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

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

July 2023
Administrative/Procedural

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

Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353; Email: druginfo@fda.hhs.gov
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

July 2023
Administrative/Procedural

TABLE OF CONTENTS

Contains Nonbinding Recommendations

CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance describes a program at FDA's Center for Drug Evaluation and Research (CDER) to make public a comprehensive listing of recognized voluntary consensus standards[2] related to pharmaceutical quality. FDA's participation in the development and use of technical voluntary consensus standards has been integral to the execution of FDA's mission. For example, FDA has used such standards to develop and/or evaluate performance characteristics of dosage forms, testing methodologies, manufacturing practices, product standards, scientific protocols, ingredient specifications, labeling of drug products, and other technical or policy criteria.

---

[1] This guidance has been prepared by the Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] In this guidance, the phrase *voluntary consensus standard* refers to

> a standard that is developed or adopted by domestic and international voluntary consensus standards bodies . . . . These bodies often have . . . policies that include provisions requiring that owners of relevant patented technology incorporated into a standard make that intellectual property available to implementers of the standard on non-discriminatory and royalty-free or reasonable royalty terms.

Office of Management and Budget Circular A-119 Revised, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (revised on January 27, 2016), available at https://www.nist.gov/system/files/revised_circular_a-119_as_of_01-22-2016.pdf. *Voluntary consensus standards bodies* refer to any "association, organization, or technical society that plans, develops, establishes, or coordinates voluntary consensus standards using a voluntary consensus standards development process that includes [specific] attributes or elements." Ibid.

Section V.A. of this guidance describes these attributes or elements.

This program facilitates submissions by external stakeholders[3] and FDA staff proposing voluntary consensus standards related to pharmaceutical quality for recognition. CDER believes that this program will help promote beneficial innovation in pharmaceutical development and manufacturing and streamline the preparation and assessment of marketing applications for products regulated by CDER.[4]

Even if an industry stakeholder references one of CDER's recognized voluntary consensus standards to support a product regulated by CDER (e.g., in an application or during an inspection), FDA may request additional information that demonstrates that the standard was followed and is fit for the intended purpose. In addition, the stakeholder's use of a recognized standard is strictly voluntary.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The National Technology Transfer and Advancement Act (NTTAA) and Office of Management and Budget (OMB) Circular A-119 direct Federal Government agencies to use voluntary consensus standards developed or adopted by a standards-developing organization (SDO) — rather than Government-unique standards — except where these standards are inconsistent with applicable law or otherwise incompatible with FDA's missions, authorities, priorities, and budgetary resources.[5]

The policies of OMB Circular A-119 are intended to: (1) encourage Federal agencies to benefit from the expertise of the private sector; (2) promote Federal agency participation in voluntary consensus standards bodies to ensure the creation of standards that are usable by Federal agencies; and (3) reduce reliance on Government-unique standards when an existing voluntary standard would suffice. CDER's program for recognition of voluntary consensus standards is consistent with the policies of OMB Circular A-119.

[3] Although regulated industry would be the primary user of standards that are within the scope of this program, any interested party may request recognition of a standard.

[4] CDER's program is different than the standards recognition program in the Center for Devices and Radiological Health. The Center for Devices and Radiological Health operates a standards recognition program under the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115).

[5] See section 12(d)(2) of the NTTAA.

III. SCOPE OF THE PROGRAM

This program recognizes voluntary consensus standards related to pharmaceutical quality for products under CDER's jurisdiction. This program considers for recognition both targeted standards (e.g., a test method for a specific product type) and standards applicable to a broad range of products and processes.[6] This program does not apply to statutory and regulatory standards that are legally binding, such as certain provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301-399h) relating to the United States Pharmacopeia (USP).[7] The standards recognized in this program do not include and are different from electronic data exchange standards.[8]

IV. PURPOSE OF THE PROGRAM

CDER established this program to:

- Use FDA expertise to evaluate and, where appropriate, recognize voluntary consensus standards related to pharmaceutical quality that are potentially useful to industry and FDA staff. Specifically, this process allows CDER to:
  - Receive a candidate consensus standard, with relevant information (e.g., the scope of the standard and the purpose), from internal or external parties for recognition
  - Determine whether to recognize a standard in whole or in part following an internal scientific and policy evaluation
  - Prepare an information sheet for each recognized standard describing the scope and the extent of CDER's recognition of that standard and any other relevant information
  - List the recognized standards and post the information sheets in a publicly searchable database on the CDER program's web page[9]

---

[6] Standards applicable to drug-device combination products under CDER jurisdiction and to the drug constituent part of such combination products are within the scope of this program. In certain circumstances, a standard applicable to a device constituent part of such combination products under CDER jurisdiction may be considered for recognition. Areas not covered by this program include, for example, standards related to drug product distribution, supply chain security, and bioresearch monitoring.

