
PHARMACEUTICAL SCIENCES

SCORING CONFIGURATION OF GENERIC DRUG PRODUCTS

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PURPOSE

- To describe the Office of Generic Drugs' (OGD) policy on the scoring configuration of tablets that are the subject of an abbreviated new drug application (ANDA) or abbreviated antibiotic application (AADA).
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BACKGROUND

- One characteristic of a tablet dosage form is that it may be manufactured with a "score" or "scores," a score being a debossed line running across the planar surface of the tablet. This characteristic is useful because the score can be used to facilitate the breaking of the tablet into fractions when less than a full tablet is required for a dose. Although there are no standards or regulatory requirements for scoring of tablets, with the passage of the Waxman-Hatch Act, the Agency recognized the need for consistent scoring between the generic product and the reference listed drug.
 - Consistent scoring assures that the patient is able to adjust the dose, by breaking the tablet, in the same manner as the listed drug. This enables the patient to switch between manufacturers of the same product without encountering problems related to the dose. Additionally, consistent scoring assures that neither the generic product nor the listed drug may have an advantage in the marketplace because of the score. Such advantage would be contrary to the intent of Waxman-Hatch.
 - For many years OGD has recognized the importance of having the scoring configuration of generic tablets be the "same as" that of the reference listed drug. It is the intent of this guide to provide further clarification of what is meant by "same as" with regard to scoring of generic drug products.
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POLICY

- **General Policy**

The scoring configuration of a generic tablet should be the same as that of the listed drug. This should be evident, in terms of the exhibit batch, when the application is submitted to OGD. Specifically:

1. If the listed drug is scored, the generic tablet should be scored to produce partial doses equivalent to that of the listed drug.
2. If the listed drug is not scored, the generic drug should not be scored.
3. If the scoring configuration of the exhibit batch does not match that of the listed drug, the generic firm will be requested to provide a commitment, prior to the application's approval, not to market the product until it is correctly scored.

- **Special Considerations**

1. Change in Listed Drug Scoring

If the scoring of the listed drug changes (scored to unscored or vice versa), the generic drug applicant should contact OGD for guidance on the appropriate scoring configuration. Upon notification of such a change, OGD may issue a letter providing direction to all affected generic applicants.

Generally, if the listed drug deletes a score solely on its own initiative, the generic product's scoring configuration may be either scored or unscored. However, if the listed drug adds a score, the generic product generally should follow the same configuration. These cases will be handled on an individual basis as they occur.

OGD recognizes that a reasonable time is necessary to accomplish the manufacturing revisions needed to implement a scoring change. Generally, "reasonable time" is considered as the first/next production batch. However, OGD acknowledges that the firm may need to obtain new tablet dies and deplete existing stock.

2. Patented scoring configuration

OGD recognizes that some scoring configurations are covered by patent. In such cases contact OGD (Labeling Review Branch) for guidance.

3. Expiration of a patented scoring configuration

When the patent for the listed drug's scoring configuration expires, a

generic firm may generally match the scoring configuration, provided there is no exclusivity on the dose obtained with that score. Before instituting any change, the firm should contact OGD (Labeling Review Branch).

4. Scoring configuration when there is no reference listed drug

This situation may occur when an abbreviated application for a tablet is accepted through the petition process. The firm may propose a scoring configuration supported by the product's labeling. OGD will determine whether the proposed scoring configuration is acceptable.

● **Reporting Requirements**

If any change in scoring configuration occurs in a generic drug product the following information should be provided by the applicant:

1. the executed batch record reflecting the manufacture of a (unscored/scored) tablet with the changed scoring configuration and a complete certificate of analysis for the batch,
2. a dissolution profile comparing the two differing scoring configurations, and
3. the revised master manufacturing batch record, certificate of analysis, and specifications sheets as well as the description of the drug product in the package insert to accurately reflect the description of the drug product.

If this information is requested as part of a preapproval commitment for an unapproved application, it should be submitted as an amendment to the unapproved application.

However, OGD may authorize the applicant to submit the information after approval. In such cases, the applicant should submit the information as a "Supplement - Expedited Review Requested." This information must be found satisfactory prior to release of the batch for marketing.

Reporting scoring configuration changes in an approved application should be done in the same manner as required for reporting changes in imprints:

For all generic drug products, other than modified release dosage forms, e.g., extended and delayed release tablets, a change in scoring configuration should be reported in the applicant's next annual report under 21 CFR 314.70(d).

For modified release dosage form tablets, the applicant should report the change

in scoring configuration in a supplemental application under 21 CFR 314.70(b)(2)(v) and demonstrate bioequivalence according to 21 CFR 320.21(c)(1). The Division of Bioequivalence should be contacted for guidance.

EFFECTIVE DATE

This guide is effective upon date of publication.