2021, a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years; may request to expand its facility capacity beyond 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and is not restricted to locating approved expansion capacity on the hospital's main campus.

Section 1877(i)(3)(A)(ii) of the Act and our regulations at § 411.362(c)(5) provide that individuals and entities in the community in which the provider requesting the exception is located must have an opportunity to provide input with respect to the provider's application for the exception. For further information, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html.* As stated in our regulations, we will solicit community input on the request for an exception by publishing a notice of the request in the **Federal Register**. Individuals and entities in the hospital's community will have 30 days to submit comments on the request. Community input must take the form of written comments and may include documentation demonstrating that the physician-owned hospital requesting the exception does or does not qualify as an ''applicable hospital'' or ''high Medicaid facility,'' as such terms are defined in § 411.362(c)(2) and (3). In the CY 2012 OPPS/ASC final rule, we gave examples of community input, such as documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries of Federal health programs; however, we noted that these were examples only and that we will not restrict the type of community input that may be submitted (76 FR 74522). If we receive timely comments from the community, we will notify the hospital, and the hospital will have 30 days after such notice to submit a rebuttal statement (§ 411.362(c)(5)).

A request for an exception to the facility expansion prohibition is considered complete as follows:

- If the request, any written comments, and any rebuttal statement include only filed Medicare hospital cost report data (Healthcare Cost Report Information System (''HCRIS'') data): (1) The end of the 30-day comment period if CMS receives no written comments from the community; or (2) the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(i)).
- If the request, any written comments, or any rebuttal statement include data from an external data source, no later than: (1) 180 days after the end of the 30-day comment period if CMS receives no written comments from the community; and (2) 180 days after the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(ii)).

The CMS decision to grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity must be published in the **Federal Register** in accordance with our regulations at § 411.362(c)(7).

## IV. Hospital Exception Request

As permitted by section 1877(i)(3) of the Act and our regulations at § 411.362(c), the following physician-owned hospital has requested an exception to the prohibition on expansion of facility capacity:

*Name of Facility:* Doctors Hospital at Renaissance, Ltd.
*Location:* 5501 South McColl Road, Edinburg, Texas 78539
*Basis for this Exception Request:* High Medicaid Facility

We seek comments on this request from individuals and entities in the community in which the hospital is located. We encourage interested parties to review the hospital's request, which is posted on the CMS website at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html.* We especially welcome comments regarding whether the hospital qualifies as a high Medicaid facility.

Individuals and entities wishing to submit comments on the hospital's request should state whether or not they are in the community in which the hospital is located. We suggest that parties review the **DATES** and **ADDRESSES** sections above to ensure timely submission of their comments.

## V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

## VI. Response to Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: February 4, 2022.

**Lynette Wilson,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2022–02739 Filed 2–8–22; 8:45 am]

**BILLING CODE 4120–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–3404]**

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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 March 11, 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 0910–0727. 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.

**Generic Drug User Fee Program**

*OMB Control Number 0910–0727—Revision*

This information collection supports implementation of FDA's Generic Drug User Fee program. The Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112–144, Title 111) were enacted to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA authorizes FDA to assess user fees to fund critical and measurable enhancements to the performance of FDA's generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications. GDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. For more information regarding GDUFA and ongoing implementation, we invite you to visit our website at *https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments.*

GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry intended to address continuing regulatory challenges. GDUFA reflects input received during an open process that includes regular public meetings, posting of meeting minutes, and consideration of comments from a public docket. We are revising the information collection to include the current GDUFA agreement, or ''goals letter,'' as reflected in the document ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022,'' available for download from our website at *https://www.fda.gov/media/101052/download.* The performance goals and program enhancements specified in the goals letter apply to aspects of the generic drug review program that are important for facilitating timely access to quality, affordable generic medicines. FDA is committed to meeting the performance goals specified in the goals letter and to continuous improvement of its performance.

Included among the performance goals is the issuance of topic-specific guidance documents. 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.

We have developed Form FDA 3794, the Generic Drug User Fee Cover Sheet, available at *https://www.fda.gov/industry/fda-user-fee-programs* which requests the minimum necessary information from generic drug applicants to account for and track user fees and to determine the amount of the fee required. Applicants complete and submit the cover sheets to accompany payments. While applicants may submit payment through multiple means, all cover sheets are prepared using FDA's web-based electronic User Fee System. Upon submitting the completed cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct fiscal year user fee assessment that is due for the submission or program. FDA requests that applicants submit a copy of this completed cover sheet along with the abbreviated new drug application, as well as other additional GDUFA fees, so FDA can verify that the applicant has paid the correct user fee and their account is current.

Respondents to the information collection are potential or actual generic drug application holders or related active pharmaceutical ingredient and finished dosage form manufacturers. Companies with multiple user fee obligations may submit a cover sheet for each user fee obligation.

In the **Federal Register** of November 19, 2021 (86 FR 64945), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Form FDA 3794 | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Generic Drug User Fee Cover Sheet ..... | 500 | 7.616 | 3,808 | 0.5(30 minutes) ..... | 1,904 |

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

Based on a review of the information collection, we have retained the currently approved burden estimate.

Dated: February 3, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–02689 Filed 2–8–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID New Innovators Awards (DP2 Clinical Trial Not Allowed).

*Date:* March 10–11, 2022.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.