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 Divisions of Medication Error Prevention and Analysis (DMEPA I and DMEPA II) in the Office of Medication Error Prevention and Risk Management (OMEPRM) 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) and supplemental 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

The Prescription Drug User Fee Act of 1992 (PDUFA) added sections 735 and 736 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), authorizing the Food and Drug Administration (FDA) to meet specific review performance goals. Since 1992, Congress has revised and extended PDUFA six times, each time for a 5-year period. 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. The most recent reauthorization is the FDA User Fee Reauthorization

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

Act of 2022, which includes PDUFA VII. The FDA User Fee Reauthorization Act of 2022 also includes the second reauthorization of the Generic Drug User Fee Amendments (GDUFA III) and the second reauthorization of the Biosimilars User Fee Act (BsUFA III).

As part of the reauthorizations FDA agreed to performance goals for review of proprietary names submitted during the IND phase or with an NDA or BLA. These goals are described in PDUFA Reauthorization Performance Goals and Procedures (see References)[2]. To meet the review performance goals, a decision about a request for a proposed proprietary name submitted during IND development must be communicated to 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 NDA/BLA, 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. For a proposed proprietary name submitted with an ANDA or supplemental ANDA, OSE and OGD will coordinate and strive to provide a decision on the proprietary name consistent with any applicable GDUFA goal dates for the submission. This may include a goal date extension, when necessary, if a late submission with a proposed proprietary name is received. The goal date extension will be in accordance with the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter)[3].

In accordance with the Delegation of Authority Memorandum, Staff Manual Guides 1410.104, paragraph 1(I), signed by the Commissioner of FDA on June 12, 2012, OSE/DMEPA has signatory authority for all decisional letters regarding review of proprietary names for drugs[4] for human use that are the subject of an IND, NDA, ANDA, or BLA for biologics under their jurisdiction, and supplements submitted or approved under the FD&C Act.

POLICY

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

- OSE will ensure that discussions and decisions for review of proprietary name requests

[2] The Commitment Letter states, "To enhance patient safety, FDA is committed to 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 https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027

[3] See GDUFA Program Performance Goals and Procedures for fiscal years 2023 through 2027, available at https://www.fda.gov/media/153631/download

[4] For the purposes of this MAPP, the term *drug* or *drug products* refers to drug products approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and therapeutic biologics and biosimilar products licensed under sections 351(a) and 351(k) of the Public Health Service Act, and drug- and biologic-led combination products, unless otherwise specified.

will be made in accordance with CDER's policy on equal voice, differing professional opinions, and, if necessary, dispute resolution[5].

- 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 or OGD will include recommendations and decisions from OSE in these letters.

RESPONSIBILITIES AND PROCEDURES

Overview

The Proprietary Name Review (PNR) process starts when the Agency receives a proposed proprietary name submission; 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 during the process to ask whether OND has any safety/other concerns with the proposed proprietary name and whether they concur with the OPDP recommendation. Once a determination is reached, OSE conveys its decision regarding the acceptability of the proposed proprietary name to OND or OGD. OPDP does not provide recommendations regarding nonprescription drug products or over-the-counter (OTC) drug product names; the Divisions of Nonprescription Drug Products (DNPD I and DNPD II) provide recommendations regarding promotional concerns with proposed nonprescription proprietary names that may misbrand the drug product. OSE writes and archives one consolidated review that incorporates all CDER viewpoints and recommendations expressed throughout the review process. The DMEPA I or DMEPA II 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.

[5] MAPP 4151.8 Rev.1 Equal Voice: Collaboration and Regulatory and Policy Decision-Making in CDER We update MAPPs periodically. For the most recent version of a MAPP, check the FDA MAPP web page at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp.

The White Oak Document Room (DR1) will:

- Process "Request for Proprietary Name Review," "Amendment to Request for Proprietary Name Review," "Request for Reconsideration of Proprietary Name," "Authorized Generics," and "Proprietary Name Withdrawal Request" 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 I and DMEPA II 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 application holder regarding incomplete Requests.

