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U.S. Food and Drug Administration (FDA)
10903 New Hampshire Ave
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Submitted electronically via email

Re: Purple Book Database of Licensed Biological Products

Dear Dr. Skibinski and Ms. Ikenberry,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP and its members wish to thank you both as key representatives of FDA's Office of Therapeutic Biologic and Biosimilars (OTBB) for ongoing communication and insights about the potential role of leveraging *Purple Book* data via the National Library of Medicine's (NLM's) RxNorm database. NCPDP is aware of your ongoing efforts with NLM's Tammy Powell and Chris Hui in bringing this goal to fruition and has worked closely with them to make the best use of this data. As part of those efforts, NCPDP's Naming Standards for Drugs, Biologics, and Biosimilars Task Group has been advising NLM on use cases whereby its members can optimally leverage *Purple Book* data in various database applications.

NCPDP is seeking clarification from the FDA on two key concepts that will greatly impact NLM's modeling of *Purple Book* data.

The first point of clarification is how best to represent the substitutability of "unbranded biologics" and "unbranded biological products." In FDA's *Purple Book* FAQs (https://purplebooksearch.fda.gov/faqs):

The term "unbranded biologic" or "unbranded biological product" generally describes an approved brand name biological product that is marketed under its approved BLA without its brand name (proprietary name) on its label. Because an unbranded biologic is marketed under the brand name biological product's BLA and is not different in strength, dosage form, route of administration, or presentation, it is not separately identified in the Purple Book. An "unbranded biologic" is not an "interchangeable biosimilar." However, an unbranded biologic is considered by FDA to be equivalent to its brand name biological product because it is the same product as the brand name biological product under the same BLA.

Since an unbranded biologic is considered by the FDA to be ***equivalent*** to its corresponding brand name biologic because it is approved under the identical Biologics License Application (BLA), NCPDP asks the FDA to clarify in its FAQ the ***equivalency*** of the two products, while not considered an "interchangeable biosimilar" per se, means they can be substituted for one another for the purposes of interchangeability. Thus, Mylan's unbranded insulin glargine (insulin glargine-yfgn) can be substituted for their branded Semglee® (insulin glargine-yfgn) as an interchangeable product for Lantus® since both Mylan products were approved under the same BLA and, therefore, are ***equivalent***. This interpretation was borne out in the "Highlights of Prescribing Information" for both the branded and unbranded Mylan products where it is stated that each is interchangeable with Lantus®. The way this FAQ is currently worded may lead some to conclude that the unbranded biologic cannot be substituted for Lantus® because it is not considered an "interchangeable biosimilar" per se. While the FDA is not responsible for substitution regulations, 48 out of 50 states' pharmacy practice regulations require *Purple Book* interchangeable status to be eligible for substitution of biosimilars.

The second point of clarification concerns the two-way interchangeability of a given reference and interchangeable biologic product. NCPDP interprets the interchangeable designation of Semglee® for Lantus® would mean that Semglee® could be substituted whenever Lantus® is prescribed and vice versa. Therefore, NCPDP requests the FDA modify its *Purple Book* FAQs to clearly state that, as the term "interchangeable" is defined and widely understood, a determination of interchangeability by the Agency for two products means "permitting mutual substitution" (*Merriam – Webster's Dictionary 2023,* https://www.merriam-webster.com/dictionary/interchangeable).

NCPDP looks forward to an ongoing collaboration with the FDA and NLM on optimally leveraging *Purple Book* data in RxNorm in support of best practices for patients.

For direct inquiries or questions related to this letter, please contact:

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Sincerely,

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