6. American President Lines, Ltd. and APL Co. Pte, Ltd. on August 2, 2017; and

7. COSCO Europe on February 27, 2024.

The above-named entities listed as being removed from the list of controlled carriers are no longer controlled carriers under 46 U.S.C. 40102(9), 46 U.S.C. chapter 407 and 46 CFR part 565. As a result, the Commission finds that there is good cause to revoke their exemptions and is issuing this notice of intent to revoke them.

The exemptions granted to OOCL,[20] OOCL (Europe),[21] and COSCO SHIPPING Lines Co., Ltd.[22] remain in place because these companies are still on the Commission's list of controlled carriers. However, the Commission may review these exemptions in the future.

III. Public Participation

A. How do I prepare and submit comments?

You may submit comments by using the Federal eRulemaking Portal at *www.regulations.gov,* under Docket No. FMC–2025–0010. Please follow the instructions provided on the Federal eRulemaking Portal to submit comments.

B. How do I submit confidential business information?

The Commission will provide confidential treatment for identified confidential information to the extent allowed by law. If you would like to request confidential treatment, pursuant to 46 CFR 502.5, you must submit the following, by email, to *Secretary@fmc.gov:*

- A transmittal letter that identifies the specific information in the comments for which protection is sought and demonstrates that the information is a trade secret or other confidential research, development, or commercial information.
- A confidential copy of your comments, consisting of the complete filing with a cover page marked ''Confidential-Restricted,'' and the confidential material clearly marked on each page.
- A public version of your comments with the confidential information excluded. The public version must state ''Public Version—confidential materials excluded'' on the cover page and on each affected page and must clearly indicate any information withheld.

[20] *Id.*

[21] *Id.*

[22] Docket No. P3–99.

C. How can I read comments submitted by other people?

You may read the comments received by the Commission at *www.regulations.gov,* under Docket No. FMC–2025–0010.

By the Commission.

David Eng,

Secretary.

[FR Doc. 2025–09786 Filed 5–29–25; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–2744 and CMS–10905]

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

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 June 30, 2025.

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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Annual Facility Survey Form; *Use:* The Program Management and Medical Information System (PMMIS) collects provider-specific and aggregate patient population data on ESRD beneficiaries treated by dialysis and transplant providers. Each facility certification/survey record represents one provider. The CMS–2744 captures certification and other information about ESRD facilities approved by Medicare to provide kidney dialysis and transplant services. Additionally, the CMS–2744 captures activities performed during the calendar year, as well as aggregate year-end population counts for both Medicare beneficiaries and non-Medicare patients. The data elements include basic provider information such as provider certification and type of ownership; aggregated dialysis patient data such as the number of patients,

number of deaths, and number of patients receiving different types of dialysis; dialysis treatment data; kidney transplant data such as number of transplants, type of transplants, and number of patients awaiting transplants; and the total number of each method used to obtain kidneys for transplants. The CMS–2744 collects data on hemodialysis patients dialyzing, vocational rehabilitation, and staffing. The accuracy of the Facility Survey depends on complete reporting by each facility.

Modifications to the CMS–2744 are (a) collection of days the dialysis facility is open; (b) shifts dialysis is provided; (c) adding ''failed'' to ''return after transplant'' for clarity; (d) removing questions related to vocational rehabilitation; and (e) aligning instructions with revisions. *Form Number:* CMS–2744 (OMB control number: 0938–0447); *Frequency:* Yearly; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 7,726; *Total Annual Responses:* 7,726; *Total Annual Hours:* 15,452. (For policy questions regarding this collection contact Christina Goatee at 410–786–6689.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Service Level Data Collection for Initial Determinations and Appeals; *Use:* The Part C and D Reporting Requirements, as set forth in §§ 422.516(a) and 423.514(a), provide CMS with the ability to collect more granular data related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions. This includes collecting more timely data with greater frequency or closer in real-time.

The proposed data elements listed in the Technical Specifications document in this proposed PRA would provide key data to CMS on the utilization of benefits, enhance audit activities to ensure plans are operating in accordance with CMS guidelines, and ensure appropriate access to covered services and benefits.

CMS staff will use this information to monitor health plans and to hold them accountable for their performance. CMS users include group managers, division managers, branch managers, account managers, and researchers.

Health plans can use this information to measure and benchmark their performance. CMS receives inquiries from the industry and other interested stakeholders about beneficiary access to the items, services, and drugs, including service level data for initial determinations and appeals, and other factors pertaining to use of government funds, as well the performance of MA plans. *Form Number:* CMS–10905 (OMB control number: 0938–New); *Frequency:* Quarterly; *Affected Public:* Private Sector, Business or other for-profits, Not for-profits and Federal Government State, Local; *Number of Respondents:* 728; *Number of Responses:* 2,912; *Total Annual Hours:* 728. (For policy questions regarding this collection contact Sabrina Edmonston at 410–786–3209 or *Sabrina.edmonston@cms.hhs.gov*).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–09813 Filed 5–29–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1138]

Meda AB and B. Braun Medical, Inc.; Withdrawal of Approval of Two New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of two new drug applications (NDAs) from two applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 30, 2025.

FOR FURTHER INFORMATION CONTACT: Jennifer Scharpf, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 240–402–8437.

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 830715	Promit (dextran1), 150 mg/mL	Meda AB, C/O Mylan Specialty L.P., 3711 Collins Ferry Rd., Morgantown, WV 26505.
NDA 890105	Hespan (6% hetastarch in 0.9% sodium chloride injection) in Excel Plastic Container.	B. Braun Medical, Inc., 824 12th Ave., PA 18018.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of June 30, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on June 30, 2025 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09781 Filed 5–29–25; 8:45 am]

BILLING CODE 4164–01–P