[7] Although much of the USP and National Formulary is legally enforceable, the USP general chapters numbered <1000> to <1999> (general information chapters) are informational and generally do not contain any mandatory requirements (see USP General Notices 3.10, Applicability of Standards).

[8] Electronic data exchange standards for submissions to CDER can be found in the FDA Data Standards Catalog, which lists the data standards and terminologies that FDA supports for use in regulatory submissions to better enable the evaluation of safety, effectiveness, and quality of FDA-regulated products.

[9] See https://www.fda.gov/drugs/cder-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality-cder-quality.

- Provide transparency to external stakeholders regarding CDER's thinking about a particular method or approach.

- Promote the visibility and use of standards applicable to its public health mission.

V. THE RECOGNITION PROGRAM FOR VOLUNTARY CONSENSUS STANDARDS RELATED TO PHARMACEUTICAL QUALITY

A. Elements of the Standards Development Process

For purposes of this program, CDER intends to consider for recognition standards developed by voluntary consensus standards bodies that adhered to the elements of openness, balance, due process, appeals process, and consensus (mentioned in the revised OMB Circular A-119[10]). For example, standards developed by the International Organization for Standardization and ASTM International usually meet these criteria, as do standards developed in adherence with the American National Standards Institute Essential Requirements.[11] The CDER program may also recognize standards developed by professional societies, industry associations, and other organizations that adhere to these elements.

1. Openness

The procedures or processes for participating in standards development are transparent and open to interested parties. Such parties are provided "meaningful opportunities to participate in standards development on a non-discriminatory basis."[12]

2. Balance

A broad range of stakeholders are provided meaningful involvement in the standards development process of the voluntary consensus standards body, with no single interest dominating the decision-making.

3. Due Process

The standards development process of the voluntary consensus standards body contains a due process provision where (1) that body's standards development policies and procedures were documented and publicly available, and (2) all stakeholders were provided adequate notice of that body's meetings and standards development activities, and given "sufficient time to review

[10] See footnote 2.

[11] See https://www.ansi.org/.

[12] See footnote 2.

drafts and prepare views and objections, access to views and objections of other participants, and a fair and impartial process for resolving conflicting views."[13]

4. Appeals Process

The standards development process of the voluntary consensus standards body contains an appeals provision, which allows that body to impartially handle any procedural appeals.

5. Consensus

During the development of consensus[14] on standards, comments and objections are considered using fair, impartial, open, and transparent processes.

B. CDER's Policies and Procedures for Evaluating Voluntary Consensus Standards Related to Pharmaceutical Quality

1. Recognition Request Submission and Communication With Requestors

FDA staff and external stakeholders can submit a recognition request electronically through the CDER Direct NextGen Collaboration Portal (the portal).[15] The portal contains the recognition request form and step-by-step instructions for recognition request submission. The standard that is the subject of the request could be either a standard that would be a new recognition for the CDER program or a new version of a standard that the CDER program has already recognized. Requestors will need the following information to prepare a recognition request:

- Name and contact information of the requestor
- Full title of the published standard, including the name of the SDO and any reference number and date
- Brief identification of the testing or performance or other characteristics of the drug(s) or manufacturing process(es) that would be addressed by the recognition of the standard, and the applicability of the standard to pharmaceutical development, establishing quality criteria, and/or regulatory assessment

The program will send the following information to the requestor through the portal: acknowledgement of request, notification of whether the program will proceed with evaluation of the standard, requests for additional information, and the recognition decision.

[13] Ibid.

[14] The revised OMB Circular A-119 defines *consensus* as a "general agreement, but not necessarily unanimity." (OMB Circular A-119 Revised; see footnote 2.)

[15] The portal can be accessed at https://edm.fda.gov.

When the program does not proceed with evaluation of a standard or does not recognize the complete standard, the program will communicate the reason(s) for the decision. For example, the program would not proceed with evaluation when the standard is outside of the program's scope, when it is unclear whether the standard's development process adhered to all the elements that are listed in the program's guidance, or when recognition of the standard would not provide enough benefit to justify allocation of resources for evaluation of the standard. The program would not recognize the complete standard when the standard conflicts with an existing regulation or published guidance. Other reasons for not proceeding with evaluation or for not recognizing the complete standard could apply and would be listed in communication from the program.

