May 12, 2020

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260

Dear Ms. Stember:

Thank you for your comments on FDA's naming convention for biological products and the display of certain proper names. We respectfully encourage you to participate in the public comment process for FDA guidance documents by reviewing the publicly available guidance documents on Nonproprietary Naming of Biological Products and submitting your comments to the public docket (Docket number FDA-2013-D-1543) on https://www/regulations.gov. [1]

As described in the guidance, FDA has carefully considered the appropriate naming convention to help ensure the safety of patients receiving biological products, enhance patient and prescriber confidence, and maximize the success of biosimilar and interchangeable biological products. We are committed to continue working with stakeholders, including manufacturers, health systems, and informatics providers to ensure the accurate identification and display of proper names under the naming convention, consistent with the recommendations in the final guidance.

The final guidance specifies that FDA's naming convention for biological products licensed under the Public Health Service (PHS) Act is a proper name consisting of a core name and an FDA-designated suffix attached to the core name with a hyphen, and we note that the specific proper names mentioned in your letter are consistent with the naming convention. For example, as identified in the FDA-approved labeling for *trastuzumab and hyaluronidase-oysk*, the fixed-combination product's core name is 'trastuzumab and hyaluronidase' and the suffix 'oysk' is attached to the core name with a hyphen.

The final guidance further specifies that in some instances designation of a proper name that includes a unique prefix is necessary to minimize certain medication errors, and the proper name *fam-trastuzumab deruxtecan-nxkl* is one such example.

[1] See guidance for industry, *Nonproprietary Naming of Biological Products* (Jan. 2017). In a Federal Register notice dated March 8, 2019, FDA also announced the availability of the draft guidance for industry, *Nonproprietary Naming of Biological Products: Update*. In the March 2019 Federal Register notice, FDA explained that the Agency intends to revise the final guidance on *Nonproprietary Naming of Biological Products* based on the comments received on the subjects addressed in the draft guidance on *Nonproprietary Naming of Biological Products: Update*. For the most recent version of a guidance, check the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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FDA is committed to supporting a robust marketplace of biological products that provide innovative, accessible therapeutic options to patients. FDA recognizes the importance of engaging stakeholders about the implementation of the naming convention and welcomes continued input from NCPDP.

Sincerely,

Lubna I. Merchant -S

Digitally signed by Lubna I. Merchant -S
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