
Qualified Infectious Disease Product Designation— Questions and Answers Guidance for Industry

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

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Procedural**

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Qualified Infectious Disease Product Designation— Questions and Answers Guidance for Industry¹

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 provides information to sponsors about FDA's implementation of Title VIII of the Food and Drug Administration Safety and Innovation Act (FDASIA),² titled Generating Antibiotic Incentives Now (GAIN). The GAIN provisions create incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. The purpose of this guidance is to provide sponsors a resource for information on FDA's policies and procedures related to the designation of a qualified infectious disease product (QIDP) under GAIN.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, 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

GAIN offers incentives for certain antibacterial and antifungal products, most notably a 5-year exclusivity extension for certain applications of drug products that have been designated as a QIDP and approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This 5-year exclusivity extension is added to any exclusivity for which the application qualifies upon approval (see section V of this guidance). Additionally, section 524A of the FD&C Act (21 U.S.C. 360n-1) requires FDA to give priority review to the first application

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

² Section 801 of FDASIA created the GAIN provisions under section 505E of the FD&C Act (21 U.S.C. 355f). See Pub. L. 112-144, 126 Stat. 993 (2012).

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submitted for approval for a QIDP (see Q10). A QIDP will also receive fast track designation at the sponsor's request (21 U.S.C. 356(b)(1)). This guidance provides responses to common questions about QIDP designation and the review of new drug applications (NDAs) for QIDP-designated products and are grouped by topic area.

III. QIDP DESIGNATION

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

- (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or
- (2) qualifying pathogens listed by the Secretary under” section 505E(f) of the FD&C Act

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

For a drug product to be designated a QIDP, the sponsor is required to demonstrate that the drug is an “antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections.”³ In its designation request, a sponsor requesting a QIDP designation may also include documentation that the product is intended to treat an “antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens” or a qualifying pathogen included in 21 CFR 317.2; however, such documentation is not required.⁴

IV. QUESTIONS AND ANSWERS

Q1. For purposes of QIDP designation, what is an antibacterial or antifungal drug intended to treat serious or life-threatening infections?

For the purpose of QIDP designation, FDA generally intends to consider a drug product to be an antibacterial or antifungal drug intended to treat serious or life-threatening infections if the sponsor can provide information to show that the drug product directly inhibits replication of, or kills, bacteria or fungi relevant to the proposed indication at concentrations that are likely to be

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

⁴ The fact that a product is intended to treat infections caused by a pathogen on the qualifying pathogens list is neither necessary nor sufficient to satisfy the standards for QIDP designation. For QIDP designation, the sponsor is required to demonstrate that the drug is an “antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections.” See section 505E(g) of the FD&C Act.

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attainable in humans to achieve the intended therapeutic effect.⁵ For purposes of QIDP designation, FDA generally does not intend to consider a drug product to be an antibacterial or antifungal drug intended to treat serious or life-threatening infections if the drug product only inhibits replication of, or kills, bacteria or fungi at concentrations that are infeasible to study in human subjects because of anticipated toxicity.

Q2. Does a QIDP designation apply to any product containing the drug substance, or does it apply only to a specific sponsor's drug product in the context of its specific proposed use?

FDA generally considers the QIDP designation as applying to a specific drug product⁶ from a specific sponsor for a specific use for which it is being studied.^{7,8} The designation is granted only to the sponsor making the request,⁹ rather than applying to a drug substance in general or beyond the specified indications.

Q3. GAIN defines QIDP as “an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections.” Could an antibacterial or antifungal drug intended to prevent or diagnose a serious or life-threatening infection be eligible for QIDP designation?

In the context of other programs under the FD&C Act intended to expedite the development of drugs and biologics to address unmet medical needs, FDA has determined that a product is intended to treat a serious or life-threatening disease or condition if it is intended to have “an effect on a serious condition or a serious aspect of the [serious or life-threatening] condition,” including diagnosing, preventing, and treating a serious aspect of the condition.¹⁰ At the time of

⁵ See question 7 for examples of types of information FDA considers appropriate to support a designation request.

⁶ 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.”

⁷ See section 505E(d) and 505E(g) of the FD&C Act.

⁸ Typically, sponsors submit a request for QIDP designation for a single drug product containing a single active ingredient. However, FDA is aware of sponsors developing fixed-combination and co-packaged drugs for the treatment of serious or life-threatening infections. A single QIDP designation request should be submitted to FDA for a fixed-combination or a co-packaged drug intended for submission in a single NDA, and that drug will generally be evaluated as a whole for purposes of QIDP designation.

⁹ However, a QIDP designation granted to a requesting sponsor continues to apply to a sponsor's successor in interest, e.g., if ownership of an IND is transferred following receipt of QIDP designation.

