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