Understanding the Impact of the FDA Guidance for Industry

General Information

Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules

US Center for Drug Evaluation and Research (CDER), part of the FDA, published its final version of a Guidance for Industry document: *(June 2015) Size, Shape, and other Physical Attributes of Generic Tablets and Capsules* applying to new abbreviated new drug applications (ANDAs). This is not applicable to products already on the market.

DESIGN OF GENERIC TABLETS & CAPSULES

The guidance conveys the FDA's current thinking in relation to the design of generic tablets and capsules; and how manufacturers should ensure the design of a generic version does not hinder patient compliance. There are recommendations based around the principle that manufacturers of generic products need to consider physical attributes when developing quality target product profiles (QTPPs) for generic tablet and capsule products.

IMPROVING EASE OF SWALLOWING

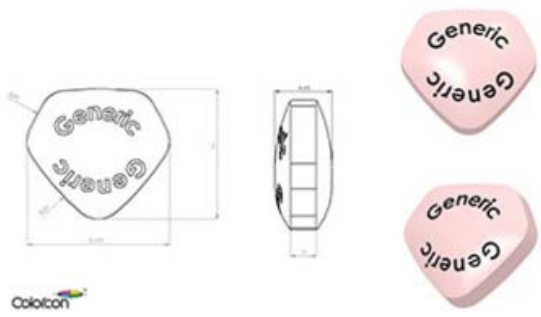
Difficulty with swallowing of tablets and capsules is cited in the guidance as a major cause of patient non-compliance with treatment regimens. The generic product, must not be more difficult, or be perceived by the patient as more difficult to swallow than the reference listed product. The guidance links ease of swallowing with size, shape and other attributes of the dosage form, such as coating.

The guidance makes a very strong case for coated tablets, and states that uncoated tablets can decrease or prevent tablet mobility compared with a coated tablet of the same size. In addition, tablet coating may also enhance patient acceptance by increasing palatability and masking odors.

IMPORTANCE OF SIZE AND SHAPE

To ensure equivalence with the reference listed product, the guideline includes some quantitative recommendations which limit the increase in dimensions of the tablet or capsule; it also recommends the shape of the generic product be similar or easier to swallow than the reference product.

The guidance recommends the use of spatial imaging or computer modelling to compare the generic product characteristics with that of the reference listed product.



FDA 2012 DRAFT GUIDANCE ON SAFETY CONSIDERATIONS FOR NDA PRODUCT DESIGN TO MINIMIZE MEDICATION ERRORS

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

1. Avoid multiple strengths that look the same
2. Ensure imprint codes are included, clearly visible and different based on strengths
3. Extended or delayed release products should be distinct from their immediate release counterparts.

Colorcon is well positioned to support the pharmaceutical market in relation to the recommendations of both the Generic and earlier Safety Considerations (NDA) draft guidance.

- BEST® unique tablet design service uses 3-D models and CAD drawings to explore tablet design options and is 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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