this draft guidance is primarily based on FDA's experience with ADCs for oncology indications, the principles discussed in this guidance are also generally applicable to the development of ADCs for other indications.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates.'' 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While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information.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 for submissions of investigational new drug applications, new drug applications, and biologic license applications in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338, respectively. In addition, the submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; and the collections of information regarding good laboratory practice in 21 CFR part 58 have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: February 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02604 Filed 2–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0101]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by March 10, 2022.

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 0910–0297. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Prescription Drug User Fee Program

OMB Control Number 0910–0297—Revision

This information collection supports implementation of the Food and Drug Administration Prescription Drug User Fee Act (PDUFA) program. PDUFA was enacted in 1992 and authorizes FDA to collect fees from companies that produce certain human drug and biological products. Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), we have the authority to assess and collect user fees for certain new drug applications (NDAs) and new biologics license applications (BLAs). Under this authority, pharmaceutical companies pay a fee for certain new NDAs and BLAs submitted to FDA for review. We have established a PDUFA page on our website at *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/* that includes resources and information regarding PDUFA topics at FDA.

Because the submission of user fees concurrently with applications is required, review of an application by FDA cannot begin until the fee is submitted. To assist respondents in this regard, we developed Form FDA 3397 entitled ''PDUFA Cover Sheet.'' Additional information and associated instructions may be found on our website at *https://www.fda.gov/industry/fda-user-fee-programs.* The cover sheet (Form FDA 3397) need not be submitted for certain FDA-regulated products, *e.g.,* generic drugs, and whole blood and blood components for transfusion. The list of exempted products is included under the instructions to Form FDA 3397. Relatedly, sections 735 and 736 of the FD&C Act also provide for waiver, reduction, refund, and reconsideration requests. We developed the guidance document entitled ''Guidance for Industry—Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products,'' and Form FDA 3971 (Small Business Waiver and Refund Request), which can be found on our website at *https://www.fda.gov/media/131797/download.*

We are revising the collection to include our current commitment goals, as set forth in the document ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,'' also found on our website at *https://www.fda.gov/media/99140/download.* PDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. The commitment goals represent the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress. FDA is committed to meeting these goals and to continuous

operational improvements associated with PDUFA implementation. The commitment goals provide for the development and issuance of topic-specific guidance. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

In the **Federal Register** of November 30, 2021 (86 FR 67958), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Prescription drug user fee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sections 735 and 736 of the FD&C Act (PDUFA waivers, not including small business waivers)	112	1.68	189	17	3,213
Section 736(d)(1)(C) of the FD&C Act and Form FDA 3971 (small business waivers)	37	1	37	2	74
Reconsideration Requests	6	1.67	10	24	240
Appeal Requests	1	1	1	12	12
User Fee Cover Sheet Form FDA 3397	174	1	174	0.5 (30 minutes)	87
Total			411		3626

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

Based on a review of Agency records, we estimate that the number of initial waiver requests submitted annually (excluding small business waiver requests under section 736(d)(1)(C)) of the FD&C Act) will be 189, submitted by 112 different applicants; and that 37 respondents annually will each submit a small business waiver request. We have included in the burden estimate the time for preparation and submission of application fee waivers for small businesses, including completion of Form FDA 3971. Small businesses requesting a waiver must submit documentation to FDA, including the number of their employees, as well as information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 10 requests for reconsideration annually (including small business waiver reconsiderations) and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving 1 request annually for appeal of user fee waiver determination, and assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA's Center for Drug Evaluation and Research.

We assume 87 hours of burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) for submission of a new drug application or biologics license application.

The information collection reflects an overall increase since our last request for OMB review and approval. We attribute this to expected fluctuations in submissions to the Agency.

Dated: February 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02617 Filed 2–7–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3815]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishment Registration and Device Listing for Manufacturers and Importers of Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with establishment registration and device listing for manufacturers and importers of devices.

DATES: Submit either electronic or written comments on the collection of information by April 11, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 11, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 11, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.