issue of bioequivalence testing must be addressed in light of formal risk-based testing standards and an understanding of the complexity involved in testing bioequivalence. For example, starting in 1997, the Food and Drug Administration withdrew bioavailability protocols from its Web site to avoid giving the idea that only the protocols mentioned are genuine or even the best option.

New horizons are opening in the creation of justification for better tools to simulate bioequivalence, as envisioned in the process and analytical technology programed. Whereas a large number of modifications to dissolution methodologies, the dissolution media, and methods of testing have been reported in the literature, multiphasic dissolution systems that characterize the drug's thermodynamic activity at the absorption site are still being developed. These simple systems are more likely to accurately imitate the absorption surface than more complex models, such as parallel artificial membrane permeation assays and Caco-2 systems.

Once the dissolution medium is capable of picking up the difference in the transport of free drug molecules across a lipophilic barrier, the thermodynamic activity is established, and when compared to a reference listed drug, the comparability of the two products is well established. The U.S. Food and drug administration allows waiver of bioequivalence for several drugs; this should continue and the list expanded to include those where there is a sufficient merit in the actual use of the product over a period of time. For all other products where the U.S. Food and Drug Administration currently requires demonstration of bioequivalence, the multisource product manufacturer will be allowed to present surrogate methods that take a fresh look at the emulation of absorption and may include the use of Nano sensors embedded in the drug product, multiphasic dissolution systems, and a host of other possibilities that have just begun to open with new technologies arriving. Of great importance is that these new technologies will appear in conducting complex studies such as those involving food effects, topical drugs, inhalation devices, and even botanical drugs. The field of biological drugs is another area that is fast evolving.

The U.S. Food and Drug Administration is developing guidelines for "biosimilar" or "follow-on" biological products and has not been able to conclude what tests would constitute demonstration of bioequivalence. Whereas these products are administered through routes that provide lesser barriers in the entry of drug to the body, the differences are related to antigenicity potential, which needs a clinical evaluation; however, studies have demonstrated that minute differences in the structure of protein drugs including dimerization, 3rd and 4th degree structural changes, and easily picked up in partitioning studies since these studies truly represent the thermodynamic potential which is quickly changed even where minor differences in the structures, often too small to be detected by even the most sophisticated instruments; in most instances, the use of instrumentation itself disturbs the structure enough to make the studies meaningless. This almost borders on the Heisenberg's principle of uncertainty. The field of bioequivalence testing continues to offer many challenges to the generic drug industry.

CONCLUSION

Given the rapidly rising costs of these trials, particularly where many studies are necessary, the generic business would benefit from better study design. Successful bioequivalence reviews are built on meticulous planning that begins well before the investigation begins. Inevitably, this design minimizes the need for costly bioequivalence study repeats, reduces the number of

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review cycles, and compresses the approval process for the Abbreviated New Drug Application. Experienced investigators and study monitors understand the need of resolving difficulties completely and effectively as soon as they emerge.