
Qualified Infectious Disease Product Designation Questions and Answers 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DRAFT GUIDANCE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)**

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Qualified Infectious Disease Product Designation Guidance for Industry Questions and Answers

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1 **Qualified Infectious Disease Product Designation**
2 **Questions and Answers**
3 **Guidance for Industry¹**
4

5
6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug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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15 **I. INTRODUCTION**
16

17 This guidance provides information on the implementation of Title VIII of the Food and Drug
18 Administration Safety and Innovation Act (FDASIA),² titled *Generating Antibiotic Incentives*
19 *Now* (GAIN). GAIN creates incentives for the development of antibacterial and antifungal drug
20 products that treat serious or life-threatening infections. The purpose of this guidance is to
21 provide a resource for information on FDA’s policies and procedures related to the designation
22 of a qualified infectious disease product (QIDP) under GAIN.
23

24 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
25 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
26 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
27 the word *should* in Agency guidances means that something is suggested or recommended, but
28 not required.
29

30
31 **II. BACKGROUND**
32

33 Title VIII, section 801 of FDASIA created the GAIN provisions under section 505E of the
34 Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355f). GAIN offers incentives
35 for the development of antibacterial and antifungal drugs for human use to treat serious or life-
36 threatening infections. The primary incentive is a 5-year exclusivity extension for certain
37 applications of drug products that have been designated as a QIDP and approved under section
38 505 of the FD&C Act. This 5-year exclusivity extension is added to any exclusivity for which
39 the application qualifies upon approval. Additionally, section 524A of the FD&C Act (21 U.S.C.
40 360n-1) requires FDA to give priority review to the first application submitted for approval for a
41 QIDP. A QIDP will also receive fast track designation at the sponsor’s request (21 U.S.C.

¹ This guidance has been prepared by the Office of Antimicrobial Products in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

² Pub.L. 112-144, 126 Stat. 993 (2012).

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42 356(b)(1)). This guidance provides responses to common questions that might arise regarding
43 QIDP designation and review of QIDP new drug applications (NDAs).

44
45

46 **III. QIDP DESIGNATION DEFINED**

47

48 Section 505E(g) of the FD&C Act provides for the designation by FDA of certain
49 antimicrobial products as QIDPs. A QIDP is defined in section 505E(g) as: “an
50 antibacterial or antifungal drug for human use intended to treat serious or life-threatening
51 infections, including those caused by –

52

53 (1) an antibacterial or antifungal resistant pathogen, including novel or emerging
54 infectious pathogens; or

55

56 (2) qualifying pathogens listed by the Secretary under” section 505E(f) of the
57 FD&C Act.

58

59 The Agency has codified the list of *qualifying pathogens* at 21 CFR 317.2.

60

61 For a drug product to be designated a QIDP, the sponsor is required to demonstrate that the drug
62 is an “antibacterial or antifungal drug for human use intended to treat serious or life-threatening
63 infections.”³ A sponsor requesting a QIDP designation may also include documentation that the
64 product is intended to treat an “antibacterial or antifungal resistant pathogen, including novel or
65 emerging infectious pathogens”⁴ or a *qualifying pathogen* as part of the designation request;
66 however, such documentation is not required.

67

68

69 **Q1. What does a QIDP designation cover (i.e., does the designation apply to any product
70 containing the drug substance, or does it apply to a specific sponsor’s drug product in the
71 context of its specific proposed use)?**

72

73 The QIDP designation applies to a specific drug product⁵ from a specific sponsor for a specific
74 use for which it is being studied. The designation is granted only to the sponsor making the
75 request, and it does not apply to a drug substance in general or beyond the specified indications.

76

77 **Q2. When can a sponsor make a request for QIDP designation?**

78

79 A sponsor may request a QIDP designation at any time prior to that sponsor’s submission of a
80 marketing application under section 505(b) for that sponsor’s drug product, as described in Q1,
81 above (see section 505E(d)(1) of the FD&C Act).