¹⁰ A guidance on Fast Track Drug Development Programs (issued Nov. 1998) explained that the agency considers drugs intended to diagnose or prevent a serious or life-threatening disease or condition as “treating” a serious or life-threatening disease or condition. This language was carried through two revisions of the stand-alone guidance, which was ultimately replaced by a guidance on numerous expedited programs in 2014, with the 2014 guidance reflecting the same interpretation of “treat” as the stand-alone guidance. See the guidance for industry *Expedited Programs for Serious Conditions—Drugs and Biologics* (May 2014). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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GAIN's enactment, Congress was aware of FDA's long-standing interpretation of the phrase "serious and life-threatening." Thus, FDA interprets the phrase "intended to treat a serious or life-threatening infection" in the context of QIDPs in a manner similar to these other programs. Accordingly, FDA generally intends to consider a drug to be "intended to treat a serious or life-threatening infection" if it is intended to diagnose, prevent, or treat such an infection.

Q4. Are biological products or devices eligible for QIDP designation?

No. The provisions of GAIN refer only to human drugs that are the subject of applications under section 505 of the FD&C Act, and therefore QIDPs must be human drugs whose applications are submitted pursuant to section 505(b) of the FD&C Act.¹¹ Accordingly, biological products that are approved for marketing pursuant to section 351 of the Public Health Service Act (42 U.S.C. 262) or devices that are cleared pursuant to section 510 of the FD&C Act (21 U.S.C. 360) or approved pursuant to section 515 of the FD&C Act (21 U.S.C. 360e) are not eligible for QIDP designation.

Q5. When can a sponsor make a request for QIDP designation?

A sponsor may request a QIDP designation at any time before submitting a marketing application under section 505(b) for that sponsor's drug product, as described in Q2, above.¹²

If a sponsor requests QIDP designation for a new indication for the sponsor's approved drug product, the sponsor should submit that request to the investigational new drug (IND) application for that drug product. The marketing application for the new indication would then be submitted as an efficacy supplement.¹³

If the proposed indication for the drug product changes before submission of a marketing application, the sponsor should request a new designation for that new indication. In addition, because QIDP designation also applies to a specific drug product, the sponsor should request a new designation when a significant change in the drug product is made during development, such as a change in dosage form. When a sponsor is uncertain whether a change necessitates a new QIDP designation request, FDA recommends the sponsor seek additional advice from the appropriate review division.

Q6. How does a sponsor request QIDP designation?

A request for QIDP designation should be submitted either to an IND or as pre-IND correspondence.¹⁴ The cover letter should include the following text in bold font at the top of the

¹¹ Applications for combination products submitted under section 505(b) of the FD&C Act may qualify for QIDP designation.

¹² See section 505E(d)(1) of the FD&C Act.

¹³ See 21 CFR 314.70.

¹⁴ Information regarding the CDER pre-IND consultation program for the Office of Antimicrobial Products is available at <https://www.fda.gov/drugs/investigational-new-drug-ind-application/pre-ind-consultation-program>.

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page: Request for Qualified Infectious Disease Product Designation. Requests for multiple indications can be combined in a single submission or made separately. The sponsor should clearly identify in the cover letter each indication for which it is requesting QIDP designation. When requests for multiple indications are combined in a single submission, FDA recommends that sponsors provide in the submission a separate rationale for each indication for which QIDP designation is requested. Requests should reflect how a sponsor anticipates the indication or indications would be described in the product's labeling.

Q7. What information should a QIDP designation request contain?

A QIDP designation request should contain a discussion of the information that supports the activity of the drug as an antibacterial or antifungal drug (see Q1). Information to support the activity of the drug may include, for example:

- In vitro data, including any available data on mechanism of action
- Data from animal models of infection
- Available human data from phase 1, phase 2, or phase 3 studies

A QIDP designation request should also contain the specific serious or life-threatening infection or infections for which the sponsor intends (or has begun) to develop the drug and the rationale or suitability for developing the drug for the proposed serious or life-threatening infection or infections. Sponsors may wish to refer to the definition of *serious* that the Agency has used in the context of other programs intended to encourage the development of drugs to treat serious and life-threatening diseases or conditions: “Whether a disease is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.”¹⁵

In addition, this request may (but is not required to) include information to demonstrate that the product is an antibacterial or antifungal drug that has the capacity to treat serious or life-threatening infections caused by either of the following:

- Resistant pathogens, including novel or emerging pathogens
- Qualifying pathogens listed in 21 CFR 317.2 (see section VI)

Q8. When should a sponsor expect to hear from FDA about its QIDP designation request?

¹⁵ See the guidance for industry *Expedited Programs for Serious Conditions—Drugs and Biologics*, which cites 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.

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FDA will respond to a QIDP designation request within 60 calendar days of submission.¹⁶ For the purposes of QIDP designation, FDA considers the date of submission to be the date FDA receives the request.

Q9. Is fast track designation granted automatically with the QIDP designation or must a sponsor specifically request fast track designation?

