

FDA Announces Pilot Program to Evaluate Proposed Drug Name Submissions

by **Marci S. Handler, Lee Rosebush**

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On May 12, 2008, the U.S. Food and Drug Administration (“**FDA**”) announced its intention to develop and implement a pilot program in which pharmaceutical manufacturers will be given the option of taking a more active role in FDA’s process of reviewing proprietary drug names.ⁱ Under current review procedures, FDA conducts *de novo* review of the proprietary names proposed by drug manufacturers and independently undertakes all testing and data analysis pertaining to both promotional and safety issues raised by proposed names. Under the proposed pilot program, pharmaceutical manufacturers will have the option of conducting tests to evaluate their proposed names and submitting to FDA for review the data generated from their evaluations. In May 2008, FDA issued a draft concept paper, entitled “PDUFA Pilot Project: Proprietary Name Review” (“**Draft Concept Paper**”),ⁱⁱ in which the Agency outlines the logistics and goals of the proposed pilot program, methodologies that applicants may use in evaluating a proposed name, and the methods by which FDA plans to review submissions under the pilot program. Additionally, FDA held a public technical meeting on June 5-6, 2008 in order to provide information and solicit feedback on the proposed program and Draft Concept Paper. FDA plans to issue a final concept paper by the end of fiscal year (“**FY**”) 2008 that describes the pilot program and the processes by which manufacturers may submit data for review. FDA is seeking comments and suggestions on the proposed pilot program and Draft Concept Paper. **Any such comments or suggestions must be submitted to FDA by July 7, 2008 at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.**

Background

FDA agreed to develop the pilot program as part of its performance goals pertaining to reauthorization of the Prescription Drug User Fee Act (“**PDUFA IV**”).ⁱⁱⁱ The pilot program is intended to increase the efficiency of FDA’s proprietary name review process.

FDA currently conducts review of proposed product names as part of its procedures for reviewing marketing applications. Through a submission process overseen by the

Division of Medication Error and Technical Support (“**DMETS**”) within the Center for Drug Evaluation and Research Office of Surveillance and Epidemiology,^{iv} FDA evaluates proposed proprietary drug names with respect to both the potential for inappropriate promotion of a product and possible safety risks that could result from use of a certain name. With regard to promotional concerns, FDA assesses whether a name could mislead consumers with respect to, for example, a product’s approved indications, efficacy for a particular indication, superiority, or risk-benefit profile.^v In evaluating a proposed drug name for safety concerns, FDA’s analysis focuses on the risk that a confusing drug name could result in medication error by a drug being misidentified during the procurement, prescription, preparation, dispensing, or administration processes.^{vi}

FDA’s current practices for evaluating drug names involve largely subjective analyses by panels of experts, including pharmacist and healthcare practitioners. Current methods include, for example, examining “look-alike” and “sound-alike” names, as well as evaluating the risk of error associated with use of a name in a product’s packaging, labeling, and associated nomenclature. FDA’s Draft Concept Paper recommends these practices, as well as additional methodologies, for manufacturers participating in the pilot program to use in generating their own data on proposed names. The additional methodologies emphasize a more scientific, empirical approach to assessing proposed names, including the use of established standards and computational methods to generate data on the risk of error associated with a proposed name. The Draft Concept Paper also provides logistical information on making submissions under the pilot program.

FDA Draft Concept Paper

Pilot Program Logistics

According to the Draft Concept Paper, FDA intends to initiate enrollment in the pilot program by the end of FY 2009 (September 30, 2009). FDA further intends to conduct the program for a two-year period, during which time the Agency hopes to receive approximately 25 to 50 submissions for review, accepting an average of one to two submissions per month. FDA proposes that manufacturers participating in the pilot program submit their name analyses and data either during the investigational new drug (“**IND**”) application process, or as part of the initial submission of a new drug application (“**NDA**”), biologic license application (“**BLA**”) or abbreviated new drug application (“**ANDA**”).^{vii}

