I. Background

FDA is announcing the availability of a final 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 drug products that treat serious or life-threatening infections. The purpose of this final 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). This guidance finalizes the draft guidance of the same name issued on January 30, 2018.

II. Guidance

1. Definitions

a. Qualified Infectious Disease Product Designation

A qualified infectious disease product (QIDP) is a drug product that is used to treat serious or life-threatening conditions caused by an infectious agent. The agent can be resistant to or have limited susceptibility to antibiotics or antifungals. The drug product must meet the criteria established by FDA in its final guidance document.

b. GAIN Provisions

The GAIN provisions under section 505E of the FD&C Act offer incentives for the development of antibiotics and antifungals. Ongoing collaborative efforts through P3 include regular updates to these provisions to reflect the current landscape of antibiotic and antifungal discovery and development.

III. Electronic Access


Dated: May 6, 2021.
Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09963 Filed 5–11–21; 8:45 am]
BILLING CODE 4164–01–P
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. 360m–1).

This guidance provides information about how FDA generally intends to implement GAIN and responses to common questions that might arise about QIDP designation and review of new drug applications for QIDPs.

This guidance finalizes the draft guidance of the same name issued on January 30, 2018 (83 FR 4216). Based on the comments submitted to the docket on the draft guidance, FDA made clarifying changes to this guidance, including further information on what drug products the Agency generally intends to consider to be an antibacterial or antifungal drug for the purposes of QIDP designation. The Agency also provided clarification about when a sponsor should submit a new request for QIDP designation and what information should be included in a QIDP designation request.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on QIDP designation. 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance.

The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs or https://www.regulations.gov.


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09986 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0074]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 11, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ilia S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

State Enforcement Notifications—21 CFR 100.2(d)

OMB Control Number 0910–0275—Extension

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in its own name and within its own jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the Federal Register of December 17, 2020 (85 FR 81932), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>100.2(d)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10</td>
</tr>
</tbody>
</table>

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

Table 1—Estimated Annual Reporting Burden

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The estimated reporting burden for § 100.2(d) is minimal because