NDA 017512/S-143

APPROVAL LETTER

Vantive US Healthcare LLC
Attention: Jennifer Boyle
Manager, Regulatory Affairs
510 Lake Cook Road
Deerfield, IL 60015

Dear Mrs. Boyle:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 19, 2025, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DIANEAL Peritoneal Dialysis Solution with Dextrose.

This Prior Approval supplemental new drug application provides for the addition of DIANEAL PD-2 Peritoneal Dialysis Solution (1.5%, 2.5% and 4.25% Dextrose) and DIANEAL Low Calcium Peritoneal Dialysis Solution (4.25% Dextrose) products, manufactured at (b) (4) for U.S. Market.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

We acknowledge your March 9, 2026, submission containing prescribing information in structured product labeling (SPL) format.

CARTON AND CONTAINER LABELS

We acknowledge your December 19, 2025, submission containing final printed carton and container labeling.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You

also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website.[1]

If you have any questions, contact Mikee Aguirre, Regulatory Business Process Manager, at mikee.aguirre@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Julia Pinto, Ph.D.
Supervisor
Division of Product Quality Assessment VIII
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling

[1] https://www.uspnf.com/

Julia Pinto

Digitally signed by Julia Pinto
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