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

DRAFT GUIDANCE

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

**February 2019
Procedural**

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

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1 **CDER’s Program for the Recognition of Voluntary Consensus**
2 **Standards Related to Pharmaceutical Quality**
3 **Guidance for Industry¹**
4

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6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
7 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
8 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
9 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
10 for this guidance as listed on the title page.
11

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13
14 **I. INTRODUCTION**
15

16 FDA’s participation in the development and use of technical voluntary consensus standards² has
17 been integral to the execution of FDA’s mission. For example, FDA has used such standards to
18 develop and/or evaluate performance characteristics of dosage forms, testing methodologies,
19 manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient
20 specifications, labeling of drug products, and other technical or policy criteria.
21

22 This guidance describes a proposed program at FDA’s Center for Drug Evaluation and Research
23 (CDER) to make public a comprehensive listing of informally recognized voluntary consensus
24 standards related to pharmaceutical quality. CDER is issuing this draft guidance to obtain public
25 comments on the proposed program. After CDER considers submitted comments, CDER will
26 establish this program and describe it by publishing a final guidance.
27

28 This program, once established, will facilitate submissions by external stakeholders and CDER
29 staff proposing voluntary consensus standards related to pharmaceutical quality for informal

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.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A119/revised_circular_a-119_as_of_1_22.pdf, at 16. *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.” Id. Section V.A of this guidance describes these attributes or elements.

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30 recognition. CDER believes that this informal program, which is different than the formal
31 recognition standards program in FDA’s Center for Devices and Radiological Health,³ will help
32 promote innovation in pharmaceutical development and manufacturing and streamline the
33 compilation and assessment of marketing applications for products regulated by CDER.
34

35 Even if an applicant decides to use one of CDER’s informally recognized voluntary standards,
36 CDER may request that the applicant provide additional information to support an
37 Investigational New Drug (IND) application or a marketing application. In addition, the
38 applicant’s use of an informally recognized consensus standard will be strictly voluntary.
39

40 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
41 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
42 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
43 the word *should* in Agency guidances means that something is suggested or recommended, but
44 not required.
45

46

II. SCOPE OF THE PROPOSED PROGRAM

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49 This program will informally recognize voluntary consensus standards related to pharmaceutical
50 quality for products under CDER’s jurisdiction.⁴ This program will not apply to statutory and
51 regulatory standards that are legally binding, such as certain provisions of the Federal Food,
52 Drug, and Cosmetic Act (21 U.S.C. 301-399h) relating to the United States Pharmacopeia
53 (USP).⁵ The standards to be recognized in this program do not include and are different from
54 electronic data exchange standards. (Electronic data exchange standards for submissions to
55 CDER can be found in the FDA Data Standards Catalog.)
56

57

III. BACKGROUND

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59
60 The National Technology Transfer and Advancement Act and Office of Management and Budget
61 (OMB) Circular A-119 direct federal government agencies to use voluntary consensus standards
62 developed or adopted by a standards developing organization—rather than Government-unique

³ The Center for Devices and Radiological Health operates a formal recognition program for standards under the Food and Drug Administration Modernization Act of 1997. Public Law 105-115.

⁴ For example, standards related to drug distribution and supply chain security and current good clinical practices are not included in this program.

⁵ Although much of the USP and NF 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).

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63 standards—except where these standards are inconsistent with applicable law or otherwise
64 impractical.⁶

65
66 The policies of OMB Circular A-119 are intended to: (1) encourage Federal agencies to benefit
67 from the expertise of the private sector, (2) promote Federal agency participation in voluntary
68 consensus standards bodies to ensure the creation of standards that are usable by Federal
69 agencies, and (3) reduce reliance on Government-unique standards when an existing voluntary
70 standard would suffice. CDER’s proposed program for informal recognition of
71 voluntary consensus standards is consistent with the policies of OMB Circular A-119.

