Bard's tunneled home drainage catheter systems business and BD's soft tissue core needle biopsy devices business to Merit. The provisions of the Consent Agreement will enable Merit to become an independent, viable, and effective competitor in the respective relevant markets and maintain the competition that currently exists.

Merit, headquartered in South Jordan, Utah, is a global company with 30 years of experience in the development, manufacture, and distribution of medical devices used in interventional, diagnostic, and therapeutic procedures. Merit offers a portfolio of products that is highly complementary to the tunneled home drainage catheter systems being acquired. Merit also recently introduced its first soft tissue core needle biopsy device product. Merit possesses substantial industry expertise in these product areas and sells its products to similar customers as BD and Bard. For these reasons, Merit is well positioned to restore the benefits of competition that would be lost due to the Acquisition.

Pursuant to the Order, Merit will receive all rights and assets related to Bard's tunneled home drainage catheter system business and BD's soft tissue core needle biopsy device business, including all of the confidential business information used in those businesses. Merit will own or receive a license to all intellectual property necessary to run the businesses. It will also acquire the equipment used in the manufacturing of the products and all documentation and other information related to the products. Respondents will also contract manufacture products for Merit until it is able to manufacture them itself, and Respondents will provide transitional services to Merit to assist the company in establishing manufacturing capabilities for the divested products.

The Respondents must accomplish the divestitures no later than 10 days after the consummation of the proposed Acquisition. If the Commission determines that Merit is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the Respondents to unwind the sale of assets to Merit and then divest the assets to a Commission-approved acquirer(s) within 180 days of the date the Order becomes final. Pursuant to the Order To Maintain Assets, Respondents must maintain the businesses pending divestiture.

The Commission has agreed to appoint a Monitor to ensure that the Respondents comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of assets to Merit. The Commission has appointed Mazars LLP as the Monitor in this matter. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

VII. Opportunity for Public Comment

The purpose of this analysis is to facilitate public comment on the Consent Agreement to aid the Commission in determining whether it should make the Order final. This analysis is not intended to constitute an official interpretation of the proposed Consent Agreement and does not modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2017–28213 Filed 12–28–17; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–262]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *January 29, 2018.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Contract Year 2019 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* We require that Medicare

Advantage and Prescription Drug Plan organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to us for review and approval. We publish beneficiary education information using a variety of formats. The specific education initiatives that utilize PBP and formulary data include web application tools on *www.medicare.gov* and the plan benefit insert in the Medicare & You handbook. In addition, organizations utilize the PBP data to generate their Summary of Benefits marketing information.

This notice replaces the 30-day **Federal Register** notice that published on December 13, 2017 (82 FR 58613) which was subsequently withdrawn on December 22, 2017 (82 FR 60744).

Form Number: CMS–R–262 (OMB control number 0938–0763); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 520; *Total Annual Responses:* 5,675; *Total Annual Hours:* 56,450. (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209.)

Dated: December 26, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–28159 Filed 12–28–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6530]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products; 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 ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of drug or biological products (hereafter referred to as products). The previous guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants'' published May 19, 2009, and the draft guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' published March 11, 2015, have been withdrawn.

DATES: Submit either electronic or written comments on the draft guidance by March 29, 2018 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–6530 for ''Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products; Draft Guidance for Industry; Availability.'' 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,