POLICY AND PROCEDURES

OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY

Procedures for Sharing Non-public Information on Pending Proposed Proprietary Names

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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's (OSE) Division of Medication Error Prevention and Analysis (DMEPA) and the Safety Regulatory Project Management (SRPM) Staff. These procedures are to be used when OSE's evaluation identifies that two or more proposed proprietary drug names submitted in pending applications[1] are so similar that they could cause confusion and result in medication errors.

In such circumstances, with the consent of the affected application holders,[2] OSE will share certain information that may be non-public with the affected application holders. The information shared will be shared for the sole purpose of facilitating discussions between the affected application holders regarding the naming conflict(s).

[1] Investigational new drug applications (INDs), new drug applications (NDAs), biologic license applications (BLAs), or abbreviated new drug applications (ANDAs).

[2] For the purposes of this MAPP, the term "affected application holder" means an application holder or the authorized representative of an application holder that has submitted a proposed proprietary name (as part of a pending application) that OSE has identified as having the potential to be confused with another proprietary name proposed as part of another pending application or applications.

BACKGROUND

OSE reviews proposed proprietary names submitted in pending applications.[3] OSE's evaluation may indicate that certain proposed proprietary names submitted in pending applications are so similar that there is potential for name confusion that could result in medication errors.

In such instances, it may be of interest to the affected application holders to have the opportunity to discuss and possibly resolve the naming conflict(s). To this end, with the consent of the affected application holders and according to the procedures specified in this MAPP, OSE will facilitate the disclosure of the following non-public information to each affected application holder: (1) the name of the affected application holder and (2) the name, title, and contact information of an authorized representative for each of these affected application holders.

POLICY

- OSE will manage the review of proprietary names in accordance with the procedures described in MAPP 6720.2 Rev. 1 *Procedures for Handling Requests for Proprietary Name Review*.

- When OSE identifies that there are two or more proprietary names under review that could result in medication errors caused by potential confusion with each other, OSE will, with the consent of the affected application holders, share certain information that may be non-public with the affected application holders. The information shared will be shared for the sole purpose of facilitating discussions among the affected application holders regarding the naming conflict(s).

- This process reflects the fact that once an IND or an application is filed with a proposed proprietary name that conflicts with a previously filed IND or an unapproved application, both proposed proprietary names are "unacceptable" until one application is approved, regardless of which application was filed first.

- OSE staff will seek consent from each affected application holder to disclose:

    - The fact that the affected application holder has submitted as part of a pending application a proposed proprietary name that OSE's evaluation indicates is

[3] See MAPP 6720.2, Rev. 1, *Procedures for Handling Requests for Proprietary Name Review.*

unacceptable due to potential confusion with a proprietary name proposed as part of one or more other pending applications.[4]

- The name, title, and contact information of the application holder or authorized representative.

- The DMEPA Division Director (DD) or designee is the signatory for the "unacceptable" letter and the "disclosure authorization request" letter.

- If one or more affected application holders fails to respond to the disclosure authorization request letter within 14 business days from the date of the request letter, or an affected application holder denies the disclosure request, OSE staff will not issue any follow-up communications regarding this matter to the affected application holders.

- If each affected application holder consents to the release of the information listed above, OSE staff will disclose the information to the affected application holders pursuant to the procedures outlined in this MAPP. OSE staff will not participate in any further actions to facilitate interactions between the affected application holders concerning the conflicting proposed proprietary names.

RESPONSIBILITIES

- **DMEPA**

  Reviews all proprietary name requests received as described in MAPP 6720.2 Rev. 1 *Procedures for Handling Requests for Proprietary Name Review*.

- **DMEPA Division Director (DD) or Designee**

  - Notifies the OSE Safety Regulatory Project Manager (SRPM) to initiate the procedure for contacting all affected application holders to request disclosure authorization when OSE's evaluation indicates that two or more pending proposed proprietary names under Agency review could result in medication errors due to potential confusion with one another.

