POLICY AND PROCEDURES

OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY

Procedures for Handling Requests for Nonproprietary Name Suffix Review for Biological Products Newly Licensed Under Section 351of the PHS Act

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PURPOSE

This MAPP describes procedures for handling requests for nonproprietary name suffix review for investigational new drug applications (INDs) and biologics license applications (BLAs)[1] for originator biological products, related biological products, and biosimilar products to be used in the Center for Drug Evaluation and Research (CDER) by the following offices;

- Office of Surveillance and Epidemiology (OSE), including the Division of Medication Error Prevention and Analysis (DMEPA) and the Safety Regulatory Project Management Staff (SRPMs),
- Office of New Drugs (OND), Therapeutic Biologics and Biosimilars Staff (TBBS),
- Office of Prescription Drug Promotion (OPDP) in the Office of Medical Policy (OMP),
- Office of Biotechnology Products (OBP) and Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ),
- Office of Regulatory Policy (ORP), and
- Office of Chief Counsel (OCC)

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

The procedures outlined in this MAPP apply to the review of distinguishing suffixes identified by FDA and requests for review[2] of suffixes proposed by a sponsor for FDA to designate in the nonproprietary names of originator biological products, related biological products, and biosimilar products (other than interchangeable products) newly licensed under section 351(a) or 351(k) of the Public Health Service Act (PHS Act).

This MAPP does not apply to biological products previously licensed under section 351(a) or 351(k) of the PHS Act. This MAPP also does not apply to biological products that are the subject of an approved application under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as of March 23, 2020, when such an application is deemed to be a biologics license application (BLA) under section 351 of the PHS Act on March 23, 2020 (*transition biological products*).[3]

BACKGROUND

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act)[4] established an abbreviated licensure pathway for products demonstrated to be biosimilar to or interchangeable with an FDA-licensed *reference product.* [5]

In January of 2017, FDA issued final guidance (REF. 1) describing FDA's current thinking on the need for biological products licensed under the PHS Act to bear a *nonproprietary name* that includes an FDA-designated suffix. Under this naming convention, the nonproprietary name designated for each *originator biological product*, *related biological product*, and *biosimilar product* is a *proper name* that is a combination of the *core name* and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters. The suffix format described in this guidance is applicable to originator biological products, related biological products, and biosimilar products licensed under section 351(a) or 351(k) of the PHS Act. The naming convention is appropriate to help facilitate safe use and pharmacovigilance for the products to which it applies.

Our final guidance notes that FDA is continuing to consider the appropriate suffix format for *interchangeable products.* FDA has issued a draft guidance for industry entitled

[2] Including requests to review primary and alternative suffix candidates as described in section V(a) and (c) of the FDA's guidance for industry, *Nonproprietary Naming of Biological Products*, along with any requests for reconsideration related to FDA's prior finding that a proposed suffix was unacceptable.

[3] See section 7002(e)(4) of the BPCI Act.

[4] Sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Public Law 111-148).

[5] See the Definitions for specific terms used throughout this MAPP.

Nonproprietary Naming of Biological Products: Update[6] which describes FDA's current thinking regarding application of the naming convention to the nonproprietary names of previously licensed biological products and transition biological products, and describes FDA's current thinking on the appropriate suffix format for the nonproprietary name of an interchangeable biological product. This draft guidance is not intended to be finalized. Based on the comments received in the docket, we intend to revise the final guidance, "Nonproprietary Naming of Biological Products," dated January 2017, and to amend sections, such as sections IV.D and V.B, in that document regarding the subjects addressed in the draft guidance. Although the procedures outlined in this MAPP apply to the review of distinguishing suffixes for the originator biological products, related biological products, and biosimilar products (other than interchangeable products) newly licensed under section 351(a) or 351(k) of the PHS Act, these procedures may be applicable to interchangeable biological products and as such we intend to revise the MAPP to reflect such changes once the guidance is finalized.

FDA anticipates that licensure of new biosimilar and interchangeable products, in addition to licensure of new products in "stand-alone" BLAs, will contribute to a growing number of biological products entering the marketplace in the coming years. Thus, to facilitate the efficient review and designation of suffixes, CDER relies on the procedures outlined in this MAPP when identifying or responding to any sponsor requests for review of distinguishing suffix(es) to designate in the nonproprietary names for biological products *submitted for licensure* under section 351(a) or 351(k) of the PHS Act.

