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May 17, 2002

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Dockets Management Branch  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20852

**Re: Docket No. 02P-0191 (Petition by Teva Pharmaceuticals USA  
Regarding Approval of Its ANDA for Tramadol Hydrochloride  
Tablets)**

These comments are submitted by R.W. Johnson Pharmaceutical Research Institute (RWJPRI) and Ortho-McNeil Pharmaceutical, Inc. (OMP) (hereafter referred to jointly as "Ortho-McNeil") in response to a citizen petition, dated April 30, 2002, submitted by Teva Pharmaceuticals USA ("Teva"). The petition requests the Food and Drug Administration (FDA) to immediately approve Teva's abbreviated new drug application (ANDA) for tramadol hydrochloride tablets. Teva's product is based on Ultram®. RWJPRI is the sponsor of the new drug application for Ultram, and OMP markets the product.

As explained in these comments, the Teva petition lacks merit, and its ANDA should not be approved. Alternatively, if FDA does approve Teva's tramadol product, the agency should not rate the product as interchangeable ("AB") with Ultram and should not permit Teva to score its tablets.

#### **I. History of Ultram Labeling Changes**

Ultram is indicated for the management of moderate to moderately severe pain. The drug has side effects that may cause patients to terminate therapy. The events most commonly associated with discontinuance of treatment are dizziness/vertigo, nausea, and vomiting.

Ultram was originally approved with a recommended dosing of 50 to 100 mg every 4 to 6 hours, not to exceed 400 mg/day. Ortho-McNeil undertook post-approval clinical studies to investigate whether other dosing regimens would reduce the adverse events associated with use of Ultram and thereby reduce the incidence of treatment discontinuance. In a study that was the basis of FDA's approval of revised labeling in August 1998, Ortho-McNeil showed that a slow titration

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of the drug beginning with 50 mg/day and increasing over ten days to 200 mg/day could reduce discontinuance due to adverse events, particularly dizziness and vertigo, in comparison to no titration or a four day titration. The study did not demonstrate a statistically significant reduction in nausea and vomiting.

Another study was subsequently undertaken to determine whether an even slower titration schedule would result in reduction of nausea and vomiting leading to termination of therapy. The study was a multicenter, randomized, double-blind study of patients with chronic pain. The study demonstrated that starting with an initial dose of 25 mg/day with gradual dosing increases to 200 mg/day through a 16-day titration schedule reduced the incidence of discontinuance due to nausea and vomiting in subjects who previously had difficulty tolerating tramadol because of nausea and/or vomiting. The percentage of subjects who discontinued treatment due to nausea – the primary cause of treatment discontinuance – and vomiting was significantly lower in the 16-day titration group (about 22%) than in the 10-day titration group (46.3%).

Based on this study, FDA on January 3, 2000, approved a change in the Dosage and Administration section of the Ultram labeling. For patients “not requiring rapid onset of analgesic effect,” the 16-day titration regimen beginning at 25 mg is recommended. For “the subset of patients for whom rapid onset of analgesic effect is required and for whom the benefits outweigh the risks of discontinuation due to adverse events associated with initial higher doses,” a nontitrated regimen of up to 400 mg/day is recommended. FDA awarded three years of exclusivity to the change and, as extended by the pediatric exclusivity provisions, the exclusivity extends through July 3, 2003.

## **II. The Teva Petition**

Teva states that its ANDA meets the requirements for FDA approval because it is proposing to omit the aspects of Ultram’s labeling that relate to the protected titration regimen. Teva asserts that the Ultram labeling provides for “two separate and distinct therapeutic uses of tramadol” – treatment of chronic pain and treatment of acute pain – and that, by omitting the titration regimen, it is seeking approval only for the acute pain use. This, Teva claims, satisfies the FDA regulations because its product is as safe and effective as Ultram for the acute pain use.

## **III. Teva’s Proposed Labeling Does Not Comply with FDA’s Regulations**

### **A. Ultram’s Labeling Does Not Set Forth Chronic Pain and Acute Pain As Distinct Therapeutic Uses**

Teva’s central argument is based on its assertion that Ultram is labeled for two distinct uses – chronic pain and acute pain – and that Teva can properly omit the labeling related to chronic pain. Teva’s argument fails, however, because the approved indication of Ultram cannot be divided into treatment of chronic pain and treatment of acute pain, as Teva claims.

