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Colleen Thomas
Center for Drug Evaluation and Research (HFD-003)
U.S. Food and Drug Administration
10903 New Hampshire Ave, Bldg 51
Silver Spring, MD 20993

Reference: Docket No. FDA-2018-D-4417, CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.

Dear Ms. Thomas:

PDA appreciates the opportunity to comment on *CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality: Guidance for Industry*.

PDA supports CDER's initiative to evaluate and informally recognize voluntary consensus standards relating to pharmaceutical quality, and to make public a comprehensive listing of all standards CDER recognizes. We agree with CDER's statement that this initiative "will help promote innovation in pharmaceutical development and manufacturing and streamline the compilation and assessment of marketing applications for products regulated by CDER."

In PDA's view, the use of voluntary consensus standards may present numerous benefits:

- Referencing a CDER-recognized standard obviates the need to reproduce lengthy requirements, testing procedures, or definitions in an application or procedure, while also providing a company with assurances that CDER has confidence in the standard. While this provides benefits to the applicant, it also may simplify and accelerate CDER's review of new drug applications and supplements, lowering the cost to government and allowing products to reach patients sooner. It also may simplify certain tasks for inspectors, allowing them to focus on critical compliance issues.
- The agency's recognition of standards, even informally, encourages participation in standards development activities. This, in turn, results in more broadly supported and credible standards.
- The recognition of voluntary consensus standards allows industry to avoid duplicating efforts unnecessarily and optimizes the use of scarce resources. International standards present even greater efficiencies.
- By referring to standards that have been harmonized internationally, CDER and industry can facilitate the elimination of barriers to trade.
- Voluntary consensus standards provide a framework that can help developing industry, but also allow flexibility that can be encourage innovation.

While PDA supports this initiative, we suggest that CDER expand the guidance slightly to add clarity and prevent confusion during implementation, as detailed in the attachment. In addition, we urge CDER to collaborate with CBER to ensure consistency of definitions and approach across drug and biological products to the extent possible. It may be useful to form a joint CBER-CDER working group that would consider standards that are relevant to biologics as well as drugs.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality, and is an ANSI-accredited standards development organization. Our comments have been prepared by a committee of experts in regulatory affairs and standards-setting on behalf of our Regulatory Affairs and Quality Advisory Board and Board of Directors.

If you have any questions, please do not hesitate to contact me via email at johnson@pda.org.

Sincerely,

Richard M. Johnson
President and CEO

cc: Tina Morris, PDA; Ruth Miller, PDA

U.S. Food and Drug Administration

CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality: Draft Guidance

March 2019

General Comments

General Comments	Rationale	Critical Comment? Y/N
For consistency and clarity, PDA recommends that CDER and CBER establish identical positions for each voluntary consensus standard, except as necessary in specific and limited circumstances. To the extent that one Center intends to define or interpret terms relevant to the standards recognition process (e.g., "conflict" and "comparable"), we strongly urge that Center to collaborate with the other to ensure consistency of interpretation. To achieve this consistency, PDA encourages CDER to communicate and collaborate with relevant CBER staff in implementing the PQSWG process. A joint CBER-CDER Working Group might be established to consider standards that are relevant to both drugs and biologics.	Not only do individual companies deal in both CDER- and CBER regulated products, some voluntary consensus standards address issues that are relevant to drug and biologic products. At the simplest level, it would seem that standards on such topics as supply chain, good distribution practices, and data integrity generally should be acceptable to CBER if acceptable to CDER, and vice versa. If CBER chose not to accept a standard recognized by CDER, this could cause confusion. Likewise, if CDER considers a voluntary consensus standard to be comparable to an official compendial standard, it would create significant confusion within industry if CBER did not take the same view, to the extent that the standard is relevant to both drugs and biologics. This alignment of perspectives between CDER and CBER would avoid confusion within industry at many stages: at adoption of the standard or use in a regulatory filing, at the time of inspection or other agency interpretation, at sunsetting of the standard, and others. It also would avoid unnecessary duplication of work within FDA.	Y

Specific Comments to the Text

Line No.	Current Text	Proposed Change	Rationale	Critical Comment? Y/N
149	The PQSWG intends to develop an internal process for informally recognizing standards in whole or in part, and document this process in a publicly	Add: The PQSWG process also will address how the PQSWG intends to review and consider updates to recognized standards. In addition, the Manual of Policies and Procedures will discuss the PQSWG's procedures for withdrawing recognition of a standard, which may occur when a standard is	These initial documents should discuss how the agency will consider updates to a recognized standard, and the steps the agency will take before it withdraws recognition of a standard, as these steps are necessary to ensuring the continuing relevance of the recognized standards. The possibility that CDER may recognize only	Y

Line No.	Current Text	Proposed Change	Rationale	Critical Comment? Y/N
	available Manual of Policies and Procedures.	superseded or when a new standard is found to be conflicting and superior.	part of a standard adds complexity to both the consideration of updates and the review of potential conflicts between standards, as discussed below, and also should be discussed more carefully in the MAPP.	
161	The PQSWG should confirm that each proposed voluntary consensus standard will not be in conflict with any statute, regulation, or policy under which FDA operates.	Add: The PQSWG also should consider whether a newly submitted standard conflicts with a standard that FDA previously has recognized. If two standards conflict, the Manual of Policies and Procedures should address the steps that PQSWG will take to provide clarity to regulated industry.	While multiple standards may occupy the same space, it is unlikely that they will exactly align. Therefore, it is critical that CDER identify and address conflicts before recognizing standards. PDA recommends that the conflict assessment process include dialogue with the relevant SDOs. Further, PDA recommends that CDER establish a process by which regulated industry can raise potential conflicts for further consideration by CDER. We caution that mere non-alignment may exist, and should be considered differently than conflict. A definition of "conflict" may be necessary.	Y
268	CDER may informally recognize alternate standards that are comparable to the USP standard or that provide advantages over the USP standard.	PDA strongly supports this approach but encourages CDER to provide more clarity around the determination of comparability. Specifically, PDA suggests that CDER define how comparability and "advantages" are to be determined or, at a minimum, the general process to be followed in	PDA believes that regulated industry is likely to need this additional information in order to be comfortable using alternate standards in place of USP standards.	Y

Line No.	Current Text	Proposed Change	Rationale	Critical Comment? Y/N
		making that determination. PDA also suggests that CDER define the parties that are permitted to determine comparability.		
164	If the proposed voluntary consensus standard for informal recognition meets the PQSWG's qualifying criteria:	Add: The PQSWG will allow public comment on the proposed voluntary consensus standard.	Public announcement of standards under consideration, with an opportunity for comment, would allow industry experts to provide technical input that may help shape CDER's review. CDER could provide this notice through the same searchable database that the Center will use to publicize the list of recognized standards.	