This MAPP does not apply to biological products *previously* licensed under section 351(a) or 351(k) of the PHS Act.

This MAPP also does not apply to those biological products that are the subject of an approved application under section 505 of the FD&C Act as of March 23, 2020; when such applications are deemed to be biologics license applications under section 351 of the PHS Act on March 23, 2020.[7]

In accordance with the Delegation of Authority Memorandum, Staff Manual Guides Volume II 1410.104, Section H, effective June 12, 2012, the Division of Medication Error Prevention and Analysis (DMEPA) officials in the Office of Surveillance and Epidemiology (OSE) are authorized to take regulatory actions related to the approval of drugs for human use that are the subject of a BLA under CDER jurisdiction, including decisional letters regarding review of the nonproprietary name suffix candidate.

[6] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM632806.pdf

[7] See section 7002(e)(4) of the BPCI Act.

POLICY

- OSE will manage review of nonproprietary name suffixes. OSE will lead an interdisciplinary review team that includes OPDP and OND, along with other CDER offices, as relevant, in the review of suffixes identified by FDA or proposed by a sponsor for designation in the nonproprietary name of original, related and biosimilar products.

- OSE staff will provide timely notification to application holders about the FDA's decision to conditionally accept or not accept a proposed nonproprietary name suffix(es).

- OSE will have the lead responsibility for communicating with industry about CDER's review of nonproprietary name suffixes identified by FDA or proposed by a sponsor, including letters (e.g., information request letters, general advice letters, and letters with the conditional acceptance or non-acceptance decisions prior to final action on marketing applications or supplements), teleconferences, and meetings.

- OSE will ensure that discussions and decisions for review of nonproprietary name suffixes will be made in accordance with CDER's policies on equal voice, differing professional opinions, and, if necessary, dispute resolution.[8]

- Where notification about conditional acceptance or non-acceptance of a proposed nonproprietary name (including suffix) is performed in conjunction with other OND regulatory actions, OND will include recommendations and decisions from OSE in action letters corresponding to such regulatory actions.

RESPONSIBILITIES

Overview

OSE leads a multidisciplinary review with input from the Office of Prescription Drug Promotion (OPDP) in the Office of Medical Policy (OMP), and the Office of New Drugs (OND). Additionally, OSE seeks expertise from the Therapeutic Biologics and Biosimilars Staff (TBBS) in the Office of New Drugs (OND), the Office of Biotechnology Products (OBP) and the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ), the Office of Regulatory Policy

[8] 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.

(ORP), and the Office of Chief Counsel (OCC) as appropriate in the review of nonproprietary name suffix candidates.

OSE Project Management staff serve as the Agency's point of contact for industry. OSE/DMEPA will review proposed suffixes if requested by the biological product sponsor or applicant or will identify a suffix for designation if requested by the sponsor or applicant or as necessary as part of FDA's licensure of a biological product. Whether proposed by the applicant or identified by FDA, each four-letter suffix candidate is reviewed by CDER to ensure that it is consistent with the principles outlined in section VI of FDA's Guidance for Industry: Nonproprietary Naming of Biological Products. DMEPA initiates the review of the proposed primary suffix. For those suffixes proposed by the applicant, if the primary suffix candidate is found unacceptable, DMEPA will initiate evaluation of additional suffixes in the order of the applicant's preference[9] until a viable suffix is evaluated, or until ten of the proposed suffixes are found unacceptable.

Once DMEPA determines a suffix candidate appears to be viable for a product, OSE seeks the advice of OPDP to evaluate whether the suffix would be false or misleading, such as by making misrepresentations with respect to safety or efficacy. DMEPA may also elect to consult other experts in FDA for advice, as appropriate to the needs of the review.

DMEPA shares the decision related to each suffix candidate reviewed by OSE and OPDP with the OND-led review team prior to finalizing its decision. DMEPA makes a final decision of the acceptability of a suffix candidate with the advisement of other appropriate CDER offices. In circumstances where DMEPA disagrees with the advice of other offices, DMEPA will ensure that discussions and decisions for review of nonproprietary name suffixes will be made in accordance with CDER's policy on equal voice, differing professional opinions, and, if necessary, dispute resolution.[10]

DMEPA writes and archives one consolidated memorandum that incorporates all CDER viewpoints and recommendations expressed by any consulted Offices throughout the review process for each suffix reviewed. The DMEPA Division Director or Designee signs the nonproprietary name suffix decisional letters that are sent to the sponsor or applicant.