82

³ See section 505E(g) of the FD&C Act.

⁴ Ibid.

⁵ As defined in 21 CFR 314.3, “*Drug product* is a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.”

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83 If a sponsor requests QIDP designation for a new indication for the sponsor's approved drug
84 product, that request should be submitted to the investigational new drug (IND) application for
85 that drug product. The marketing application for the new indication would then be submitted as
86 an efficacy supplement.

87

Q3. How does a sponsor make a request for QIDP designation?

89

90 A request for QIDP designation should be submitted either to an IND or as pre-IND
91 correspondence.⁶ The cover letter should include the following text in bold font at the top of the
92 page: **Request for Qualified Infectious Disease Product Designation**. Requests for multiple
93 indications can be combined in a single submission or made separately. The sponsor should
94 clearly identify each indication for which it is requesting QIDP designation.

95

Q4. What information should a QIDP designation request contain?

97

- 98 • A discussion of the information that supports the activity of the drug as an antibacterial or
99 antifungal drug. For example:
 - 100 ○ In vitro data, including any available data on mechanism of action
 - 101 ○ Data from animal models of infection
 - 102 ○ Any available human data from phase 1, phase 2, or phase 3 studies
- 103 • The specific serious or life-threatening indication(s) for which the sponsor intends (or has
104 begun) to develop the drug and the rationale or suitability for developing the drug for the
105 proposed serious or life-threatening infection(s). Sponsors may wish to refer to the
106 definition of *serious* that the Agency has used in the context of other programs intended
107 to encourage the development of drugs to treat serious and life-threatening diseases or
108 conditions: "Whether a disease is serious is a matter of clinical judgment, based on its
109 impact on such factors as survival, day-to-day functioning, or the likelihood that the
110 disease, if left untreated, will progress from a less severe condition to a more serious
111 one."⁷
- 112 • In addition, this request may (but is not required to) include information to demonstrate
113 that the product is an antibacterial or antifungal drug that has the capacity to treat a
114 serious or life-threatening infection caused by either of the following:
 - 115 ○ Resistant pathogen(s), including novel or emerging infectious pathogens
 - 116 ○ Qualifying pathogens listed in 21 CFR 317.2 (see Q12)

119

⁶ Information regarding the CDER pre-IND consultation program for the Office of Antimicrobial products is available at

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/default.htm>.

⁷ See guidance for industry *Expedited Programs for Serious Conditions—Drugs and Biologics*, citing the definition used in the preamble to the proposed rule, "New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval," 57 FR 13234 at 13235 (April 15, 1992) and 21 CFR 312, subpart I. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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120 **Q5. When should a sponsor expect to hear from FDA regarding its QIDP designation**
121 **request?**

122
123 FDA will respond to a QIDP designation request within 60 calendar days of submission (see
124 section 505E(d)(1) of the FD&C Act). For the purposes of QIDP designation, FDA considers
125 the date of submission to be the date FDA receives the request.
126

127 **Q6. Is fast track designation granted automatically with the QIDP designation or must a**
128 **sponsor specifically request fast track designation?**

129
130 Although a product designated as a QIDP is eligible for fast track designation,⁸ the sponsor must
131 specifically request fast track designation. If fast track has not previously been granted for the
132 indication that is being considered for QIDP designation, fast track designation can be requested
133 in the same letter with the QIDP designation request submitted to the sponsor's IND. If fast
134 track designation has already been granted for this indication of the sponsor's proposed drug,
135 there is no need to make an additional request. Fast track designation may also be requested at
136 any time after the QIDP designation. Although QIDP designation may be requested prior to
137 submission of an IND, a request for fast track designation may only be made concurrently with,
138 or any time after, submission of an IND (see section 506(a)(2) of the FD&C Act).
139

140 **Q7. GAIN defines QIDP as “an antibacterial or antifungal drug for human use intended**
141 **to treat serious or life-threatening infections...” Could an antibacterial or antifungal drug**
142 **intended to prevent or diagnose a serious or life-threatening infection be eligible for QIDP**
143 **designation?**

