times,[84] and redesign of BioSC's software, which has been unreliable and rendered some systems inoperable.[85] The Proposed Transaction will allow these innovations to be achieved and will accelerate product development by enabling each company's engineering personnel to work together under one roof[86] with a unified and stronger strategic focus on developing these products more quickly and cost-effectively.[87]

Combining Sartorius and Novasep technologies, IP, engineering personnel, and know-how also will accelerate innovation in the BioSMB product line. Planned innovations include value-engineering BioSMB's SU flow-kits to reduce their cost, developing BioSMB-specific applications data for additional types of therapies, and line extensions, such as the planned, [REDACTED].[88]

The Proposed Transaction will ensure that Novasep's products are effectively manufactured, marketed, and supported by an innovative supplier with the infrastructure that biopharma customers rely on to make long-term capital investments in these products. With the support of Sartorius's global manufacturing, supply chain, sales, and service infrastructure,[89] customers will have the confidence to purchase Novasep equipment as a long-term capital investment. All of these benefits will be particularly pronounced in the U.S., where Novasep has been unable to successfully commercialize BioSC or its other LPLC product lines.

V. Request for Confidential Treatment

This petition, including its related documents, contains certain confidential and competitively sensitive business information relating to Sartorius, Novasep, and the Proposed Transaction. Disclosure of such confidential information may prejudice Sartorius and Novasep, and cause harm to the ongoing competitiveness of both companies. Pursuant to Sections 2.41(f)(4) and 4.9(c) of the FTC's Rules of Practice and Procedure,[90] Sartorius has redacted such information from the public version of this application, and requests confidential treatment for such redacted information under Section 4.10(a)(2) of the FTC's Rules of Practice and Procedure[91] and Sections 552(b)(4) and (b)(7) of the Freedom of Information Act.[92] In the event that a determination is made that any material marked as confidential is not subject to confidential treatment, Sartorius requests that the FTC provide prompt notice of that determination and adequate opportunity to appeal such a decision.

Respectfully submitted,

/s/Fiona A. Schaeffer

Fiona A. Schaeffer,
Andrew S. Wellin,
MILBANK, LLP, 55 Hudson Yards, New York, NY 10001.

Counsel for Sartorius Stedim Biotech, S.A.

Dated: October 28, 2021.

[FR Doc. 2021–25150 Filed 11–17–21; 8:45 am]

BILLING CODE 6750–01–P

[84] The average time from order to delivery for a BioSC system is significantly longer than for a BioSMB system, in part because Sartorius has a superior manufacturing process and efficiencies, and many of Novasep's products are manufactured on an ETO basis, which is more costly and time-consuming. SART_0000464—SART0000471, at SART0000468; *see also* SART_0001130—SART_1177, at SART_0001142 (regarding Sartorius's plans for significant additional investment in product development); *id.* at SART_0001151 (regarding Sartorius's acquisition business case, which includes a multiyear investment in the development of BioSC M).

[85] *See Why Novasep is Not a Competitive Constraint—White Paper Prepared for the U.S. Federal Trade Commission,* dated June 4, 2021, at 17, n.25 (regarding BioSC software challenges).

[86] *See* SART_0001130—SART_0001177, at SART_0001136; SART_0002571—SART_0002591, at SART_0002576 (outlining Sartorius' integration plans, including highlighting the creation of a centralized research and development site as ''priority #1'' as it will benefit from ''automation expertise for [the] full chromatography portfolio,'' the ''use of existing supplier network/cooperation partner—short distances (250km radius) to established suppliers/sub-contractors of BioSMB/Allegro systems,'' ''[c]lose collaboration with French [Sartorius] colleagues in Aubagne for single-use systems,'' and the ''[o]pportunity to hire former Pall people because of close proximity to Dreieich'').

[87] Although Sartorius's research and development plans confirm that it intends to do much more than maintain the status quo for Novasep's products, Sartorius also made specific guarantees to maintain and invest in Novasep at least at current levels for a three-year period in connection with French foreign investment approval, which demonstrates its commitment to Novasep's technologies and employees. *See* Andrew S. Wellin Letter to Lisa DeMarchi Sleigh, dated July 1, 2021 (regarding Sartorius's commitments in connection with French foreign investment approval of the Proposed Transaction).