[9] FDA plans to review up to ten of the proposed suffixes sequentially in the order of the applicant's preference until a viable suffix candidate is evaluated. In the event that none of the proposed suffixes are acceptable for a product with a pending BLA or the BLA is otherwise amended after filing to propose suffix candidate(s), FDA may review such suffixes if time and resources permit. In the alternative, if time and resources do not permit review of the proposed suffixes, FDA may defer review of the suffixes until a subsequent review cycle or assign an FDA-identified suffix at the time of product licensure to avoid unnecessary delays to the licensure of a biological product. In either case, FDA would communicate its plans to the applicant.

[10] 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.

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

The DMEPA Biologics Workload Coordinator (BWC) will:

- Add all the suffix candidates to FDA's internal Phonetic and Orthographic Computer Analysis (POCA) database

- Each quarter, notify via email of any BLAs approved:
  - FDA's SPL team (spl@fda.hhs.gov), which serves as a designated point-of-contact for RxNorm at the National Library of Medicine
  - FDA liaison to the United States Adopted Name Council.

The OSE Safety Regulatory Project Manager (SRPM) will:

- Serve as the point of contact for communications with the biological product sponsor or applicant regarding nonproprietary name suffixes.

- For requests for FDA designation of a suffix or review of a proposed suffix that are received early in development (i.e., Pre-IND or IND), the SRPM will contact the sponsor or applicant to inform them the review of the proposed suffix(es) will not be conducted and inform them on when such review would be conducted based on the application status.

- Ensure that all newly recieved BLAs are identified to the DMEPA biological workload coordinator (BWC).

- For all newly received BLAs, create a suffix review record and assign to the DMEPA TL and FYI to BWC to coordinate reviewer assignments.

- Upon notification by the DMEPA Safety Evaluator or Team Leader that suffix candidates are ready for OPDP evaluation, send the proposed suffixes and any attachments provided by the DMEPA SE to facilitate OPDP's review in the Weekly Name Report (WNR) via email to OPDP-PNR@fda.hhs.gov.

- With DMEPA, co-lead the multidisciplinary review team and meetings with biological product sponsor or applicant.

- If directed by the DMEPA Division director or designee, work with the DMEPA Safety Evaluator and Team Leader to issue consults seeking expertise from others on the multidisciplinary review team.

- Draft and, upon concurrence from the DMEPA Division Director or Deputy Director, process the decisional letter to the sponsor or applicant with a copy to

OND following the finalization of a memorandum documenting the review of proposed suffix(es) in the administrative record.

The DMEPA Biological Safety Evaluator (SE) will:

- Accept suffix assignments made by the DMEPA Team Leader.

- Co-lead with OSE SRPM, the multidisciplinary review and any meetings with biological product sponsor or applicant.

- Generate a four-letter suffix candidate that is devoid of meaning upon request of the sponsor or applicant or the DMEPA Director.

- Initiate the assessment of the proposed or generated suffix taking into consideration the criteria listed in section VI of the final guidance for industry (REF. 1), using the checklist provided in Appendix A to guide their review. Assessments will consider any supporting data provided by the sponsor.

    - If the DMEPA SE determines a suffix candidate is unacceptable based on the evaluation completed in any of the steps in the checklist provided in Appendix A, that candidate generally would not proceed to the subsequent steps of CDER review and the finding will be communicated to the applicant in a decisional letter.
    - The DMEPA SE will review suffix candidates in the order of listed preference by the applicant in their request, up to 10 proposed suffixes. When the DMEPA SE finds a suffix candidate is acceptable, the DMEPA SE will not initiate review of other suffixes listed in the request unless there is a subsequent concern identified by FDA that would render the suffix candidate unacceptable. DMEPA will only share the findings of those suffix(es) that undergo review.