  - Signs the proposed proprietary name "unacceptable" letter and the "disclosure authorization request" letter to be sent to the affected application holders.

[4] In certain circumstances, this information may reveal confidential commercial information of an affected application holder. For example, FDA is prohibited from disclosing or acknowledging the existence of a pending application unless the existence of that application has been previously disclosed or acknowledged by an authorized source. See, e.g., 21 C.F.R. §§ 312.130, 314.430, 601.50, and 601.51.

- Signs the letters transmitting non-public information.

- **OSE SRPM**

  - Drafts the proprietary name "unacceptable" letter and disclosure authorization request letter to the application holders or authorized representatives.

  - Drafts and processes and/or sends letters disclosing non-public information (Attachment II) to the application holders or authorized representatives upon receipt of written authorization from all affected application holders or authorized representatives.

PROCEDURES

1. DMEPA evaluates all proprietary name review requests as described in in MAPP 6720.2 Rev. 1 *Procedures for Handling Requests for Proprietary Name Review* and determines if a proposed proprietary name under review is potentially in conflict with another proposed proprietary name under review.

2. The DMEPA DD or designee notifies OSE SRPM when DMEPA's evaluation indicates that two or more pending proposed proprietary names are in conflict to initiate procedures for sharing non-public information on pending proposed proprietary names.

3. OSE SRPM:
   a. Drafts a proprietary name "unacceptable" letter and a "disclosure authorization request" letter (Attachment I) for each affected application holder.
   b. Obtains letter clearance from the DMEPA DD or designee.
   c. Processes and/or sends the "unacceptable" letters and the "disclosure authorization request" letters to the affected applicants.

4. DMEPA DD or designee:
   a. Reviews the "unacceptable" letters and the "disclosure authorization request" letters.
   b. Signs cleared "unacceptable" letters and the "disclosure authorization request" letters.
   c. Reviews the "Transmitting Non-Public Information Letter" letters
   d. Signs cleared "Transmitting Non-Public Information Letter" letters

5. OSE SRPM:

   a. Processes and/or sends a letter to each affected application holder disclosing the non-public information (Attachment II) after receiving a signed disclosure authorization letter from all affected application holders.

   b. When no response is received from one or more of the affected application holders, communicates the following to any of the affected application holders who send the Agency a query regarding the disclosure of non-public information:

      "Due to the lack of response from the other affected application holder, we are unable to share any further information."

   c. When a negative response is received from one or more of the affected application holders, communicates to any of the affected application holders who send the Agency a query regarding the disclosure of non-public information:

      "Due to the negative response received from the other affected application holder, we are unable to share any further information."

   Note: If no response or a negative response is received from one or more of the affected application holders, the Agency will not issue any follow-up communications to any of the affected application holders.

REFERENCES

1. 21 C.F.R. §§ 20.61, 312.130, 314.430, 601.50, and 601.51.

2. 18 U.S.C. § 1905, 5 U.S.C. § 552(b)(4). Disclosure of Confidential Information Generally.

3. Guidance for industry, *Contents of a Complete Submission for Evaluation of Proprietary Names*. *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformatin/Guidances/UCM075068.pdf*

4. CDER MAPP 6720.2 Rev.1, *Procedures for Handling Requests for Proprietary Name Review*, effective 1/7/2016. http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM182730.pdf

5. Draft Guidance for Industry, *Best Practices in Developing Proprietary Names for Drugs*. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm398997.pdf

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
09/21/16	Initial	N/A

ATTACHMENT I – Disclosure Authorization Request Letter

[If there are more than two affected application holders, modify the language below accordingly.]