[88] *See* SART_0000487—SART_0000498, at SART_0000496; SART_0009752, at SART_0009754–55 (illustrating Sartorius' development plans for BioSMB); SART_0153310, at 14 (listing ongoing BioSMB PD improvement projects).

[89] Currently, Sartorius has 306 sales and service employees in the BPS organization. Following the closing of the Danaher/Pall divestiture, Sartorius created a 20-person chromatography ''task force'' dedicated solely to chromatography sales with a special focus on intensified/continuous chromatography equipment. Over half of Sartorius's chromatography task force is located in the U.S.

[90] 16 CFR 2.41(f)(4) and 4.9(c).

[91] 16 CFR 4.10(a)(2).

[92] 5 U.S.C. 552(b)(4), 552(b)(7).

FEDERAL TRADE COMMISSION

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

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice and request for comment.

SUMMARY: The FTC requests that the Office of Management and Budget (OMB) extend for three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the rules and regulations under the Pay-Per-Call Rule (Rule). That clearance expires on November 30, 2021.

DATES: Comments must be received by December 20, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. The *reginfo.gov* web link is a United States Government website produced by OMB and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

FOR FURTHER INFORMATION CONTACT: P. Connell McNulty, Attorney, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Mail Code CC–5201, 600 Pennsylvania Ave. NW, Washington, DC 20580, (202) 326–2061.

SUPPLEMENTARY INFORMATION:

Title: Trade Regulation Rule Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992 (''Pay-Per-Call Rule''), 16 CFR part 308.

OMB Control Number: 3084–0102.

Type of Review: Extension of a currently approved collection.

Abstract: The existing reporting and disclosure requirements of the Pay-Per-Call Rule are mandated by the Telephone Disclosure and Dispute Resolution Act of 1992 (TDDRA) to help prevent unfair and deceptive acts and practices in the advertising and operation of pay-per-call services and in the collection of charges for telephone-billed purchases. The information obtained by the Commission pursuant to the reporting requirement is used for law enforcement purposes. The disclosure requirements ensure that consumers are told about the costs of

using a pay-per-call service, that they will not be liable for unauthorized non-toll charges on their telephone bills, and how to deal with disputes about telephone-billed purchases.

Likely Respondents: telecommunications common carriers (subject to the reporting requirement only, unless acting as a billing entity), information providers (vendors) offering one or more pay-per-call services or programs, and billing entities.

Estimated Annual Hours Burden: 1,029,570 hours (18 + 1,029,552).

Reporting: 18 hours for reporting by common carriers.

Disclosure: 1,029,552 [(21,240 hours for advertising by vendors + 21,732 hours for preamble disclosure which applies to every pay-per-call service + 7,080 burden hours for telephone-billed charges in billing statements (applies to vendors; applies to common carriers if acting as billing entity) + 11,500 burden hours for dispute resolution procedures in billing statements (applies to billing entities) + 968,000 hours for disclosures related to consumers reporting a billing error (applies to billing entities)].

Estimated annual cost burden: $50,456,136 (solely relating to labor costs).[1]

Request for Comment

On August 18, 2021, the FTC sought public comment on the information collection requirements associated with the Rule. 86 FR 46254. The Commission received no germane comments. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rules.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2021–25104 Filed 11–17–21; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9132–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2021, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone number
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the FEDERAL REGISTER	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI Collections of Information	William Parham	(410) 786–4669
VII Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites.	Sarah Fulton, MHS	(410) 786–2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786–7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786–3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities.	David Dolan, MBA	(410) 786–3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786–3365
All Other Information	Annette Brewer	(410) 786–6580

[1] Non-labor (*e.g.,* capital/other start-up) costs are generally subsumed in activities otherwise undertaken in the ordinary course of business (*e.g.,* business records from which only existing information must be reported to the Commission, pay-per-call advertisements or audiotext to which cost or other disclosures are added, etc.). To the extent that entities incur operating or maintenance expenses, or purchase outside services to satisfy the Rule's requirements, staff believe those expenses are also included in (or, if contracted out, would be comparable to) the annual burden hour and cost estimates provided below (where such costs are labor-related), or are otherwise included in the ordinary cost of doing business (regarding non-labor costs).