- After evaluation of the suffix candidate by the DMEPA SE and concurrence by the DMEPA Division Director or Designee(s) of the preliminary review findings, add any potentially viable suffix candidates to the WNR circulated to DMEPA by the OSE SRPM in order to send to OPDP for their recommendation on the acceptability of the suffix(es) under review.
    - The DMEPA SE will also include a link to any materials submitted in support of a suffix candidate, along with a draft of their suffix evaluation memorandum which will be attached to the WNR. The draft DMEPA review includes the relevant information about the product and applicant (or sponsor) to aid OPDP's review.

- Upon completion of the suffix candidates evaluation, share DMEPA's and OPDP's findings, if applicable, and overall recommendations regarding the

acceptability of the proposed nonproprietary name suffixes with the OND review team.

- If directed by the DMEPA Director or designee, assist the SRPM in issuing consults seeking expertise from others on the multidisciplinary review team. Write and archive a memorandum incorporating the input of other CDER review disciplines received throughout the review cycle regarding the acceptability of proposed suffix candidates reviewed by FDA, and ensure that the OSE SRPM staff, OBP labeling reviewer, TBBS, OND review division Regulatory Project Manager (RPM), and other relevant disciplines receive a copy.

- Provide letter-ready comments to the OSE SRPM that convey FDA's conditionally acceptable or unacceptable decision regarding the application holder's nonproprietary name suffix.

- Review requests for reconsideration of proposed suffixes that were found unacceptable based on any concerns relevant to DMEPA.

The DMEPA Team Leader (TL) will:

- Assign all suffix reviews to the appropriate DMEPA reviewer.

- Ensure that viewpoints from relevant CDER disciplines are sought and incorporated into the suffix 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 nonproprietary name suffix review and ensure that the review is accurate and complete.

- If directed by the DMEPA Division Director or Designee, assist the SRPM and DMEPA SE in issuing consults seeking expertise from others necessary to contribute to the multidisciplinary review.

- Co-lead with DMEPA SE and OSE SRPM, the multidisciplinary review and meetings with biological product sponsor or applicant.

The DMEPA Division Director or Designee will:

- Provide tertiary review and clearance of the DMEPA SE's evaluation of suffix candidates.

- Direct DMEPA SE to generate a four-letter suffix candidate that is devoid of meaning in the following circumstances if the sponsor or applicant:
    - Requests FDA to generate the suffix, or
    - During the course of FDA's BLA review, does not submit a request for review of proposed suffix(es), or
    - Has not proposed a viable suffix candidate that is found conditionally acceptable.[11]

- If appropriate to the needs of the review, request that the DMEPA SE and TL work with the SRPM to issue consults seeking expertise from others on the multidisciplinary review team.

- Sign the nonproprietary name suffix decisional letter (conditionally acceptable or unacceptable) to the application holder.

The OPDP Contact will:

- When consulted, provide OPDP's recommendations to the OSE SRPM on the suffix candidate(s) within 14 calendar days.

- Review requests for reconsideration forwarded by OSE for any proposed suffixes that were found unacceptable based on any concerns relevant to OPDP.

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

[11] FDA plans to review up to ten of the proposed suffixes sequentially in the order of the applicant's preference until a viable suffix candidate is identified. In the event that none of ten proposed suffixes are acceptable for a product with a pending BLA or the BLA is otherwise amended after filing to propose suffix candidate(s), FDA may review such suffixes if time and resources permit. In the alternative, if time and resources do not permit review of the proposed suffixes, FDA may defer review of the suffixes until a subsequent review cycle or assign an FDA-generated suffix at the time of product licensure to avoid unnecessary delays to the licensure of a biological product. In either case, FDA would communicate its plans to the applicant.

The OND Regulatory Project Manager (RPM) in the OND therapeutic division will:

- Triage submissions (e.g., document room shelf triage) concerning a request (e.g., meeting request, correspondence) for nonproprietary name suffix review or a request for FDA to designate a suffix to ensure that they are correctly identified and routed to the OSE SRPM.

- Inform the OSE SRPM and TBBS RPM (OND Therapeutic Biologics and Biosimilars PM Staff) if they become aware of a request for nonproprietary name suffix review or a request for FDA to designate a suffix.

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

- Maintain contact with the OSE SRPM regarding changes in the application that would affect review of the suffixes under consideration, such as fileability, withdrawal, changes in the application goal date or action date, and clinical holds.

- For 351(a) or 351(k) applications that previously received a complete response letter, notify the OSE SRPM and TBBS RPM upon receipt of a BLA resubmission so that OSE can determine the need for a reassessment of any nonproprietary name suffixes reviewed before the complete response was issued.

