

Elite Laboratories, Inc. et al.; Withdrawal of Approval of 16 Abbreviated New Drug Applications; Correction

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The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register on June 3, 2026. The document announced the withdrawal of approval of 16 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of July 6, 2026. The document indicated that FDA was withdrawing approval of ANDA 207366 for ribavirin solution, 6 grams/vial, held by Navinta LLC, 1499 Lower Ferry Rd., Ewing, NJ 08618; ANDA 212957 for fosaprepitant dimeglumine powder, Equivalent to (EQ) 150 milligrams (mg) base/vial, held by Navinta LLC; and ANDA 218638 for nicardipine hydrochloride (HCl) capsule, 20 mg and 30 mg, held by Navinta LLC. Before FDA withdrew the approval of these ANDAs, Navinta LLC informed FDA that they did not want the approval of the ANDAs withdrawn. Because Navinta LLC timely requested that approval of the ANDAs not be withdrawn, the approval is still in effect. This notice removes the entries for ANDA 207366, ANDA 212957, and ANDA 218638.

Agency: Health and Human Services Department; Food and Drug Administration.

Source: Federal Register

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<https://www.federalregister.gov/documents/2026/10/09/2026-20730/elite-laboratories-inc-et-al-withdrawal-of-a-approval-of-16-abbreviated-new-drug-applications>

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