Information Required for Submission

FDA will require that manufacturers applying for proprietary name review under the pilot program make two separate submissions to the Agency. The first submission should contain the information that FDA requires to conduct its current *de novo* review of proposed names. Such information includes, for example, proposed primary and secondary proprietary names, intended uses, dosage forms, dosage strengths, routes of administration, draft labeling, and draft professional inserts.^{viii} FDA will use this information to conduct independent testing and analyses of the proposed names using

its traditional methods. The second submission, which will be examined under the pilot program standards, should contain a comprehensive evaluation of the proposed primary and secondary names based on testing conducted by the sponsor of the data submission. The information should include “[d]ata-driven analyses of the acceptability of the proposed proprietary name, including a clear description of the methods, the data sources, and the data.”

Recommended Testing and Analyses

The Draft Concept Paper recommends various testing procedures and analyses for sponsors to perform when generating data for submission under the pilot program. These analyses involve review of a proposed name for promotional and safety considerations, with an emphasis on FDA’s primary goal of avoiding medication errors.^{ix}

Analyses that FDA recommends for addressing promotional considerations include review by experts in marketing, regulatory affairs, psychology, and law to evaluate whether a proposed name could be misleading or contain inappropriate marketing implications. The Draft Concept Paper outlines methodologies for designing controlled studies to evaluate the promotional implications of proposed drug names on an empirical basis.^x

Analyses that FDA recommends to address safety considerations include the following:^{xi}

- **Preliminary Screening.** Assesses common causes or contributors to medication errors, including name abbreviations, names that suggest drug composition, and names that suggest dosage forms or routes of administration.
- **USAN Stem Search.** Screens proposed names against the stem list created by the United States Adopted Names (“USCAN”) Council.
- **Orthographic and Phonetic Similarities.** Considers name spelling, pronunciation, letter and syllable placement, and appearance when scripted.
- **Computational Methods.** Use of computerized methods to identify orthographic and phonetic similarities between names.
- **Medication Error Data.** Use of data obtained from case reports of medication errors.
- **Name Simulation Studies.** Testing the response of healthcare practitioners to a proposed name by using the name in simulations of practical scenarios.
- **Failure Mode and Effects Analysis (“FMEA”).** Examines a product’s packaging, labeling, and associated nomenclature.

Evaluation of Pilot Submissions

FDA plans to evaluate the adequacy of the test methodology and data submitted by sponsors, as well as to conduct its own, independent analysis of a proposed name using its current practices.^{xii} FDA plans to use two different reviewers to evaluate results obtained from its traditional test methods and those obtained from data submitted by the sponsor. In doing so, FDA intends for these reviewers to compare the analyses performed by the Agency to those performed by the sponsor, as well as to compare the final conclusion reached by each as to the acceptability of the proposed name.^{xiii} According to the Draft Concept Paper, if FDA determines that the sponsor used sound methodology to generate the data submitted under the pilot program, the Agency will take this data into account, along with its own data, to make a final decision concerning approvability of a proposed name.^{xiv} The Agency also plans to use sponsors' data to determine whether the process of data submission used under the pilot program could improve the effectiveness and efficiency of FDA's current proprietary name review procedures.^{xv}

Technical Meeting

On June 5-6, 2008, FDA held a public technical meeting during which representatives from FDA, members of industry, and members of the public discussed various issues, questions, and concerns raised by the proposed pilot program. In particular, the meeting was designed to address technical developments in the testing and analysis of proprietary names, discuss the current accepted best practices with regard to taking a scientific approach to this evaluation, and voice suggestions and comments on the proposed pilot program.^{xvi} In drafting the final concept paper, FDA will take into account feedback received during this meeting, as well as comments received on the Draft Concept Paper. During the meeting, participants raised various concerns and requested clarification on several issues, including the following:

- **Scientific versus Subjective Analyses.** While the pilot program urges manufacturers to use a more empirical approach to generating and analyzing name data, FDA is using the pilot program partly to assess the effectiveness of these methodologies. Therefore, unless and until FDA decides to adopt such methodologies as part of its standard practices in reviewing name submissions, members of FDA stated that DMETS will continue during the course of the pilot program to make ultimate determinations on approvability of proposed names. In response to questions on methodology, members of FDA suggested that DMETS likely would continue to make these determinations using its current, largely subjective approaches.
- **Gap Period Between End of Pilot Program and Evaluation of Pilot Program.** FDA plans for the pilot program to run through the end of FY 2011. At the end of the program, there naturally will be a gap period during which FDA plans to evaluate the effectiveness of the pilot program and determine whether to formally adopt the pilot methodologies. Meeting participants raised questions as to what methods FDA would use to assess proposed names during that gap period; that is, whether the Agency would rely on its traditional methods, the pilot methods, or a hybrid approach that might develop during the course of the program.

- **Reconciling Inconsistent Reviews.** As FDA plans during the pilot program to use two different reviewers, one to evaluate FDA's data and the other to evaluate the sponsor's data, participants raised questions as to how FDA intends to reconcile conflicts between the reviewers' conclusions. While FDA stated that a member of DMETS likely will continue to make final determinations on approvability, the Agency also suggested that it may develop an appeals process to address the specific situation of conflicting conclusions by reviewers.
- **Dual Rejection.** Meeting participants expressed concern over the possibility of a sponsor's proposed name being rejected by both reviewers under the pilot program. Participants speculated that having one submission declined under both approaches could cast doubt on future name proposals submitted by that sponsor.
- **Cost/Benefit Analysis.** Several meeting participants questioned what, if any, potential benefit there is to manufacturers participating in the pilot program, particularly as FDA appears still uncertain as to the criteria to be used for determining approvability of proposed names under the pilot program. While members of FDA suggested that participation in the pilot program could result in a more interactive review process between DMETS and sponsors, questions remained as to whether it makes financial sense for sponsors to participate in the pilot program when conducting the tests necessary for submission could total hundreds of thousands of dollars.

Manufacturers and sponsors should review FDA's Draft Concept Paper and determine whether to take advantage of the comment period to provide comments or suggestions to FDA on the proposed pilot program. Manufactures also should consider the issues noted above to inform their comments and suggestions to FDA on outstanding questions concerning the proposed pilot program.

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For questions regarding this alert and topic, please contact:

Marci S. Handler
Washington, DC
202/861-1382
mhandler@ebglaw.com

Lee Rosebush
Washington, DC
202/861-5324
lrosebush@ebglaw.com

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Lynn Shapiro Snyder, Esq.
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Endnotes:

- ¹ 73 Fed. Reg. 27,001 (May 12, 2008).
- ² Draft Concept Paper “PDUFA Pilot Project: Proprietary Name Review (May 2008), available at http://www.fda.gov/cder/drug/MedErrors/meeting_names.pdf.
- ³ See Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Pub. L. 110-85, 121 Stat. 823, which was signed into law and includes the reauthorization and expansion of the Prescription Drug User Fee Act (“PDUFA IV”).
- ⁴ See <http://www.fda.gov/cder/Offices/ODS/divisions.htm>.
- ⁵ See Draft Concept Paper “PDUFA Pilot Project: Proprietary Name Review (May 2008) at 21, available at http://www.fda.gov/cder/drug/MedErrors/meeting_names.pdf.
- ⁶ *Id.* at 3.
- ⁷ *Id.* at 7.
- ⁸ *Id.* at 29; 73 Fed. Reg. 27,001.
- ⁹ *Id.* at 24.
- ¹⁰ *Id.* at 21.
- ¹¹ *Id.* at 10-19.
- ¹² *Id.* at 24.
- ¹³ *Id.* at 7-8.
- ¹⁴ *Id.* at 9.
- ¹⁵ *Id.*
- ¹⁶ See 73 Fed. Reg. 27,002.