VIA ELECTRONIC SUBMISSION

September 25, 2019

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-D-2397; Using the Inactive Ingredient Database; Draft Guidance for Industry; Availability

Dear Sir/Madam,

The United States Pharmacopeia (USP)[1] appreciates the opportunity to comment on the Food and Drug Administration's (FDA or the Agency) draft guidance, *Using the Inactive Ingredient Database*. USP also submitted comments to the 2015 docket in which FDA solicited input from stakeholders to identify the Inactive Ingredients Database's (IID) limitations and improve the IID.[2]

USP commends FDA on the issuance of this draft guidance to enhance the utility and usability of FDA's IID. We have seen marked enhancements in the IID and look forward to continuing to engage with the Agency on excipient nomenclature.

We believe the information presented in the draft guidance will help reduce discrepancies between the IID and *USP-NF* monograph names by aligning preferred terms for single substance excipients with the *USP-NF* excipient monograph official title. The draft guidance clarifies that when a *USP-NF* monograph exists for a single ingredient substance, the Global Substances Registration System (GSRS) preferred term is the same as the *USP-NF* monograph title for that excipient. Although the draft guidance states that the preferred term for the excipient is as it appears in the GSRS, we note that the current IID list contains some single substance excipients that have yet to be updated to align with the *USP-NF* monograph names.[3]

For multiple substance excipients, we have a track record of working with FDA and stakeholders to successfully update *USP-NF* monograph titles in cases where a lack of alignment with names in the IID has been identified.[4] We seek to continue to work

[1] USP is an independent, scientific, nonprofit organization dedicated to improving health through the development of public standards for medicines, foods, and dietary supplements. Through a longstanding collaboration with FDA, we have worked continuously to benefit public health through accessible quality medicines.

[2] See USP comments to Docket No. FDA-2015-N-2986 (Oct. 19, 2015).

[3] For example, the IID lists anhydrous dextrose, whereas the official *USP-NF* monograph name is dextrose.

[4] For example, the *NF* Glyceryl Monocaprylocaprate monograph was split into two monographs: Type I – Glyceryl Mono and Dicaprylocaprate and Type II – Glyceryl

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with FDA and others to align excipients where the IID name and the *USP-NF* name differ for multiple substance excipients.[5]

The draft guidance states that in cases where co-processed excipients and excipient mixtures have *USP-NF* official monographs, such excipients will generally retain their monograph names in GSRS and the IID and will be updated to be consistent with a revised *USP-NF* monograph when such updates occur. We agree that this consistency is important to ensure clarity and appreciate reference to the official nomenclature of *USP-NF* in such instances.

For excipients that do not have a *USP-NF* monograph, USP seeks to work with the Agency early in the process to identify appropriate monograph names. We note that during the FDA approval process, applicants can use the USP Pending Monograph Program for revision or development of excipient monographs.[6] We welcome discussions with the Agency on how this process may be used to support the alignment of naming in the IID and *USP-NF*.

To support the consistency of naming excipients globally, USP's Expert Committee[7] is developing an excipient nomenclature guideline. The Expert Committee intends to include standardized approaches for naming complex excipients, including mixtures and polymers in the guideline, and publish it on USP's website.

Regarding Unique Ingredient Identifiers (UNII), we support the Agency's effort to align UNII with the preferred term and agree that this supports public health information technology initiatives. We welcome the opportunity to work with FDA to include UNII in corresponding excipient *USP-NF* monographs.

USP continues to support the Agency's efforts to provide a clearer understanding of the information and terminology provided in the IID and to reduce nomenclature discrepancies. We welcome the opportunity to work with FDA on the various nomenclature topics, discussed above, including alignment of multiple substance excipient names, incorporation of UNII in *USP-NF* monographs, and identifying monographs that need to be updated.

Monocaprylocaprate. Type I and Type II appeared in IID as Caprylic/capric mono/diglycerides and glyceryl caprylate/caprate. After splitting, the IID was updated and replaced with the two corresponding *NF* titles assigned to these *NF* monographs.

[5] For example, Ethyl Acrylate and Methyl Methacrylate Copolymer excipient has an *NF* monograph for its dispersion form, titled as Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion. However, it is listed as its substance form Ethyl Acrylate and Methyl Methacrylate Copolymer (2:1; 750000 MW) in the IID.

[6] Additional information can be found on the Pending Monograph website, at https://www.uspnf.com/pending-monographs.

[7] The full name of the Expert Committee is: Excipient Monographs Expert Committee, Excipient Nomenclature Joint Subcommittee, which includes an FDA government liaison.

Again, thank you for the opportunity to comment. For more information, please contact Elizabeth Miller, Vice President, U.S. Public Policy and Regulatory Affairs, at ehm@usp.org; (240) 221-2064.

Sincerely yours,

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