- Forward all meeting requests concerning proposed nonproprietary name suffixes to the OSE SRPM.

- Where notification about acceptance or non-acceptance of a proposed nonproprietary name (including suffix) is performed in conjunction with other OND regulatory actions, then OND will include recommendations and decisions from OSE in letters corresponding to such regulatory actions.

- When an application action for the BLA occurs, notify the OSE SRPM and DMEPA BWC via email (OSEConsults@cder.fda.gov and propname@fda.hhs.gov).

The TBBS Director or Designee will:

- When consulted, review the findings and recommendations regarding the acceptability of the proposed nonproprietary name suffixes and provide feedback on the findings within the requested time.

- Participate, as needed, in meetings with sponsors or applicants or in internal multidisciplinary review team meetings on proposed suffixes.

The OBP Labeling Reviewer will:

- When consulted, review the findings and recommendations regarding the acceptability of the proposed nonproprietary name suffixes and provide feedback on the findings within the requested time.

- Participate, as needed, in meetings with sponsors or applicants or in internal multidisciplinary review team meetings on proposed suffixes.

The OPPQ Reviewer will:

- When consulted, review the findings and recommendations regarding the acceptability of the proposed nonproprietary name suffixes and provide feedback on the findings within the requested time.

- Participate, as needed, in application holder meetings or in internal multidisciplinary review team meetings on proposed suffixes.

The ORP Regulatory Counsel will:

- When consulted, review the findings and recommendations regarding the acceptability of the proposed nonproprietary name suffixes and provide feedback on the findings within the requested time.

- Participate, as needed, in meetings with sponsors or applicants or in internal multidisciplinary review team meetings on proposed suffixes.

The OCC Staff Attorney will:

- Respond to consult requests for review of the findings and recommendations regarding the acceptability of the proposed nonproprietary name suffixes and provide feedback on the findings within the requested time.

- Participate, as needed, in meetings with sponsors or applicants or in internal multidisciplinary review team meetings to reach on proposed suffixes.

REFERENCES

1. Guidance for industry, *Nonproprietary Naming of Biological Products*. To make sure you have the most recent version of guidance, check the FDA Drugs Guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

2. 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.

3. 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

4. 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)

5. MAPP 4151.2, "Documenting Differing Professional Opinions and Dispute Resolution—Pilot Program"

6. FDA Staff Manual Guide, Volume II - Delegation of Authority Regulatory-Human Drugs, SMG 1410.104, Approval of New Drug Applications and Their Supplements, effective June 12 2012 (https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/staffmanualguides/ucm336918.pdf)

7. The USAN Council (tri-sponsored by the American Medical Association (AMA), the United States Pharmacopeial Convention, and the American Pharmacists

Association) aims for global standardization and unification of drug nomenclature and related rules to ensure that drug information is communicated accurately and unambiguously, working closely with the International Nonproprietary Name Programme of the World Health Organization, and various national nomenclature groups. This Web site is publicly available, managed by the AMA, and contains lists of all of the recognized USAN stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems).

8. Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological)

9. Phonetic and Orthographic Computer Analysis (POCA) is a system designed by FDA. As part of the name similarity assessment, POCA is used to evaluate proposed names for similarity to other drug names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly available by requesting the system from FDA.

DEFINITIONS

Biosimilar Product means a biological product submitted in a 351(k) application that has been shown to be highly similar to the reference product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product (see section 351(i)(2) of the PHS Act).

Core Name means the component shared among an originator biological product and any related biological product, biosimilar product, or interchangeable product as part of the proper names of those products. Two examples of a *core name* are filgrastim and epoetin alfa.

Interchangeable Product means a biological product that has been shown to meet the standards described in section 351(k)(4) of the PHS Act and may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product (see section 351(i)(3) of the PHS Act).

Nonproprietary Name means a name unprotected by trademark rights that is in the public domain. It may be used by the public at large, both lay and professional.

Originator Biological Product means a biological product submitted in a BLA under section 351(a) of the PHS Act (i.e., a stand-alone BLA) that is not a related biological product.

Proper Name means the nonproprietary name designated by FDA in the license for a biological product licensed under the PHS Act. (See section 351(a)(1)(B)(i) of the PHS Act (42 U.S.C. 262(a)(1)(B)(i) and 21 CFR 600.3(k).)

