Understand Bioequivalence and Product-Specific Guidances

The FDA regularly issues new and revised product-specific guidances to facilitate the availability of generic drugs and assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating the evidence needed to support ANDA approval. These guidances represent the Agency’s current thinking regarding generic drugs and describe expectations on how Sponsors should develop drugs that are bioequivalent to the relevant reference drug.

Over the past two years, the FDA has issued 97 new and revised product-specific guidances. This high level of activity is significant because it demonstrates the Agency’s commitment to supporting the development of generic drugs.

Why the Flood of Guidances?

Prior to the passage of the Generic Drug User Fee Act (GDUFA), the FDA provided guidance on how to design bioequivalence (BE) studies for specific products only when asked for assistance by individual applicants. With the increase in the number of abbreviated new drug application (ANDA) submissions, as well as the number of requests for bioequivalence information during the last few years, the process of providing bioequivalence study recommendations became extremely time-consuming for the Agency.

Understanding that applicant-specific and general guidance wasn’t enough, the Agency developed mechanisms that would allow it to conserve resources while responding to the needs of the generic drug industry. The result is this new approach to making guidance available concerning product-specific bioequivalence studies.

As always, the Agency intends to develop bioequivalence study recommendations based on its understanding of the characteristics of the listed drug, information derived from published literature, Agency research, and consultations within different offices in the Center for Drug Evaluation and Research (CDER) as needed based upon the novelty or
complexity of the bioequivalence considerations. Once developed, the Agency releases its recommendations for specific drugs to the general public.

It’s important to note that the FDA is not required to publish draft or final product-specific bioequivalence study guidances before it approves an ANDA for the drug. If the Agency determines that an ANDA contains sufficient evidence that the proposed generic drug product is bioequivalent to its reference listed drug and the application meets the other requirements for approval, the FDA will approve the ANDA.

It’s About Bioequivalence

The content of a guidance is intended to assist the generic pharmaceutical industry with identifying the most appropriate methodology and evidence needed to support a generic drug’s approval. It all comes down to bioequivalence, with the FDA giving recommendations concerning BE studies.

For an ANDA to be approved, a Sponsor must demonstrate that its product has the same active ingredient, dosage form, strength, route of administration, and conditions of use as the listed drug. Essentially, the Sponsor must also demonstrate that the drug under development is bioequivalent to the reference listed drug (RLD).

The bottom line with the FDA is clear: it is very important to conduct a bioequivalence study that follows an existing guidance. If there is no guidance, the FDA will determine whether the methodology used by the Sponsor shows bioequivalence.

ProPharma Group is Here to Support You

Drug Sponsors turn to ProPharma Group for assistance with developing their generic drug products; we support them by monitoring the FDA’s website each day. This is important because we want to know when there is a new product-specific guidance that may apply to a drug being developed by one of our clients. Armed with this knowledge, we are proactive in helping our clients move their drug through the development process.

Even when there is no product-specific guidance for a generic drug being developed by one of our clients, we can still help. Thanks to in-depth experience, our team can work with that client to hopefully get them a meeting with the FDA to discuss what the process of demonstrating bioequivalence ought to be for their specific drug.

Interested in learning more? Contact us today for additional information about how we can help you achieve successful interactions with the FDA.