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Recent FDA Concept Paper for Drug Name Submission Pilot Could Impact Pharmaceutical Manufacturers More Broadly in Light of Ongoing Legal Developments

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In October, the FDA issued its concept paper on its Pilot Project for Proprietary Name Review under the Prescription Drug User Fee Act ("PDUFA Pilot"). The issuance of this concept paper represents the culmination of the FDA's multi-year effort to develop and implement a pilot program that would allow pharmaceutical companies to conduct their own trademark evaluations consistent with "best practices" and to submit the data generated from those evaluations to the FDA for review. The pilot is designed to allow the FDA to compare this new model for name submissions versus the existing model whereby industry submits a name and the FDA conducts its own de novo review of the name.

Pharmaceutical companies intending to participate in the PDUFA Pilot should begin to consider immediately its processes for trademark clearance and review in anticipation of submissions it may wish to make under the pilot in 2009 and 2010. To that end, we have provided below a summary of the planned Pilot as it is described in the FDA concept paper. A complete copy of the FDA concept paper is available by clicking here.

The initiation of the PDUFA Pilot, however, is not an isolated event. When considered in combination with recent related legal developments, pharmaceutical manufacturers should be aware of the potential that these developments may well impact pharmaceutical trademark clearance in the US beyond simply the mechanics of a preparing a pilot-version submission. Indeed, as the FDA prepares to accept submissions under PDUFA Pilot, the legal environment for conducting these reviews is also changing. For example, in December, 2007 Dennis Quaid and his wife filed an action against Baxter Healthcare Corp. alleging that Baxter should be held liable for a mix-up involving medications given to their children. The medications were manufactured by Baxter, and the Quaids allege that Baxter's use of allegedly similar labels on the medications caused the mix-up. This case remains pending.

At the same time, in the case of *Wyeth v. Levine* the U.S. Supreme Court is deliberating whether and to what extent pharmaceutical and medical device manufacturers may be held liable under state court claims for harm caused by FDA-approved products. A ruling from the Court in this case will likely determine the degree to which approval of a product by the FDA may prevent manufacturers from being held liable for harm caused by such approved products. The outcome of these cases will likely affect materially how pharmaceutical manufacturers conduct trademark and label reviews and to what degree they provide relevant data to the FDA in support of approval of the chosen trademark and label.

In light of this, the potential impact of the model being proposed by the FDA in the PDUFA Pilot on the

pharmaceutical trademark attorney should not be underestimated. For example, as the data and output of the legal clearance work becomes an integrated part of the safety review process and if this safety review could also impact potential exposure to liability arising from harm caused by mix-ups, then the analysis and decisions of the pharmaceutical trademark attorney in evaluating confusion issues involving other pharmaceutical brands may no longer be distinct from the safety review process, at least as a practical matter. As a result, the judgment and expertise of the pharmaceutical trademark attorney on issues of confusion may be extended by necessity to the regulatory approval process as well.

Therefore, one of the less obvious—but equally important—aspects of the PDUFA Pilot may be its effect on the role of the pharmaceutical trademark attorney. To the extent pharmaceutical trademark attorneys are not already playing a central role in both the legal and regulatory aspects of trademark clearance and approval, the PDUFA Pilot combined with the developing legal environment will likely thrust such a role upon them.

The following summary briefly outlines the program detailed in the FDA concept paper on the PDUFA Pilot.

Overview:
• Participation will be voluntary. Traditional submissions will still be accepted.
• Enrollment is expected to begin by September 30, 2009, and the pilot will run for two years.
• The FDA plans to accept one or two submissions per month for a total of 25 to 50 submissions under the program during its term.

Participation:
• Submissions under the program may be made during the IND process (if the product has completed phase 2 of clinical development) or as part of the initial submission of the NDA, BLA, or ANDA.
• Participants should register with the FDA in advance of any planned pilot submission, notifying the FDA of the expected submission date.
• 120 days prior to the intended submission date, the participant should contact the FDA to discuss details of the planned pilot submission.

Submissions:
• A complete submission under the program should contain the following:
  o At least one proposed name,
  o Identification of the first-choice name if more than one name is submitted,
  o A pilot version of the submission that includes all of the applicable analysis and data on acceptability of the name (a “pilot-version submission”), and
  o A traditional version of the submission (i.e., proposed name, product profile, labels, and labeling) .
• The FDA is requesting both versions because it will conduct an independent review of each version so that it may compare their effectiveness.
• The FDA is “targeting” completion of review of submissions within 180 days (90 days if submitted with the NDA or BLA).
• The FDA will continue its current practice of reviewing second-choice names only if the first-choice name is found unacceptable.

• Much of the FDA concept paper discusses evaluation methods that the FDA currently believes should be carried out in support of a name submission. Participants, however, are not required to use these methods if they are able to justify alternative data-driven processes. Alternative processes should be discussed with the FDA prior to submission.
• Participants may also request the FDA to review promotional aspects of name submissions as part of the pilot, but this aspect of a submission is optional.
• The FDA describes the following template for the safety review portion of a pilot-version submission:
  o Preliminary screening for readily identifiable objections, e.g., incorporating into a proposed trademark any dosing indications such as “BID” or indications of dosage forms or routes of administration such as “TABS” or other medical abbreviations.
  o Results of USAN stem searches.
  o Trademark searches, which should take into account not only legal comparisons but also considerations arising from the spelling, pronunciation, and scripting of names throughout the medication use system. Note: FDA-recommended resources are included in Appendix A to the paper, which may include sources not included in many traditional availability searches; therefore, such availability searches may need to be supplemented.
  o Results of computerized comparisons. The FDA recommends for the pilot that participants use computerized comparison programs in addition to other traditional comparison methods.
  o Medication error database reviews.
  o Results of name simulation studies along with a description of methodologies.
  o Results of failure mode and effects analysis (a systematic attempt to foresee potential errors and the effects of these errors).

[1] The FDA recently released a draft guidance on “Contents of a Complete Submission for the Evaluation of Proprietary Names.” Although this draft guidance does not provide any surprising new information, it does provide a formal description of the submissions requirements under the FDA’s existing practice. It is available at http://www.fda.gov/cder/guidance/7935dft.pdf.

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