144
145 In the context of other programs under the FD&C Act intended to expedite the development of
146 drugs and biologics to address unmet medical needs, FDA has determined that a product is
147 intended to treat a serious or life-threatening disease or condition if it is intended to have “an
148 effect on a serious condition or a serious aspect of the [serious or life-threatening] condition,”
149 including diagnosing, preventing, and treating a serious aspect of the condition.⁹ At the time of
150 GAIN's enactment, Congress was aware of FDA's long-standing interpretation of the term
151 “serious and life-threatening.” Thus, FDA interprets the phrase “intended to treat a serious or
152 life-threatening infection” in the context of QIDPs in a similar manner to these other programs.
153 Accordingly, FDA will consider a drug to be “intended to treat a serious or life-threatening
154 infection” if it is intended to diagnose, prevent, or treat such an infection.
155

156 **Q8. Are biologic products or devices eligible for QIDP designation?**

157
158 No. The provisions of GAIN refer only to human drugs that are the subject of applications under
159 section 505 of the FD&C Act, and therefore, QIDPs must be human drugs whose applications
160 are submitted pursuant to section 505(b) of the FD&C Act.¹⁰ Accordingly, biologic products that
161 are approved for marketing pursuant to section 351 of the Public Health Service Act (42 U.S.C.

⁸ See section 524A of the FD&C Act.

⁹ See guidance for industry *Expedited Programs for Serious Conditions—Drugs and Biologics*.

¹⁰ Applications for combination products submitted under section 505(b) of the FD&C Act may qualify for QIDP designation.

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162 262) or devices that are cleared pursuant to section 510 of the FD&C Act (21 U.S.C. 360) or
163 approved pursuant to section 515 of the FD&C Act (21 U.S.C. 360e) are not eligible for QIDP
164 designation.

165

166 **Q9. Is priority review designation automatically given to any application or efficacy**
167 **supplement submitted for a QIDP?**

168

169 No. FDA automatically gives priority review designation to *the first* application or efficacy
170 supplement submitted for a specific drug product and indication for which QIDP designation was
171 granted (see section 524A of the FD&C Act, as amended by section 3101(a)(2)(N) of the 21st
172 Century Cures Act).¹¹ A subsequent original application or efficacy supplement from the same
173 sponsor for the same product and indication will receive priority review designation only if it
174 otherwise meets the criteria for priority review.

175

176

177 **IV. GAIN EXCLUSIVITY**

178

179 Subject to the specified statutory limitations, a drug that is designated as a QIDP and is approved
180 for the use for which the QIDP designation was granted will receive a 5-year extension to any
181 exclusivity for which the application qualifies upon approval. Section 505E of the FD&C Act
182 lists the following limitations under which the 5-year GAIN exclusivity extension is not
183 available:

184

185 (c) LIMITATIONS—Subsection (a) does not apply to the approval of—

186 (1) a supplement to an application under section 505(b) for any qualified infectious
187 disease product for which an extension described in subsection (a) is in effect or has
188 expired;

189 (2) a subsequent application filed with respect to a product approved under section 505
190 for a change that results in a new indication, route of administration, dosing schedule,
191 dosage form, delivery system, delivery device, or strength; or

192 (3) a product that does not meet the definition of a qualified infectious disease product
193 under subsection (g) based upon its approved uses.

194

195 **Q10. When is an efficacy supplement to an approved NDA eligible for the 5-year GAIN**
196 **exclusivity extension?**

197

¹¹ Certain applications for QIDPs may qualify to receive a tropical disease priority review voucher (PRV) under section 524 of the FD&C Act, a rare pediatric disease PRV under section 529, or a material threat medical countermeasure PRV under section 565A. In order to receive a PRV, the application must be deemed (under section 524 or section 529) or determined (under section 565A) by the Agency to be eligible for priority review. In determining whether an application for a QIDP that receives priority review pursuant to section 524A is also eligible for priority review within the meaning of these provisions, if a PRV is requested, the Agency will determine whether the application satisfies the criteria for eligibility for a priority review designation, i.e., whether the drug treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. For more information on the priority review designation, see guidance for industry *Expedited Programs for Serious Conditions—Drugs and Biologics* (May 2014); see also Manual of Policies and Procedures 6020.3 Rev. 2, 6/25/13.

