



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0002]

B. Braun Medical, Inc.; Withdrawal of Approval of Three New Drug Applications and One Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of three new drug applications (NDAs) and one abbreviated new drug application (ANDA) held by B. Braun Medical, Inc. B. Braun Medical, Inc., notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: B. Braun Medical, Inc., 901 Marcon Blvd., Allentown, PA 18109, has informed FDA that the following three NDAs and one ANDA are no longer marketed and has requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). By its request, B. Braun Medical, Inc., has also waived its

opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

NDA/ANDA	Proprietary Name
BN 090024	Dextran 70, 6% Dextran 70 in 0.9% NaCl Injection
BN 160767	Dextran 40, 10% Dextran 40 in 0.9% NaCl Injection and 10% Dextran 40 in 5% Dextrose
BN 890104	Pentaspán® (10% Pentastarch in 0.9% NaCl Injection in EXCEL Containers)
BA 740283	Hespan® (6% Hetastarch in 0.9% NaCl in EXCEL Containers)

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Introduction or delivery for introduction into interstate commerce for products without an approved NDA or ANDA violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on the date that this notice becomes effective (see the DATES section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise becomes violative, whichever occurs first.

Dated: July 31, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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