Although a product designated as a QIDP is eligible for fast track designation,¹⁷ the sponsor must specifically request fast track designation.¹⁸ If fast track has not previously been granted for the indication that is being considered for QIDP designation, the sponsor can request fast track designation in the same letter with the QIDP designation request submitted to the sponsor's IND. If fast track designation has already been granted for this indication of the sponsor's proposed drug, the sponsor need not make an additional request. The sponsor may also request fast track designation at any time after the QIDP designation. Although a sponsor may request QIDP designation before submitting an IND, a request for fast track designation may be made concurrently with, or any time after, submission of an IND.¹⁹

Q10. Is priority review designation automatically given to any application or efficacy supplement submitted for a QIDP?

No. FDA automatically gives priority review designation to the first application or efficacy supplement submitted for a specific drug product and indication for which QIDP designation was granted.^{20,21} A subsequent original application or efficacy supplement from the same sponsor for the same product and same indication will receive priority review designation only if it otherwise meets the criteria for priority review. A subsequent efficacy supplement for a new indication will

¹⁶ See section 505E(d)(1) of the FD&C Act.

¹⁷ See section 524A of the FD&C Act.

¹⁸ See section 506(b)(1) of the FD&C Act.

¹⁹ See section 506(a)(2) of the FD&C Act; see also the guidance for industry *Expedited Programs for Serious Conditions—Drugs and Biologics*, p. 28.

²⁰ 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. For an applicant 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. See sections 524, 529, or 565A of the FD&C Act. 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 sections 524, 529, or 565A of the FD&C Act, 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). See section 101(b) of the Prescription Drug User Fee Amendments of 2012. For more information on the priority review designation, see the guidance for industry *Expedited Programs for Serious Conditions—Drugs and Biologics*; see also the Manual of Policies and Procedures 6020.3 Rev. 2.

²¹ See section 524A of the FD&C Act, as amended by section 3101(a)(2)(N) of the 21st Century Cures Act.

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automatically receive priority review if the sponsor received QIDP designation for the same drug product for the new indication before submitting the supplement.

V. GAIN EXCLUSIVITY

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

- (c) LIMITATIONS—Subsection (a) does not apply to the approval of—
- (1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;
 - (2) a subsequent application filed with respect to a product approved under section 505 for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or
 - (3) a product that does not meet the definition of a qualified infectious disease product under subsection (g) based upon its approved uses.

Q11. When is an efficacy supplement to an approved NDA eligible for the 5-year GAIN exclusivity extension?

An efficacy supplement²² to an approved NDA may be eligible for the 5-year GAIN exclusivity extension if the following conditions apply:²³

- The application that is being supplemented has not previously received the 5-year GAIN exclusivity extension
- The supplement is for an indication for which the product has received a QIDP designation prior to submission of the supplement
- The supplement qualifies for 3-year exclusivity²⁴ and/or orphan drug exclusivity,²⁵ as applicable

²² See 21 CFR 314.3(b) for definition of an efficacy supplement.

²³ Section 505E(a) and (c) of the FD&C Act.

²⁴Section 505(c)(3)(E)(iv) and 505(j)(5)(F)(iv) of the FD&C Act.

²⁵ Section 527 of the FD&C Act.

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Q12. Can a subsequent application for a previously approved product be eligible for the 5-year GAIN exclusivity extension?

Under section 505E(c)(2) of the FD&C Act, a subsequent application for a previously approved product is not eligible for the 5-year GAIN exclusivity extension if the applicant (or its predecessor in interest) previously received approval and received the 5-year exclusivity extension pursuant to section 505E(a), and the subsequent application is seeking approval for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength.²⁶

VI. QUALIFYING PATHOGENS

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

- 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*.

Q13. Where can I find the list of qualifying pathogens mentioned in GAIN?

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 Act,” was published on June 5, 2014.²⁷ The final rule describes the factors FDA considered and the methodology used for developing the list.

Q14. Must a product be intended for the treatment of an infection caused by a qualifying pathogen to be eligible for QIDP designation?

No. The statutory standard for inclusion on FDA’s list of qualifying pathogens is different from the statutory standard for QIDP designation. QIDP designation, by definition, requires that the drug in question be “an antibacterial or antifungal drug intended to treat a serious or life-threatening infection.”²⁸ *Qualifying pathogen* is defined according to a different statutory standard; the term means “a pathogen identified and listed by the Secretary...that has the

²⁶ Section 505E(c)(2) of the FD&C Act.

²⁷ 79 FR 32464.

²⁸ See section 505E(g) of the FD&C Act.

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potential to pose a serious threat to public health” (emphasis added).²⁹ That is, a drug intended to treat a serious or life-threatening bacterial or fungal infection caused by a pathogen that is not included on the list of qualifying pathogens may be eligible for designation as a QIDP; however, a drug that is intended to treat an infection caused by a pathogen on the list may not always be eligible for QIDP designation if it is not intended to treat a serious or life-threatening infection.

²⁹ See section 505E(f) of the FD&C Act.