72
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IV. PURPOSE OF THE PROPOSED PROGRAM

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76 The purpose of the proposed program will allow CDER to:

77

- 78 • Use Agency expertise to evaluate and informally recognize voluntary consensus
79 standards related to pharmaceutical quality that are potentially useful to industry and
80 CDER staff. Specifically, this process will allow CDER to:
 - 81 - Receive a candidate consensus standard, with relevant information (e.g., the scope of
82 the standard and the purpose, from internal or external parties for informal
83 recognition.
 - 84 - Determine whether to informally recognize a standard in whole or in part following
85 an internal scientific evaluation.
 - 86 - List the informally recognized standards in a publicly searchable database on CDER’s
87 website, accompanied by an information sheet describing the scope and the extent of
88 CDER’s informal recognition of that standard and any other relevant information
89 about it.
- 90 • Provide transparency to industry and other stakeholders regarding CDER’s thinking
91 about a particular method or approach.
- 92 • Promote the visibility and use of standards applicable to its public health mission.

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V. THE PROPOSED INFORMAL RECOGNITION PROGRAM FOR VOLUNTARY 100 CONSENSUS STANDARDS RELATED TO PHARMACEUTICAL QUALITY

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A. Elements of the Standards Development Process

⁶ Consistent with Section 12(d)(2) of the NTTAA, agencies should participate when consultation and participation is “in the public interest and is compatible with their missions, authorities, priorities, and budgetary resources.”

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105 For purposes of this proposed program, CDER intends to consider for informal
106 recognition standards developed by voluntary consensus standards bodies that adhered to
107 the following five elements (mentioned in the revised OMB Circular A-119⁷):
108

109 *1. Openness*

110
111 The procedures or processes for participating in standards development are transparent
112 and open to interested parties. Such parties are provided “meaningful opportunities to
113 participate in standards development on a non-discriminatory basis.”⁸
114

115 *2. Balance*

116
117 A broad range of stakeholders are provided meaningful involvement in the standards-
118 development process of the voluntary consensus standards body, with no single interest
119 dominating the decision making.
120

121 *3. Due Process*

122
123 The standards development process of the voluntary consensus standards body contains a
124 due process provision where (1) that body’s standards development policies and
125 procedures were documented and publically available and (2) all stakeholders were
126 provided adequate notice of that body’s meetings and standards development activities,
127 “sufficient time to review drafts and prepare views and objections, access to views and
128 objections of other participants, and a fair and impartial process for resolving conflicting
129 views.”⁹
130

131 *4. Appeals Process*

132
133 The standards development process of the voluntary consensus standards body contains
134 an appeals provision, which allows that body to impartially handle any procedural
135 appeals.
136

137 *5. Consensus*

138
139 During the development of consensus¹⁰ on standards, comments and objections are
140 considered using fair, impartial, open, and transparent processes.
141

⁷ See footnote 2.

⁸ Id.

⁹ Id.

¹⁰ The revised OMB Circular A-119 defines *consensus* as a “general agreement, but not necessarily unanimity.” OMB Circular A-119 Revised, See footnote 2.

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142 **B. CDER’s Policies and Procedures for Evaluating Voluntary Consensus** 143 **Standards Related to Pharmaceutical Quality** 144

145 CDER’s Pharmaceutical Quality Standards Working Group (PQSWG) serves as a
146 coordination and advisory group for FDA’s participation in standards activities associated
147 with pharmaceutical quality. After CDER considers any public comments it receives in
148 response to the issuance of this draft guidance,¹¹ the PQSWG intends to develop an
149 internal process for informally recognizing standards in whole or in part, and document
150 this process in a publicly available Manual of Policies and Procedures. This documented
151 process should reflect that for every proposed pharmaceutical quality-related standard
152 submitted by an internal or external party for informal recognition, the PQSWG intends
153 to adhere to the following general policies and procedures:
154

