considerations, including commuting patterns, traffic flows, and outlet characteristics. Consumers typically choose between nearby retail fuel outlets with similar characteristics along their planned routes. The geographic markets for the retail sale of diesel may be similar to the corresponding geographic markets for retail gasoline as many diesel consumers exhibit the same preferences and behaviors as gasoline consumers.

The Transaction would substantially increase the market concentration in each of the five local markets, resulting in five highly concentrated markets for the retail sale of gasoline and the retail sale of diesel. In four of the five local gasoline retail markets, the Transaction would reduce the number of competitively constraining independent market participants from three to two. In the fifth local gasoline retail market, the Transaction would reduce the number of competitively constraining independent participants from four the three. In three of the five retail diesel markets, the Transaction would result in a merger to monopoly. In the fourth diesel market, the Transaction would reduce the number of competitively constraining independent participants from three to two. In the fifth diesel market, the Transaction would reduce the number of competitively constraining independent participants from four to three.

The Transaction would substantially lessen competition for the retail sale of gasoline and the retail sale of diesel in these local markets. Retail fuel outlets compete on price, store format, product offerings, and location, and pay close attention to competitors in close proximity, on similar traffic flows, and with similar store characteristics. The combined entity would be able to raise prices unilaterally in markets where Marathon and Express Mart are close competitors. Absent the Transaction, Marathon and Express Mart would continue to compete head to head in these local markets.

Moreover, the Transaction would enhance the incentives for interdependent behavior in local markets where only two or three competitively constraining independent market participants would remain. Two aspects of the retail fuel industry make it vulnerable to such coordination. First, retail fuel outlets post their fuel prices on price signs that are visible from the street, allowing competitors to observe each other's fuel prices without difficulty. Second, retail fuel outlets regularly track their competitors' fuel prices and change their own prices in response. These repeated interactions give retail fuel outlets familiarity with how their competitors price and how changing prices affect their sales.

Entry into each relevant market would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects arising from the Acquisition. Significant entry barriers include the availability of attractive real estate, the time and cost associated with constructing a new retail fuel outlet, and the time associated with obtaining necessary permits and approvals.

V. The Proposed Consent Agreement

The proposed Consent Agreement would remedy the Acquisition's likely anticompetitive effects by requiring Marathon to divest certain Speedway and Express Mart retail fuel outlets and related assets to Sunoco in five local markets.

The proposed Consent Agreement requires that the divestiture be completed no later than 90 days after Marathon consummates the Acquisition. This Agreement protects the Commission's ability to obtain complete and effective relief given the small number of outlets to be divested. The proposed Consent Agreement further requires Marathon and Express Mart to maintain the economic viability, marketability, and competitiveness of each divestiture asset until the divestiture to Sunoco is complete. For up to twelve months following the divestiture, Marathon and Express Mart must make available transitional services, as needed, to assist the buyer of each divestiture asset.

In addition to requiring outlet divestitures, the proposed Consent Agreement also requires Respondents to provide the Commission notice before acquiring designated outlets in the five local areas for ten years. The prior notice provision is necessary because acquisitions of the designated outlets likely raise competitive concerns and may fall below the HSR Act premerger notification thresholds.

Presently, in Rochester, New York, one local market of concern, Sunoco serves as the wholesale supplier to a retail fuel outlet that is an independent competitor to Speedway and Express Mart. By purchasing the Speedway outlet, Sunoco will also become a competitor to the outlet for which it is currently a wholesale supplier. To address this concern, Sunoco has agreed to implement a firewall between its wholesale and retail fuel pricing businesses in that local market. The firewall will restrict Sunoco retail pricing personnel's access to wholesale information, prohibiting Sunoco retail from knowing, among other information, how its pricing decisions affect the competing location's volumes.

The proposed Consent Agreement contains additional provisions designed to ensure the effectiveness of the proposed relief. For example, Respondents have agreed to an Order to Maintain Assets that will issue at the time the proposed Consent Agreement is accepted for public comment. The Order to Maintain Assets requires Respondents to operate and maintain each divestiture outlet in the normal course of business, through the date the Respondents' complete divestiture of the outlet. During this period, and until such time as the buyer no longer requires transitional assistance, the Order to Maintain Assets authorizes the Commission to appoint an independent third party as a Monitor to oversee the Respondents' compliance with the requirements of the proposed Consent Agreement.

The purpose of this analysis is to facilitate public comment on the proposed Consent agreement, and the Commission does not intend this analysis to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2018–24078 Filed 11–2–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1967]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars 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: Fax written comments on the collection of information by December 5, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written

comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0718. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Biosimilars User Fee Program

OMB Control Number 0910–0718—Extension

This information collection supports FDA's Biosimilars User Fee Program. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), amended the Public Health Service Act by adding section 351(k) (42 U.S.C. 262(k)) to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. This allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications as a type of application under ''human drug application'' for the purposes of the prescription drug user fee provisions.

The Biosimilar User Fee Act of 2012 (BsUFA) authorized FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development (BPD). BsUFA was reauthorized for an additional 5 years in August 2017 (BsUFA II). FDA's biosimilar biological product user fee program requires FDA to assess and collect user fees for certain meetings concerning biosimilar BPD (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biologic license applications (BLAs).

Form FDA 3792, entitled ''Biosimilars User Fee Cover Sheet'', is submitted by each new BPD entrant (identified via a new meeting request or IND submission) and new BLAs. Form FDA 3792 requests the minimum necessary information to identify the request and determine the amount of the fee to be assessed, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an activity with the actual submission or activity by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, and BLAs, and to account for and track user fees associated with BPD meetings.

In addition to the Biosimilars User Fee Cover Sheet, the information collection includes an annual survey of all BsUFA II participants designed to provide information to FDA of anticipated BsUFA II activity in the upcoming fiscal year. This information helps FDA set appropriate annual BsUFA II fees.

FDA has also developed the guidance entitled, ''Assessing User Fees Under the Biosimilar User Fee Amendments of 2017'' to assist industry in understanding when fees are incurred and the process by which applicants can submit payments. The guidance also explains how respondents can request discontinuation from the BPD program as well as how respondents can request to move products to the discontinued section of the biosimilar list. Finally, the guidance provides information on the consequences of failing to pay BsUFA II fees, as well as processes for submitting reconsideration and appeal requests. The guidance is available on our website at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM584984.pdf.*

In the **Federal Register** of June 29, 2018 (83 FR 30746), 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]

Information collection title	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Biosimilar User Fee Cover Sheet; Form FDA 3792	35	1	35	*0.5	17.5
Annual Survey	35	1	35	1	35
Request for discontinuation from BPD program	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list	5	1	5	*0.5	2.5
Total					57

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

We have increased our estimate by an additional 15 respondents since last OMB approval of the information collection. This estimated increase is based on our expectation that participation in the BPD program will continue to grow, consistent with our experience since establishment of the information collection in 2012.

Dated: October 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24130 Filed 11–2–18; 8:45 am]

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