2. Recognition Request Evaluation

CDER's Pharmaceutical Quality Standards Working Group (PQSWG) serves as a coordination and advisory group for FDA's participation in standards activities associated with pharmaceutical quality. The PQSWG is composed of CDER experts who conduct application assessment, compliance, inspection, surveillance, policy, and research activities related to pharmaceutical quality. The PQSWG has developed and documented an internal process for evaluating recognition requests. The process timelines are flexible and depend on the complexity of the assignment and the availability of FDA staff with expertise relevant to the standard.

The following general policies and procedures apply to the PQSWG's evaluation of each recognition request submitted by an internal or external party:

- When the program receives a recognition request, the PQSWG:
  - Determines whether each voluntary consensus standard proposed for recognition is in conflict with any statute or regulation under which FDA operates and aligns with FDA's current thinking on the topic.
  - Determines whether each voluntary consensus standard proposed for recognition is within the program's scope and adheres to the five elements of standards development listed in section V.A.
  - Determines whether recognition would provide enough benefit to justify allocation of FDA resources for review of the standard for possible recognition.
- If the voluntary consensus standard proposed for recognition meets the PQSWG's qualifying criteria:
  - The PQSWG recommends the formation of a subgroup of FDA subject matter experts (i.e., individuals with the necessary knowledge, experience, training, and skills related to the scope of that standard) to review the standard. When necessary, the PQSWG works with relevant experts within FDA organizational units affected by the technical content of the standard.

- The PQSWG may also recommend that an FDA laboratory evaluate the proposed standard.

- If the standard will be recognized in whole or in part, the FDA subject matter experts, in collaboration with the PQSWG, prepare the information sheet describing the scope and the extent of CDER's recognition of that standard and any other relevant information about that standard (see section VI.F.). The PQSWG reviews and approves the information sheet before publication on the CDER program's public web page.

3. Updating the CDER Program's Recognized Standards Database

The PQSWG adheres to the following general policies and procedures for updating the CDER program's searchable database of recognized standards:

- When a standard is recognized in whole or in part, the PQSWG lists the standard and publishes the accompanying information sheet in a searchable database on CDER's public web page as soon as practicable and within 6 months of completion of the evaluation process.

- The PQSWG periodically reviews the recognized standards database to identify the following:

  - Standards that have been withdrawn by the SDO or replaced by a new version

  - Standards that are no longer in alignment with current pharmaceutical quality-related statutes, regulations, or policies under which FDA operates

  - Standards that are no longer appropriate for meeting regulatory expectations

- The PQSWG initiates withdrawal of recognition status and evaluation of new versions of standards, as appropriate. The PQSWG may also initiate evaluation of new versions of standards in response to a recognition request submission.

- When a new version of a standard is recognized, the PQSWG replaces the previous version with the new version in CDER's recognized standards database as soon as practicable.

VI. QUESTIONS AND ANSWERS ABOUT THE PROGRAM

A. What Does It Mean if CDER Recognizes a Voluntary Consensus Standard?

CDER's recognition of a voluntary consensus standard communicates to FDA staff and external stakeholders that the standard has been evaluated by the process described in section V.B.2. and

has been found to be potentially helpful in satisfying a regulatory requirement. As stated earlier, even when a stakeholder references one of CDER's recognized standards to support a product regulated by CDER (e.g., in an application or during an inspection), FDA may request additional information that demonstrates that the standard was followed and is fit for the intended purpose. FDA may determine that a standard is used in a way that is not applicable to, or appropriate for, the specific product or set of circumstances. Ultimately, FDA's assessment of appropriate use of recognized standards is data-driven, risk-based, and patient-centered. A stakeholder's use of any such recognized standard is voluntary. Additionally, the program does not prevent stakeholders from using standards that are not listed in the CDER program's database of recognized standards.

B. How Would the Use of Recognized Standards Benefit the Pharmaceutical Industry?

The CDER program is intended to promote innovation in pharmaceutical development and manufacturing by leveraging the expertise of the pharmaceutical sector and facilitating the establishment of shared expectations among industry stakeholders. Standards recognition by CDER complements FDA guidances by providing transparency to industry on CDER's thinking on a particular standard, which could help stakeholders more predictably meet regulatory expectations for products under CDER's jurisdiction. For example, use of a recognized standard has the potential to streamline an applicant's preparation and FDA's assessment of marketing applications. Because CDER, through the PQSWG recognition process described in section V.B., would have already evaluated the validity of a particular standard, FDA would be able to focus on the output of that standard (e.g., the attribute evaluated by the standard test method). The principles of standards development described in section V.A. ensure that these benefits are available to all stakeholders.