- 155 • The PQSWG should evaluate all requests for informal recognition of voluntary
156 consensus standards.
- 157
- 158 • The PQSWG should confirm that each proposed voluntary consensus standard will
159 not be in conflict with any statute, regulation, or policy under which FDA operates.
160
- 161 • The PQSWG should confirm that each proposed voluntary consensus standard
162 adheres to the five elements listed in section V.A.
163
- 164 • If the proposed voluntary consensus standard for informal recognition meets the
165 PQSWG’s qualifying criteria:
166
 - 167 - The PQSWG may recommend the formation of a subgroup of subject matter
168 experts (i.e., individuals with the necessary knowledge, experience, training, and
169 skills related to the scope of that standard) to review the standard. When
170 necessary, the PQSWG should work with relevant experts within organizational
171 units impacted by the technical content of the standard.
172
 - 173 - The PQSWG may also recommend that an FDA laboratory evaluate the proposed
174 standard.
175
 - 176 - The subject matter experts, in collaboration with the PQSWG, will prepare the
177 information sheet describing the scope and the extent of CDER’s informal
178 recognition of that standard (in whole or in part) and any other relevant
179 information about that standard. The PQSWG will review and approve the
180 information sheet prior to publication.
181
 - 182 - CDER intends to list the voluntary consensus standard and publish the
183 accompanying information sheet on a searchable database on CDER’s public
184 website.
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¹¹ See section I of this draft guidance.

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VI. QUESTIONS AND ANSWERS ABOUT THE PROPOSED PROGRAM

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

CDER’s informal recognition of a voluntary consensus standard would communicate to FDA staff and external stakeholders that a voluntary consensus standard has been evaluated by relevant CDER experts for the specific scope outlined in an information sheet (which should describe the scope and the extent of CDER’s informal recognition of that standard (in whole or in part) and other relevant information) and found potentially helpful to industry and CDER staff. As stated earlier in this draft guidance, even if an applicant decides to use one of CDER’s informally recognized voluntary standards, CDER may request that the applicant provide additional information to support an IND application or a marketing application. An applicant’s use of any such informally recognized standard is voluntary.

B. How Will CDER Assign a Review Team When a Recognition Request Is Received?

Standards that are developed in accordance with the elements described in section V.A should be evaluated by the PQSWG, which consists of staff with the necessary knowledge, experience, training, and skills related to the scope of a particular voluntary consensus standard. PQSWG will identify reviewers with relevant expertise based on the technical content of the standard.

C. How Will CDER Determine Whether to Informally Recognize a Voluntary Consensus Standard?

CDER intends to develop an internal process for informally recognizing standards in whole or in part. Please refer to section V.B for more information about this process.

D. Where Will the Informally Recognized Standards Be Posted?

CDER proposes to maintain a listing of informally recognized voluntary consensus standards related to pharmaceutical quality on a searchable database that may be accessed via CDER’s public website. On that website, an information sheet should accompany every recognized standard.

E. What Information Should Accompany a Published Standard?

Every consensus standard listed on CDER’s searchable database should be accompanied by an information sheet that specifies the following:

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- 232 • The address(es) where the standard can be obtained.
- 233
- 234 • The scope and extent of CDER’s informal recognition of that standard (in
- 235 whole or in part).
- 236
- 237 • The full title, version, and date of the standard that is recognized.
- 238
- 239 • Any other information pertinent to the use of the standard.
- 240

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

244 Use of an informally recognized standard has the potential to streamline the
245 compilation and review of marketing applications for products that are under
246 CDER’s jurisdiction. Because CDER, through the PQSWG informal recognition
247 process described in section V.B, would have already evaluated the validity of a
248 particular standard, the Agency would be able to focus on the output of that
249 standard (e.g., the attribute evaluated by the standard test method). In addition,
250 this program will provide transparency to industry on CDER’s thinking on a
251 particular standard and promote innovation in pharmaceutical development and
252 manufacturing. The principles of standards development described in section V.A
253 will ensure that these benefits are available to all applicants.

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

255 Yes. CDER can informally recognize multiple standards that meet its criteria for
256 standards development and are determined to be useful for applicants and CDER
257 staff.

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

262 CDER’s informal recognition of a voluntary consensus standard will not impact
263 the regulatory status of the USP standard; however, in this proposed program,
264 CDER may informally recognize alternate standards that are comparable to the
265 USP standard or that provide advantages over the USP standard.¹² Although the
266 use of a non-compendial procedure may be adequate for release and stability
267 testing, the article that is the subject of a USP monograph must nevertheless
268 comply with compendial standards when tested as directed in the relevant
269 monograph.¹³

¹² Please note that the suitability of any *analytical* procedure used shall be verified under actual conditions of use. See 21 CFR 211.194(a)(2).

¹³ See USP General Notices 3.10, Applicability of Standards.