The Indications and Usage section of the Ultram labeling states, in full, that “Ultram is indicated for the management of moderate to moderately severe pain.” There is no reference to chronic pain or acute pain in this section. The Ultram labeling differs substantially in this regard from the labeling for Ultracet™, which Teva cites as an example of FDA’s approving a regimen for the treatment of acute pain. The Indications and Usage section of the Ultracet labeling states that “Ultracet is indicated for the short-term (five days or less) management of acute pain.” The Ultracet labeling demonstrates that FDA distinguishes between treatment of acute pain and treatment of chronic pain though the Indications and Usage section of product labeling, not in Dosage and Administration.

Teva’s argument that FDA has approved Ultram for the two distinct uses – treatment of chronic pain and treatment of acute pain – is based solely on the Ultram’s Dosage and Administration section. To make its argument, Teva misquotes the Ultram labeling by stating that what it calls “Use 2” – the purported acute pain use – is identified in the Ultram labeling as treatment of “pain for which ‘rapid onset of analgesic effect is required.’” (Teva Petition at 3) Teva’s argument is misleading, however, as it fails to quote both of the criteria specified in the Ultram labeling.

The Ultram labeling identifies the subset of patients who are suitable for the nontitration regimen as including patients who not only require rapid onset of analgesic effect but also those for whom “the benefits outweigh the risk of discontinuance due to adverse events associated with higher initial doses.” The Ultram labeling does not draw a distinction between use for chronic pain and use for acute pain as Teva argues. Instead, the dosing instructions require a weighing of the benefits and risks of using higher initial doses, without regard to type of pain.

The history of changes to this portion of the Ultram labeling supports the conclusion that FDA has not recognized two distinct uses in the Ultram labeling. The original dosing regimen in the Ultram labeling stated:

“For the treatment of painful conditions, ULTRAM 50 mg to 100 mg can be administered as needed for relief every four to six hours, not to exceed 400 mg per day. For moderate pain, ULTRAM 50 mg may be adequate as the initial dose, and for more severe pain, ULTRAM 100 mg is usually more effective as the initial dose.”

Clearly, nothing in this original labeling could possibly be construed as referring to treatment of acute pain, treatment of chronic pain, or both as distinct uses. Insofar as the labeling recommends what might be viewed as a crude titration regimen – starting with 50 mg as the initial dose – the patient population for which that dose is recommended is those with moderate pain, without specifying whether the pain is acute or chronic.

After Ortho-McNeil conducted additional studies and found a titration regimen that reduced adverse effects and discontinuances, FDA approved revised labeling in 1998, in which the dosing instructions read as follows:

“For the treatment of painful conditions, ULTRAM 50 mg to 100 mg can be administered as needed for relief every four to six hours, not to exceed 400 mg per day. For moderate pain, ULTRAM 50 mg may be adequate as the initial dose, and for more severe pain, ULTRAM 100 mg is usually more effective as the initial dose. In a clinical trial, fewer discontinuances due to adverse events, especially dizziness and vertigo, were observed when titrating the dose in increments of 50 mg/day every 3 days until an effective dose (not exceeding 400 mg/day) was reached.”

Even with a titration regimen in the dosage instructions, nothing in the 1998 language can be read as recognizing treatment of chronic pain and treatment of acute pain as distinct uses, and nothing links the new titration regimen to chronic pain patients.

Teva’s entire argument depends on an assertion that, when the improved 25 mg titration regimen was introduced into the Ultram labeling in 2000 to replace the previous 50 mg titration regimen, FDA concurrently intended, for the first time, to establish the separate and distinct uses of the product for treatment of chronic pain and treatment of acute pain. But all that was intended by this labeling change was the introduction of a superior titration regimen.