You have been notified in the unacceptable letter dated *date of letter* that the proprietary name, *add proposed name*, you proposed could result in medication errors due to confusion with another product's proposed proprietary name that is also under review. The ultimate acceptability of your proposed proprietary name is dependent upon which underlying application is approved first. If you would like the contact information of the other affected application holder or authorized representative that has submitted the conflicting name as part of a pending application, please complete and submit contact information (non-public information) within 14 business days from the date of this correspondence. You should submit this information on your letterhead to your application as a general correspondence, and provide a copy to OSE SRPM [insert PM name here]. You will find below a suggested format for your authorization letter permitting FDA to disclose your non-public information to the other affected application holder.

If OSE receives written authorization from **both** application holders or authorized representatives, OSE will provide each applicant with the name, title, and contact information of the authorized representative for the affected application holder for each affected application. OSE will not participate in any discussion between the application holders or authorized representatives. If all affected parties do not consent to disclosure of their contact information, OSE will not provide any further information to you about the product with the conflicting proposed proprietary name.

Example:

> NDA/BLA/ANDA/IND #
>
> [Insert FDA contact address]
> RE: FDA sharing of non-public information concerning **[NDA/BLA/ANDA/IND #]** and regarding proposed proprietary name, **[enter proposed proprietary name]**
>
> Dear [**FDA contact name (OSE SRPM)**]:
>
> On behalf of **[NDA/BLA/ANDA/IND application holder or authorized representative]**, I authorize the United States Food and Drug Administration (FDA) and its staff to disclose the information described below to the holder (or its authorized representative) of the pending application that contains a proposed proprietary name that CDER believes is in conflict with the proprietary name contained in a pending application **[NDA/BLA/ANDA/IND #]** submitted by **[NDA/BLA/ANDA/IND application holder]**. The information will be shared

for the purpose of facilitating discussions between **[NDA/BLA/ANDA/IND application holder]** and the other affected application holder about the conflicting proposed proprietary names.

I understand that this information may constitute confidential commercial information that would ordinarily be protected from disclosure under FDA's regulations and relevant law. (This includes, without limitation, 21 C.F.R. §§ 20.61, 312.130, 314.430, 601.50, and 601.51; 18 U.S.C. § 1905 (the "Trade Secrets Act," and 5 U.S.C. § 552(b)(4) (the "FOIA."). I agree to hold FDA harmless for any injury caused by FDA disclosing the information to be shared.

To this end, I hereby authorize FDA to disclose the following information, understanding that doing so will also disclose the fact that **[NDA/BLA/ANDA/IND application holder]** has submitted as part of a pending application a proposed proprietary name that CDER believes is unacceptable due to potential confusion with a proprietary name proposed as part of one or more other pending applications: **Name, title, and contact information (address, telephone number, and email address) of authorized representative for NDA/BLA/ANDA/IND application holder**.

As indicated by my signature, I am authorized to provide this consent on behalf of **[NDA/BLA/ANDA/IND application holder]**, and my full name, title, address, telephone number, and email address are set out below.

Sincerely,
(Signature)
(Printed name)
(Title)
(Address, telephone number, and email address)

ATTACHMENT II –Transmitting Non-Public Information Letter

NDA/BLA/ANDA/IND #

[Insert Sponsor Contact address]

RE: FDA sharing of non-public information concerning **[NDA/BLA/ANDA/IND #]** and regarding proposed proprietary name, **[enter proposed proprietary name]**

Dear [**Application Holder or Authorized Representative Name from Disclosure Authorization Request Letter**]:

The United States Food and Drug Administration (FDA) and its staff have been authorized to disclose to you the information included below. This disclosure is for the purpose of facilitating discussions between you and the authorized representative of the holder of the pending application for the product that CDER believes has a proposed proprietary name that conflicts with the proprietary name you have proposed for your product. All parties have provided their written consent to this disclosure and agree to hold FDA harmless for any injury caused by this disclosure of their contact information.

The information that the other authorized representative has consented to share with you is as follows:

Include the following from the Disclosure Authorization Request Letter: Name, title, and contact information (address, phone number, and email address) of application holder or authorized representative.

Sincerely,

Signature block of DMEPA Division Director