POLICY AND PROCEDURES

OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY

Procedures for Handling Requests for Proprietary Name Review

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PURPOSE

This MAPP describes procedures to be used in the Center for Drug Evaluation and Research (CDER) by the Office of Surveillance and Epidemiology (OSE), including the Division of Medication Error Prevention and Analysis (DMEPA) and the Safety Regulatory Project Management Staff (SRPMs), and by the Office of New Drugs (OND), Office of Generic Drugs (OGD), and the Office of Prescription Drug Promotion (OPDP) in the Office of Medical Policy for handling requests for proprietary name review that may be submitted to investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs)[1], efficacy supplements, labeling supplements (Efficacy/Labeling Supplements) or abbreviated new drug applications (ANDAs).

The procedures outlined in this MAPP apply to all types of requests submitted for review of proposed proprietary names (primary, alternate, or names for reconsideration).

BACKGROUND

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) was enacted, which reauthorized the Prescription Drug User Fee Act of 1992 (PDUFA) in Title I, Prescription Drug User Fee Amendments of 2007 (PDUFA IV). In conjunction with the reauthorization of PDUFA, the Food and Drug Administration (FDA) agreed to meet specific review performance goals. These goals are described in

[1] For the purposes of this MAPP, BLAs include only therapeutic biological products regulated by CDER

PDUFA Reauthorization Performance Goals and Procedures (see References).[2] Under the PDUFA IV goals, CDER agreed to develop a MAPP by the end of fiscal year 2009 to ensure that FDA internal processes for review of proposed proprietary names are consistent with meeting the stated review goals. To meet the review performance goals, a decision about request for a proposed proprietary name submitted during IND development must be communicated ot the application holder within 180 days of receipt of the request. For a proposed proprietary name submitted with an NDA/BLA or as part of a supplemental application, a review must be completed and a decision must be communicated to the applicant within 90 days of the receipt of the request to meet the review performance goals.

Additionally, on July 9, 2012, the Generic Drug User Fee Amendments (GDUFA) was signed into law to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. Under GDUFA, FDA agreed to meet certain obligations as laid out in the GDUFA Commitment Letter,[3] including review performance goals. To meet these goals, OSE and OGD will coordinate and strive to provide a decision regarding a request for a proposed proprietary name review to meet any applicable GDUFA goals. .

In accordance with the Delegation of Authority Memorandum, Staff Manual Guides 1410.104, paragraph 1(I), signed by the Acting Commissioner of FDA on April 29, 2009, OSE/DMEPA has signatory authority for all decisional letters regarding review of proprietary names.

POLICY

- OSE will manage review of proposed proprietary names. OSE will lead an interdisciplinary review team, including OND, OPDP, and other CDER offices, as relevant, in the review of proposed proprietary names.

- OSE will ensure that discussions and decisions for review of proprietary name requests will be made in accordance with CDER's policy on equal voice, differing professional opinions, and, if necessary, dispute resolution.[4]

[2] The Goal Letter states, "To enhance patient safety, FDA will utilize fees to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names and such factors as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design." The letter also includes review performance goals for drug/biological product proprietary names. (See http://www.fda.gov//ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm.)

[3] See GDUFA Program Performance Goals and Procedures for fiscal years 2015 through 2017, available at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.

[4] MAPP 4151.1, Resolution of Disputes: Roles of Reviewers, Supervisors and Management: Documenting Views and Findings and Resolving Differences, and MAPP 4151.2, Documenting Differing Professional Opinions and Dispute Resolution – Pilot Program

- OSE staff will notify application holders about the acceptance or non-acceptance of proposed proprietary names within specified time frames (i.e., Proprietary Name goal dates).

- OSE will have the lead responsibility for communicating with industry about CDER review of proposed proprietary names, including letters (e.g., information request letters and letters with the conditional acceptance or non-acceptance decisions prior to final action on marketing applications or supplements), teleconferences, and meetings.

- Where notification about acceptance or non-acceptance of a proposed proprietary name is performed in conjunction with other regulatory actions for which delegation of authority is not with OSE, then OND will include recommendations and decisions from OSE in these letters.