Proprietary Name means the trademark or brand name.

Reference Product means the single biological product licensed under section 351(a) of the PHS Act against which a biological product is evaluated in a 351(k) application (section 351(i)(4) of the PHS Act).

Related Biological Product means a biological product submitted in a BLA under section 351(a) of the PHS Act (i.e., a stand-alone BLA) for which there is a previously licensed biological product submitted in a different section 351(a) BLA that contains a drug substance for which certain nomenclature conventions (e.g., United States Adopted Names (USAN) Guiding Principles[12]) would be expected to provide for use of the same drug substance name.[13]

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
xx/xx/2018	Initial	n/a

Appendix A. Summary tasks for evaluating suffix candidate acceptability.

[12] The United States Pharmacopeial Convention, 2016, Guiding Principles for Coining United States Adopted Names for Drugs (*2016 USP Dictionary of USAN and International Drug Names at* http://www.uspusan.com/usan/pub/index1.html).

[13] FDA's description of a biological product as a *related biological product* in this guidance is separate from any determination FDA may make about whether a related biological product is eligible for a period of exclusivity under section 351(k)(7) of the PHS Act.

	Evaluation task	Focus of the Review	Review Considerations
Step 1:	OSE evaluates the format of the suffix to ensure consistency with the guidance	-Is the suffix unique? -Is the suffix devoid of meaning? -Is the suffix composed of four lower case letters? -Are at least three of the four letters distinct? -Is the suffix attached to the core name with a hyphen?	The DMEPA SE ensures that the suffix candidate does not include numerals or symbols, aside from the hyphen attaching the suffix to the core name. The DMEPA SE is responsible for evaluating the suffix candidate for any apparent meaning, including whether the suffix candidate could connotate the license holder The DMEPA SE compares the spelling of the suffix to the spelling of the company name and the proposed proprietary name of the product to identify letters that may be common to both, and is responsible for comparing the spelling of the suffix candidate to all suffixes accepted or approved for other biological products held by the same manufacturer.
Step 2:	OSE reviews the suffix to assess whether a suffix candidate may inadvertently cause confusion that could lead to medication errors	-Does the suffix include abbreviations commonly used in clinical practice? *If the proposed suffix is composed (in whole or in part) of abbreviations, DMEPA SE will consider whether the inclusion within the suffix may lead to misinterpretation as another element on the prescription or order or otherwise cause confusion in clinical practice settings.* -Does the suffix look similar to or could be mistaken for the name of a marketed product? Does the suffix contain or suggest any drug	To identify the presence of any USAN stems with a suffix candidate, the DMEPA SE searches the USAN stem list (REF. 8) to see whether the suffix is in whole or in part composed of a USAN stem. To identify the presence of any abbreviations within a suffix candidate, the DMEPA SE searches lists of commonly used medical abbreviations to assess whether the suffix is in whole or in part composed of letters that could be misconstrued as a medical abbreviation. To identify similar drug names, the DMEPA SE uses the Phonetic and Orthographic Computerized Analysis (POCA) tool (REF. 7) and sets the program to search those names listed

		substance name or core name? *When assessing the potential risk of any suffix identified as similar to other product name, the DMEPA SE will evaluate whether the suffix would an increase the risk of confusion or medical errors with the product and/or other products in the clinical setting.* -	on drugs@fda (REF. 8) and Name Entered by Safety Evaluator database. To identify similar suffixes, the DMEPA SE uses the POCA tool and sets the program to search for suffixes that are similar in spelling, writing or pronunciation to those suffixes that have been conditionally accepted or approved by FDA.[14]
Step 3:	OPDP evaluates whether the suffix candidate would be false or misleading	Is the suffix candidate false? Is the suffix candidate misleading by making misrepresentations with respect to safety or efficacy?	The OPDP is responsible for considering all product information forwarded in the Weekly Name Report to assess whether the suffix candidate is false or misleading.

[14] FDA maintains two separate repositories of suffixes using the POCA tool: one will be publicly accessible and allow users to search their suffix candidate against only those suffixes that are associated with approved biological products, the other non-public repository will consist of those suffixes associated with INDs and pending BLAs and will only be accessible to FDA staff to use in their review of suffix candidates.