



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-7001]

Qualified Infectious Disease Product Designation Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Qualified Infectious Disease Product Designation Questions and Answers.” The Food and Drug Administration Safety and Innovation Act (FDASIA) creates incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. The purpose of this draft guidance is to provide a resource for information on FDA’s policies and procedures related to the designation of a qualified infectious disease product (QIDP).

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-7001 for "Qualified Infectious Disease Product Designation Questions and Answers; Draft Guidance

for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993-0002, 301-796-1182.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Qualified Infectious Disease Product Designation Questions and Answers.” Title VIII of FDASIA created the Generating Antibiotic Incentives Now (GAIN) provisions under section 505E of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355f). GAIN offers incentives for the development of antibacterial and antifungal drugs for human use to treat serious or life-threatening infections. The primary incentive contained in GAIN is a 5-year extension of exclusivity for which a QIDP-designated application qualifies upon approval under the FD&C Act. QIDPs also receive fast track designation at the sponsor’s request (21 U.S.C. 356(b)(1))

and the first marketing application submitted for approval of a QIDP is granted priority review (21 U.S.C. 360n-1).

This draft guidance provides information on the implementation of GAIN and responses to common questions that might arise regarding QIDP designation and review of QIDP new drug applications.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on qualified infectious disease product designation questions and answers. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501-3520) (PRA), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Qualified Infectious Disease Product Designation Questions and Answers

Description: As described in the draft guidance, a sponsor may request a QIDP designation at any time prior to that sponsor's submission of a marketing application under section 505(b) of the FD&C Act (21 U.S.C. 355(b)) for that sponsor's drug product. A request for QIDP designation should be submitted either to an investigational new drug (IND) application or as pre-IND correspondence.

The cover letter for the QIDP designation request should include the following text in bold font at the top of the page: "Request for Qualified Infectious Disease Product Designation Questions and Answers." Requests for multiple indications can be combined in a single submission or made separately. The sponsor should clearly identify each indication for which it is requesting QIDP designation.

As described further in the draft guidance, each request should include: (1) a discussion of the information that supports the role of the drug as an antibacterial or antifungal drug, for example, in vitro data, including any available data on mechanism of action; data from animal models of infection; (2) any available human data from phase 1, phase 2, or phase 3 studies; (3) the specific serious or life-threatening indication(s) 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(s); and (4) the 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 a serious or life-threatening infection caused by either of the following: resistant pathogen(s), including novel or emerging infectious pathogens, and qualifying pathogens listed in 21 CFR 317.2.

We estimate that approximately 33 requests for QIDP designation, as described in the draft guidance, will be submitted annually by approximately 25 sponsors, and that it will take approximately 60 hours to prepare and submit each request.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Requests for a QIDP Designation	25	1.32	33	60	1,980

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: January 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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