#### **B. Teva’s Proposed Labeling Is Unsatisfactory**

Apart from the issue of whether the Ultram labeling establishes different uses for treatment of chronic pain and treatment of acute pain, the specific labeling proposed by Teva would be confusing and would fail to adequately advise physicians how to treat patients. Teva proposes that the Dosage and Administration section of its product labeling state as follows:

“For patients for whom rapid onset of analgesic effect is required and for whom the benefits outweigh the risk of discontinuance due to adverse events associated with higher initial doses, tramadol hydrochloride tablets 50 mg to 100 mg can be administered as needed for pain relief every four to six hours, not to exceed 400 mg per day.”

No other changes would be made. There are serious problems with this proposal.

First, physicians will almost certainly not read this sentence as limiting the indication of Teva’s product to patients with acute pain. In the current Ultram labeling, it is clear that all patients should be titrated unless rapid onset of analgesic effect is required. By asserting that it is only seeking approval for treatment of acute pain, however, Teva is arguing that physicians will interpret its proposed dosing instruction as telling physicians to prescribe a different drug for patients who do not need rapid onset of analgesic effect. Since the indication for tramadol includes all patients with moderate to moderately severe pain, it is unlikely that physicians will understand that many patients with moderate to moderately severe pain should nevertheless not be prescribed the drug because of language in the Dosage and Administration section. This

confusion will result in patients suffering nausea, vomiting, dizziness, and vertigo that could have been avoided and in patients' failing in their therapy when they might have succeeded.

Second, as discussed above, there is more to the description of the suitable patient population than a requirement for rapid onset of analgesic effect. In conformity with the Ultram labeling, Teva's proposed labeling would also limit the category of suitable patients to those "for whom the benefits outweigh the risk of discontinuance due to adverse events associated with higher doses." This advice, however, is largely unintelligible in the absence of the titration instructions present in the Ultram labeling.

Under Teva's proposal, physicians would prescribe its product only after weighing the benefits to particular patients against the "risk of discontinuance due to adverse events associated with higher doses." The reference to "higher doses" only makes sense when accompanied by the titration regimen that Teva proposes to delete. Moreover, although Teva proposes to require physicians to evaluate the "risk of discontinuance due to adverse events," physicians would have no information about that risk because relevant information about risks in the Clinical Studies section of the Ultram labeling, as well as the graph showing the benefits of titration, would have to be deleted.

Teva's proposed language does not convey intelligible or even complete information to physicians about the appropriate use of tramadol. Teva cannot characterize the labeling resulting from its proposal as simply "treatment of acute pain" and thereby avoid dealing with the confusion that the actual language of its proposed labeling would create.

**C. Omission of the Titration Regimen Would Render Teva's Product Less Safe and Less Effective In Violation of FDA Regulations**

The FDA regulations provide that the labeling of a generic product must generally be identical to the labeling of the reference listed drug but that the generic may omit aspects of the reference drug's labeling that are protected by patent or exclusivity if the resulting differences in the labeling "do not render the proposed drug product less safe or effective than the listed drug for all remaining, non-protected conditions of use." 21 C.F.R. §§ 314.94(a)(8)(iv); 314.127(a)(7).

As outlined above, Ortho-McNeil's clinical studies have demonstrated that the 16-day titration regimen, which starts patients at 25 mg/day, is safer than the nontitrated regimen, which starts patients at doses of up to 400 mg/day. The titration regimen was proven to result in lower incidences of dizziness/vertigo, nausea, and vomiting. The titration regimen is also more effective than high initial doses because the side effects of the higher initial doses result in a higher rate of treatment discontinuance.

If the titration regimen is deleted from the labeling of a generic tramadol product, the resulting product would be less safe and less effective for the remaining nontitrated dosing regimen. As the approved labeling states, the nontitrated regimen should be used only if the benefits of rapid onset of analgesic effect outweigh the adverse effects on safety and effectiveness associated with

that regimen. Unless the comparative benefits of the titration regimen are explained in the labeling, a physician would have no basis for assessing whether the benefits of the nontitrated regimen outweigh its risk of discontinuance due to adverse events. As we have shown above, the truncated labeling Teva suggests will likely result in the prescription of the nontitrated, up-to-400 mg/day regimen for patients who should be prescribed the titration regimen, and these patients will suffer a higher incidence of adverse effects and a higher discontinuance rate. Thus, if presented in the labeling by itself, the nontitrated regimen would be less safe and less effective than it is when presented in the context of the full approved labeling. Under the standard in the FDA regulations, labeling that includes only the nontitrated regimen may therefore not be approved.