RESPONSIBILITIES AND PROCEDURES

Overview

The Proprietary Name Review (PNR) process starts when OSE receives a proposed proprietary name submission from the document room; OSE then leads the review process, seeking expertise from other CDER offices as appropriate to the needs of the review. OSE asks OPDP for recommendations regarding any promotional concerns that may misbrand the drug. OSE consults OND twice in the process. Initially, OSE asks whether OND has any preliminary safety concerns with the proposed proprietary name and whether they concur with the OPDP recommendation. Approximately midway through the proprietary name review cycle, OSE conveys its decision regarding the acceptability of the proposed proprietary name and asks whether any factors have been identified that may impact the acceptability of the proposed proprietary name. OSE writes and archives one consolidated review that incorporates all CDER viewpoints and recommendations expressed throughout the review process. The DMEPA Division Director or Designee signs the proprietary name letters that are sent to the application holder.

This section outlines the responsibilities of all CDER participants involved in the proprietary name review process.

The White Oak Document Room (DR1) will:

- Process “Request for Proprietary Name Review”, “Amendment to Request for Proprietary Name Review” and “Request for Reconsideration of Proprietary Name” submissions (all are hereafter referred to as Requests).

- Ensure that the correct status and reviewer assignments are made in the application tracking database(s) for each Request according to the instructions of the OSE SRPM.

The DMEPA Workload Coordinator (WLC) will:

- Evaluate the Request for completeness (refer to the *Guidance for Industry: Contents of a Complete Submission for the Evaluation of Proprietary Names*).

- Notify the OSE SRPM if the Request is incomplete and therefore cannot be reviewed. Provide any relevant information to the OSE SRPM for inclusion in the letter to the applicant holder regarding incomplete Requests.

- Assign a complete Request it to the appropriate DMEPA reviewer.

- Send reviewer assignments to DR1 and the OSE SRPM

The OSE Safety Regulatory Project Manager (SRPM) will:

- Serve as the point of contact for communications with the application holder regarding proprietary names.

- Contact the application holder if a proprietary name request was not submitted appropriately. If necessary, refer them to the *Guidance for Industry: Contents of a Complete Submission for the Evaluation of Proprietary Names.*

- Evaluate the weekly report to ensure that all new proposed proprietary name submissions are assigned to a DMEPA reviewer.

- If notified by the DMEPA WLC that the Request is incomplete, send the regulatory response governing the incompleteness of the submission to the application holder within 30 days of receipt of the request for name review and ensure the proprietary name review clock has been stopped.

- Maintain and generate a weekly list of newly submitted proposed proprietary names and names for reconsideration, available in OSE's electronic tracking system, and forward the list to OPDP for their recommendation on the acceptability of the proposed proprietary name from a promotional perspective that may misbrand the product.

- Forward OPDP recommendations by e-mail to the OND RPM for OND Division concurrence/non-concurrence, requesting any additional OND comments.

- When necessary, schedule a joint meeting with pertinent parties to reconcile differences of opinion regarding the acceptability or concerns with the proposed proprietary name.

- Schedule internal and industry proprietary name meetings, complete and communicate minutes to application holder as needed, and copy OND, OPDP, and other offices when minutes and letters are electronically filed.

- Maintain contact with the OND RPM through regular updates regarding the DMEPA reviewer assignments and status of OSE's review of proposed proprietary names.

- Draft, and upon concurrence from the DMEPA Division Director or Deputy Director, send and/or process the decisional letter to the application holder, with a copy to OND no later than the specified goal date (90 days for NDA/BLA and 180 days for INDs), and ensure that the proprietary name review clock has been stopped.

The DMEPA Safety Evaluator (SE) will:

- Initiate safety assessment of the proposed proprietary name and discuss the overall findings with the DMEPA Division Director or Designee(s) at midpoint of the review.

- Convey DMEPA's decision regarding the acceptability of the proposed proprietary name to the OND RPM and copy the OSE SRPM.

- Write and archive a review incorporating the input of other CDER review disciplines received throughout the review cycle regarding the acceptability of all proposed proprietary names, and ensure OPDP, OND, and other relevant disciplines are copied on the review. The review will include the recommendation provided by OPDP and any comments or concerns from OND.

- Provide letter ready comments to the OSE SRPM that conveys FDA's decision regarding the application holder's proposed proprietary name by the specified goal date.

The DMEPA Team Leader will:

- Ensure that viewpoints from relevant CDER disciplines are sought and incorporated into the DMEPA review that timelines are met, and that relevant CDER disciplines are copied on the review.

- Provide secondary review for the DMEPA SE on the proposed proprietary name review.

The DMEPA Division Director or Designee will:

- Provide tertiary review and clearance of the DMEPA SE review.

- Sign the proprietary name decisional letter to the application holder.

The OPDP Contact will:

- Provide OPDP's recommendations to the OSE SRPM on the proposed proprietary names from the weekly list of newly submitted names, and review requests for reconsideration of proposed proprietary names that were found unacceptable based on any promotional concerns that may misbrand the drug.