- Assign a complete Request to the appropriate DMEPA I or DMEPA II reviewer as instructed by the DMEPA I or DMEPA II team leader in the assignment tracking system.

The OSE Safety Regulatory Project Manager (SRPM) will:

- Serve as the point of contact for communications with the application holder regarding proprietary names and upload the communication to the regulatory history of the application.

- 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.*

- If notified by the DMEPA I or DMEPA II WLC that the Request is incomplete, send the letter noting the incompleteness of the submission to the application holder within 30 days of Agency receipt of the Request and ensure the proprietary name review clock has been stopped.

- Ensure newly submitted proposed proprietary names and names for reconsideration for prescription drug products are captured in the weekly, system-generated list, which is automatically sent to OPDP for its review[6].

[6] For nonprescription proprietary names, the Divisions (DNPD I and DNPD II) are asked to provide the promotional review.

- 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, OGD, OPDP, and other offices when minutes and letters are electronically filed.

- Draft, and upon concurrence from the DMEPA I or DMEPA II Division Director or Designee, send and/or process the decisional letter to the application holder, with a copy to OND and OGD (as applicable), no later than the specified goal date (90 days for NDA/BLA and 180 days for INDs, or in accordance with any applicable GDUFA goal dates for ANDA submissions), and ensure that the proprietary name review clock has been stopped.

The DMEPA I and DMEPA II Safety Evaluator (SE) will:

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

- Convey DMEPA I's or DMEPA II's decision regarding the acceptability of the proposed proprietary name via the centralized workflow management application for tracking reviews of proprietary names (i.e., NEXUS).

- 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, OGD and other relevant disciplines are copied on the review. The review will document the recommendation(s) 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 I or DMEPA II Team Leader will:

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

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

The DMEPA I or DMEPA II Division Director or Designee will:

- Provide tertiary review and clearance of the DMEPA I or DMEPA II 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:

- Review submissions 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.

- 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 I's or DMEPA II's decision regarding the acceptability of the proposed proprietary name with the OND Division review team.

- Maintain contact with the OSE SRPM regarding changes in the application that would affect the DMEPA I or DMEPA II 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 I and DMEPA II reviews.

- 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. Section A: PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 Through 2012 (PDUFA IV) https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-legislation-and-background-pdufa-iv

2. PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027

3. Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (April 2016) We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents

4. CDER MAPP 4151.8, Rev. 1: Equal Voice: Collaboration and Regulatory and Policy Decision-Making in CDER, Effective 04/12/22. https://www.fda.gov/media/157807/download

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

6. Delegation of Authority, SMG 1410.104, Approval of New Drug Applications and Their Supplements, June 12, 2012 https://www.fda.gov/media/84863/download)

DEFINITIONS

- Drug or Drug Product: For the purposes of this MAPP, drug or drug products refers to human drug products, including therapeutic biological products and drug- and biologic-led combination products regulated by CDER, unless otherwise specified.

- Medication error: A medication error is any preventable event that may cause or lead to inappropriate medication use or medication-related 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[7].

- Proprietary name: The proprietary name of a drug product is its brand name[8].

EFFECTIVE DATE

This MAPP is effective upon date of publication.

[7] See also National Coordinating Council for Medication Error Reporting and Prevention, available at https://www.nccmerp.org/about-medication-errors, last accessed on October 17, 2023

[8] Sometimes referred to as the products "trade name"

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
09/16/2009	Initial	n/a
01/07/2015	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.
08/08/2024	Rev 2	1. Updates to include new division names due to office organization 2. Updates background with information on user fee reauthorizations 3. Updates footnotes and references with new user fee links 4. Clarifies roles for promotional review of nonprescription drug proprietary names 5. Updates frequency and timing of touchpoints with relevant involved offices 6. Updates responsibilities and procedures to reflect the use of CDER's centralized workflow management application for the tracking of reviews of proprietary names.