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198 An efficacy supplement¹² to an approved NDA may be eligible for the 5-year GAIN exclusivity
199 extension if the following conditions apply:

- 200
- 201 (1) The application that is being supplemented has not previously received the 5-year
202 GAIN exclusivity extension,
 - 203
 - 204 (2) The supplement is for an indication for which the product has received a QIDP
205 designation prior to submission of the supplement, and
 - 206
 - 207 (3) The supplement qualifies for 3-year exclusivity¹³ and/or orphan drug exclusivity,¹⁴ as
208 applicable.
 - 209

Q11. Can a subsequent application for a previously approved product be eligible for the 5-year GAIN exclusivity extension?

210
211
212 Under section 505E(c)(2) of the FD&C Act, a subsequent application for a previously approved
213 product is not eligible for the 5-year GAIN exclusivity extension if the applicant (or its
214 predecessor in interest) previously received approval and received the 5-year exclusivity
215 extension pursuant to section 505E(a), and the subsequent application is seeking approval for a
216 change that results in a new indication, route of administration, dosing schedule, dosage form,
217 delivery system, delivery device, or strength.

218

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V. QUALIFYING PATHOGENS

223 Section 505E(f) of the FD&C Act instructs the Secretary (and thus FDA, by delegation) to
224 establish and maintain a list of “qualifying pathogens,” and make public the methodology for
225 developing the list. A *qualifying pathogen* is defined as:

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. . . a pathogen identified and listed by the Secretary . . . that has the potential to pose a
serious threat to public health, such as —

- (A) resistant gram positive pathogens, including methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant enterococcus;
- (B) multi-drug resistant gram negative bacteria, including *Acinetobacter*, *Klebsiella*, *Pseudomonas*, and *E. coli* species;
- (C) multi-drug resistant tuberculosis; and
- (D) *clostridium difficile*.

Q12. Where can I find the list of “qualifying pathogens” mentioned in GAIN?

236

237

238

239

The list of “qualifying pathogens” can be found in 21 CFR 317.2. The final rule, “Establishing a List of Qualifying Pathogens Under the Food and Drug Administration Safety and Innovation

¹² See 21 CFR 314.3(b) for definition of an efficacy supplement.

¹³Section 505(c)(3)(E)(iv) and 505(j)(5)(F)(iv) of the FD&C Act.

¹⁴ Section 527 of the FD&C Act.

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240 Act,” was published on June 5, 2014.¹⁵ The final rule describes the factors FDA considered and
241 the methodology used for developing the list.

242

243 **Q13. Must a product be intended for the treatment of an infection caused by a qualifying**
244 **pathogen to be eligible for QIDP designation?**

245

246 No. The statutory standard for inclusion on FDA’s list of qualifying pathogens is different from
247 the statutory standard for QIDP designation. QIDP designation, by definition, requires that the
248 drug in question be “an antibacterial or antifungal drug intended to treat a serious or life-
249 threatening infection” (section 505E(g) of the FD&C Act). *Qualifying pathogen* is defined
250 according to a different statutory standard; the term means “a pathogen identified and listed by
251 the Secretary...that has the potential to pose a serious threat to public health” (section 505E(f) of
252 the FD&C Act) (emphasis added). That is, a drug intended to treat a serious or life-threatening
253 bacterial or fungal infection caused by a pathogen that is not included on the list of qualifying
254 pathogens may be eligible for designation as a QIDP; however, a drug that is intended to treat an
255 infection caused by a pathogen on the list may not always be eligible for QIDP designation if it is
256 not intended to treat a serious or life-threatening infection.

¹⁵ 79 FR 32464.