Safety Considerations for Product Design to Minimize Medication Errors

The US Center for Drug Evaluation and Research (CDER), part of the FDA, published a Guidance for Industry document: *(April 2016) Safety Considerations for Product Design to Minimize Medication Errors*, applicable to all new drug applications (NDA), abbreviated new drug applications (ANDA) and OTC monograph drugs.

Reducing Medication Errors

The purpose of the guidance is to minimize or eliminate hazards contributing to medication errors at the product design stage. The guidance conveys the FDA's current thinking in relation to how a **"Safety by Design"** approach to new product development can be an effective tool in reducing the unintentional medication errors that result in 44,000-98,000 deaths in the United States each year. (Institute of Medicine Report, 2000).

Design of Tablets & Capsules

The guidance encourages manufacturers to consider how the drug product will be used, who will use the drug and in which environment the drug will be administered, to ensure that an appropriate product design can be employed to help reduce the potential for medication errors. Product design should start in the early stages of drug development taking into account factors such as the active, strength(s), dosage form, product appearance, size, shape, swallowability and palatability. The recommended process involves a risk assessment of the properties of the product design that may predispose end users to medication errors. It is preferred to eliminate or minimize these risks at the product design stage, as product labelling or education may not always overcome these.

Key Points

- Avoid multiple strengths that look the same
- Identify different strengths clearly with imprint codes
- Visually differentiate extended or delayed release products
- Simulate in-use testing as part of the risk assessment

End Users and Environment

It is important to take into account the end users, which may vary from doctors in hospitals to geriatric or pediatric patients at home; they all have different levels of understanding, capabilities and interact with the drug product in different ways. The guidance stresses the importance of the environment in which the drug product will be dispensed or taken. Of particular importance here is the presence of other drug products that are the same or a similar drug class, and whether their use is similar to the product being proposed.

Considerations for Dosage Form Design

When developing multiple strengths to cover the therapeutic dosing range or proposing a newer version of an existing product, ideally the dosage forms should look different from each other (e.g. color, shape, size, and imprint). Solid oral dosage forms that look similar to each other have led to dispensing and administration of the wrong strength ("look-alike" errors) which can result in serious effects for patients.

The guidance states that formulators should consider the size, coating, swallowability and palatability of oral products during development. Tablets with a larger cross-sectional area (e.g. tablets that are thicker or wider) would generally be more difficult to swallow than tablets of the same volume but with smaller cross-sectional areas. Tablet coating, weight, surface area, disintegration time, and palatability should be considered when designing oral products to avoid medication errors related to swallowability and patient compliance.

Hardness or friability of tablets should also be evaluated, as excessive hardness of tablets has led to medication administration errors. The FDA has received reports of chewable tablets being too hard to chew and breaking teeth and dentures; also tablets being too friable to remove intact from a blister pack.

The color, shape and size of various strengths of extended or delayed release products should differ from the immediate release products of the same strength. This may help minimize the risk of medication errors in prescribing, leading to dispensing and administration of the immediate release product instead of the intended modified release product. The risk for medication error may increase when strengths overlap.

Summary

Key points, in the guidance, outline the use of size, shape, and color for the benefit of prescribers and patients to identify the medication easily:

Colorcon is well positioned to support the pharmaceutical market in relation to the recommendations of the FDA's new Guidance related to Safety by Design.

- BEST® unique tablet design service to explore options: available to evaluate tablet shapes and sizes for ease of swallowing and color for differentiation.
- Over 50 years' experience in the design, development and manufacture of fully formulated systems for tablet coating, each optimized for color requirement and specific application.

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