- Participate as needed in application holder meetings or in meetings to reach CDER alignment.

The OND Regulatory Project Manager (RPM) will:

- Triage Requests (e.g., document room shelf triage) to ensure that they are correctly identified and routed to the OSE SRPM.
- Inform the OSE SRPM if they become aware that a request for proprietary name review was not submitted in accordance with the *Guidance for Industry: Contents of a Complete Submission for the Evaluation of Proprietary Names.*
- Participate as needed in application holder meetings or in meetings to reach CDER alignment.
- Send OPDP recommendations to the review team for concurrence or comments.
- Obtain any OND Division preliminary safety concerns with the proposed proprietary name and concurrence or non-concurrence (including any other comments) on OPDP's recommendations (received through the OSE SRPM) regarding any misbranding or misleading aspects of the proposed proprietary name.
- Share DMEPA's decision regarding the acceptability of the proposed proprietary name with the OND Division and determine if any factors have been identified that may impact the acceptability of the proposed proprietary name, and forward to the OSE SRPM.
- Maintain contact with the OSE SRPM regarding changes in the application that would affect the DMEPA review, such as fileability, withdrawal, changes to proposed indication or other product characteristics, changes in the application/supplement goal date or action date, significant safety issues, and clinical holds.
- Notify the OSE SRPM upon receipt of a resubmission after a complete response to a NDA, BLA, or Supplement, so that OSE can determine the need for a proprietary name review.
- Forward all meeting requests (MR) concerning proposed proprietary names to the OSE SRPM and revise the application tracking database(s), if needed, to reflect the OSE SRPM as the lead for the meeting request.

The OGD Project Manager will:

- Review submissions to the ANDA and notify the OSE SRPM of Requests to ensure that they are correctly identified, coded and routed to OSE.
- Participate as needed in application holder meetings or in meetings to reach CDER alignment.
- Maintain contact with the OSE SRPM and WLC, via the appropriate e-mail distribution list, regarding changes in the application that would affect the DMEPA review.
- Notify the OSE SRPM upon receipt of a resubmission after a complete response to an ANDA if the applicant has submitted a proprietary name in the past.
- Forward all MR concerning proposed proprietary names to the OSE SRPM and revise the application tracking database(s), if needed, to reflect the OSE SRPM as the lead for the meeting request.

REFERENCES

1. PDUFA Reauthorization Performance Goals and Procedures, Food and Drug Administration Amendments Act of 2007 (http://www.fda.gov//ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm)

2. Guidance for Industry on Contents of a Complete Submission for the Evaluation of Proprietary Names (February 2010) http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf

3. Memorandum of Agreement between the Office of New Drugs and the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research (June 2009) http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111520.pdf

4. The Goal Letter states, "To enhance patient safety, FDA will utilize fees to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names and such factors as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design." The letter also includes review performance goals for drug/biological product proprietary names. (See http://www.fda.gov//ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm.)

5. CDER MAPP 4151.8, Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions, Effective 09/16/10.

http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM229014.pdf

6. National Coordinating Council for Medication Error Reporting and Prevention (http://www.nccmerp.org)

7. MAPP 4151.1, "Resolution of Disputes: Roles of Reviewers, Supervisors, and Management: Documenting Views and Findings and Resolving Differences" (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffPoliciesandProcedures/ucm073557.pdf)

8. MAPP 4151.2, "Documenting Differing Professional Opinions and Dispute Resolution—Pilot Program" http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffPoliciesandProcedures/ucm073558. pdf

9. Delegation of Authority, SMG 1410.104, Approval of New Drug Applications and Their Supplements, April 29, 2009 (http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm049625.html)

DEFINITIONS

- Drugs: For the purposes of this MAPP, drug refers to human drug products, including therapeutic biological products regulated by CDER.

- Medication error: The National Coordinating Council for Medication Error Reporting and Prevention describes medication error as

  "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use"[5].

- Proprietary name: The proprietary name is the exclusive name of a drug product owned by a company under trademark law regardless of registration status with the U.S. Patent and Trademark Office.

[5] National Coordinating Council for Medication Error Reporting and Prevention Website, http://www.nccmerp.org/aboutMedErrors.html

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
09/16/2009	Initial	n/a
xx/xx/2015	Rev 1	1. Updates to include new office names 2. Updates references and definitions 3. Updates responsibilities. 4. Combines the responsibilities and procedure section 5. Deletes the procedure table and moves the information under responsibilities and procedures.