#### **D. The Case Law Cited By Teva Does Not Support Its Position**

Neither of the two cases Teva cites supports its position. In *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493 (D.C. Cir. 1996), the court upheld FDA's position that generic drugs could omit indications approved for the reference drug. The court's decision is specific to the issue of omitted indications and relies on a statutory provision and legislative history that deal only with indications. Nothing in the court's opinion endorses omitting dosing instructions for part of the patient population for which a product is indicated.

*Zeneca Inc. v. Shalala*, 213 F.3d 161 (4th Cir. 2000), upheld FDA's decision to permit a generic drug to bear a warning statement related to a preservative in the product, even though the labeling of the reference drug, which used a different preservative, did not include the warning. The court held that, since the statute authorized the generic manufacturer to use a different preservative, it was permissible for the generic product to have different labeling. Since FDA had concluded in that case that the generic product was safe for use because of its warning statement, Teva argues that there would similarly be no safety concerns with its proposed tramadol product because it would delete "the chronic pain use and titration schedule that is exclusive for that use." (Teva Pet. at 4) This argument fails because, as discussed in detail above, there is no distinct chronic pain use in the Ultram labeling. Moreover, Teva's proposed labeling is both confusing and incomplete and would therefore inevitably result in unnecessary adverse effects and treatment discontinuances because patients who should be titrated would not be.

#### **IV. Teva's Product, With the Labeling It Proposes, Could Not Be AB-Rated To Ultram**

Teva issued a press release stating that its tramadol product would be AB-rated to Ultram. If FDA approves Teva's product as proposed, it cannot be AB-rated.

The standards for therapeutic equivalence ratings are set forth in the preamble to *Approved Drug Products with Therapeutic Equivalence Ratings* (the "Orange Book"). Products rated "A" are

considered to be therapeutically equivalent to other pharmaceutically equivalent products.<sup>1</sup> The “AB” rating means that the determination of therapeutic equivalence is supported by a study submitted to FDA.<sup>2</sup>

The Orange Book explicitly provides that an A rating is conferred on a product only if its expected side effects when used according to its labeling are the same as those of the reference drug. Thus, the preamble states:

“Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.”<sup>3</sup>

This requirement is repeated later in the preamble when it states:

“Products evaluated as therapeutically equivalent can be expected, in the judgment of FDA, to have equivalent clinical effect and no difference in their potential for adverse effects when used under the conditions of their labeling.”<sup>4</sup>

In the case of tramadol, the titration regimen included in the current Ultram labeling was proven by a clinical study to reduce adverse effects compared to the original Ultram dosing regimen. There can be no doubt that the safety profile of a generic product using the labeling proposed by Teva would be far different than the safety profile of the current Ultram product. Consequently, current FDA policy does not allow an A rating to a generic product whose labeling does not include Ultram’s current titration regimen, which has been clinically proven to improve the safety profile of the drug.

Moreover, to be considered therapeutically equivalent and receive an A rating, a generic drug may have only minor differences in its labeling compared to the labeling of its reference drug. The Orange Book states that drugs considered to be therapeutically equivalent may differ only in

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<sup>1</sup> Orange Book at xiv.

<sup>2</sup> *Id.* at xvi.

<sup>3</sup> *Id.* at viii (emphasis added). The Orange Book further states that “FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.” *Id.*

<sup>4</sup> *Id.* at xii (emphasis added).

“minor aspects of labeling (e.g., the presence of specific pharmacokinetic information).”<sup>5</sup> The reference to pharmacokinetic information is telling because such information would rarely if ever be used by a physician in prescribing a product. By contrast, an entirely different dosing regimen for a product would be pivotal to how it is used and could hardly be characterized as a difference in a minor aspect of its labeling.