C. Does the CDER Standards Recognition Program Include FDA Participation in Standards Development Activities?

Participation in standards development activities is outside the scope of the CDER standards recognition program, and the program is not intended to replace such activities. FDA participation in development of a standard is not a prerequisite for recognition of that standard, nor does FDA participation imply that the standard would be recognized by CDER through the program. The program considers only published standards.

D. Will the CDER Program Communicate With SDOs Regarding Recognition Requests?

If an SDO submits a recognition request, the program will send information regarding the request as described in section V.B. Regardless of the origin of a recognition request, CDER may contact the SDO during the evaluation process to determine whether the standard is within the program's scope and whether the standard was developed in accordance with the principles listed in section V.A. Otherwise, CDER does not intend to communicate with SDOs regarding a request to recognize one or more of its standards. SDOs that own a standard previously

recognized by the program are encouraged to use the program's mailbox[16] to communicate any plans to revise the standard.

E. Where Are the Recognized Standards Posted?

CDER maintains a listing of recognized voluntary consensus standards related to pharmaceutical quality in a searchable database that may be accessed via CDER's public web page.[17] On that web page, an information sheet accompanies every recognized standard.

F. What Information Accompanies a Recognized Standard?

Every consensus standard listed in CDER's searchable database is accompanied by an information sheet that specifies the following:

- The organization that developed the standard
- The full title, version, and date of the standard that is recognized
- The scope and extent of CDER's recognition of that standard (in whole or in part)
- Relevant regulations, guidance, and/or supporting publications
- Any other information pertinent to the use of the standard, as determined by the PQSWG

G. Can Multiple Standards Be Recognized for the Same Intended Purpose?

Yes. CDER can recognize multiple standards that meet its criteria for standards development and are determined to be useful for stakeholders and CDER staff.

H. If There Is an Enforceable Compendial Standard From the USP and CDER Has Recognized Another Standard for the Same Purpose, What Is the Effect of CDER's Recognition?

CDER's recognition of a voluntary consensus standard does not affect the regulatory status of the USP standard; however, in this program, CDER may recognize alternate standards that are comparable to the USP standard or that provide advantages over the USP standard.[18] An alternative method or procedure is defined as any method or procedure other than the compendial method or procedure for the article in question. The alternative method or procedure should be fully validated and should produce equivalent or better results compared to the compendial method or procedure. This determination would be made by regulators (e.g., during assessment of an application or during an inspection). Although the use of a noncompendial procedure may be adequate for release and stability testing, the article that is the subject of a USP monograph

[16] CDERStandardsCoordinationRequest@fda.hhs.gov

[17] See https://www.fda.gov/drugs/cder-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality-cder-quality.

[18] The suitability of any analytical procedure used must be verified under actual conditions of use. See 21 CFR 211.194(a)(2).

must nevertheless comply with compendial standards when tested as directed in the relevant monograph.[19]

I. What Are CDER's Expectations When a Recognized Standard Is Referenced in a Marketing Application?

Applicants should clearly identify the standard (including the version) and demonstrate that the standard is fit for the intended purpose. Any modifications of the standard or use beyond the intended scope should be described and would be evaluated by the appropriate CDER organizational unit. If a new version of the standard becomes available while the application is being assessed, CDER would determine whether the applicant should reference the new version in the application. Applicants must follow applicable reporting requirements for changes to use of a recognized standard after a marketing application has been approved.[20] For example, an applicant would be required to report postapproval changes to use of a recognized standard that assesses the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product.[21] Stakeholders could also use recognized standards to support premarketing activities (e.g., an investigational new drug application).

J. What Are CDER's Expectations When a Recognized Standard Is Referenced for Drug Products That Are Legally Marketed Without an Approved Application?

Drug products that are legally marketed without an approved application should clearly identify the standard (including the version) and maintain appropriate documentation demonstrating that the standard is fit for the intended purpose. Such information must be readily available for FDA review during an inspection.[22]

K. How Will the CDER Program Affect Other FDA Centers?

Product quality aspects assessed by FDA centers other than CDER are outside the scope of the CDER program. The CDER program is not intended to establish policies for other FDA centers or to affect assessment practices of other FDA centers, including during cross-center actions. In addition, the CDER program is not intended to affect application of the standards recognition program in the Center for Devices and Radiological Health. However, the CDER program allows for consultation of FDA staff outside of CDER during evaluation of a standard for possible recognition, when appropriate.

---

[19] See USP General Notices 3.10, Applicability of Standards.

[20] See 21 CFR 314.70, 21 CFR 314.97, or 21 CFR 601.12 regarding changes to an approved new drug application, abbreviated new drug application, or biologics license application, respectively.

[21] Ibid.

[22] See 21 CFR 211.180(c).