This is not a situation in which the generic drug would omit an indication approved for the innovator drug. The indication for treatment of moderate to moderately severe pain would be the same for both drugs, but the dosing instructions would differ substantially, and Teva’s proposed labeling would fail to provide instructions for a large portion of the patients who could benefit from the indicated use.

#### **V. Any FDA Approval of Scored Tablets Would Violate Ultram’s Exclusivity Rights**

Ortho-McNeil believes that at least some of the applicants for generic versions of tramadol, possibly including Teva, have proposed to manufacture 50 mg scored tablets. Ultram’s scoring permits the tablets to be divided into 25 mg segments to carry out the titration regimen for which Ultram still has exclusivity rights.

Scoring the Ultram 50 mg tablet to allow use of a 25 mg dose was an integral part of the change approved in the supplemental new drug application for the 25 mg titration regimen. As a result, the tablet scoring, as well as the related labeling change, is protected for three years from generic copying.

Tablet scoring is a product characteristic subject to exclusivity rights. For example, tablet scoring can be patented. See *Mead Johnson & Co. v. Barr Laboratories, Inc.*, 38 F. Supp. 2d 289 (S.D.N.Y. 1999). Protection of rights over scoring is also recognized in the CDER MAPP 5223.2 (attached), which indicates (under “Special Considerations” ¶¶ 2-3) that a generic product cannot duplicate the patented scoring of the reference listed drug until the patent has expired. Thus, until the current exclusivity period expires, FDA cannot lawfully approve a 50 mg generic tramadol product that is scored to permit creation of a 25 mg dose.

In addition to Ultram’s exclusivity over the scoring itself, allowing a generic product to duplicate Ultram’s scoring would violate the exclusivity rights over the labeling change recommending a dosing regimen starting at 25 mg. Accordingly, even if FDA somehow concluded that the physical scoring was not protected by exclusivity rights, use of the scoring would nevertheless still be protected. Through a costly clinical trial, RWJPRI demonstrated that a titration regimen starting at 25 mg significantly reduced certain side effects of tramadol and thereby reduced the incidence of patient discontinuation. It would effectively eviscerate Ultram’s exclusivity over

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<sup>5</sup> *Id.* at viii. Similarly, to be pharmaceutical equivalents, drugs may have different labeling “within certain limits.” *Id.*

this dosing regimen if a generic product were permitted to bear scoring that would permit its use in the protected dosing regimen.

MAPP 5223.2 explicitly prohibits generic drug scoring in this circumstance. In discussing patents on scoring configurations, the MAPP states (under "Special Considerations" ¶ 3) that, upon expiration of such a patent, "the generic firm may generally match the scoring configuration, provided there is no exclusivity on the dose obtained with that score" (emphasis added). Thus, the MAPP recognizes that, even when a scoring configuration is itself not protected by exclusivity rights, generic products are nevertheless barred from adopting the scoring if the scoring is used to facilitate dosing that is protected by exclusivity. Although the MAPP specifically addresses patent rights, there is no basis to reach a different conclusion in the case of non-patent exclusivity.

## **VI. Conclusion**

FDA should deny Teva's petition. As evidenced by its language and the history of its revisions, the Ultram labeling does not establish the distinct uses of treatment for chronic pain and treatment for acute pain, as Teva argues. Moreover, the particular labeling proposed by Teva's would be confusing and largely incomprehensible and would be less safe and less effective than Ultram for the uses it recommends because of the omission of the explanatory language related to the titration regimen.

If FDA were to conclude that it could approve Teva's ANDA under its labeling proposal, FDA must deny an AB rating to the product because of the labeling differences. Moreover, FDA cannot permit Teva's tablets to be scored during the remainder of Ultram's exclusivity rights over the scoring and the related 25 mg titration regimen.

Very truly yours,



Helen Torelli

Attachment

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PHARMACEUTICAL SCIENCES

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SCORING CONFIGURATION OF GENERIC DRUG PRODUCTS

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CONTENTS

**PURPOSE**  
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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.

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**EFFECTIVE DATE**

This guide is effective upon date of publication.

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