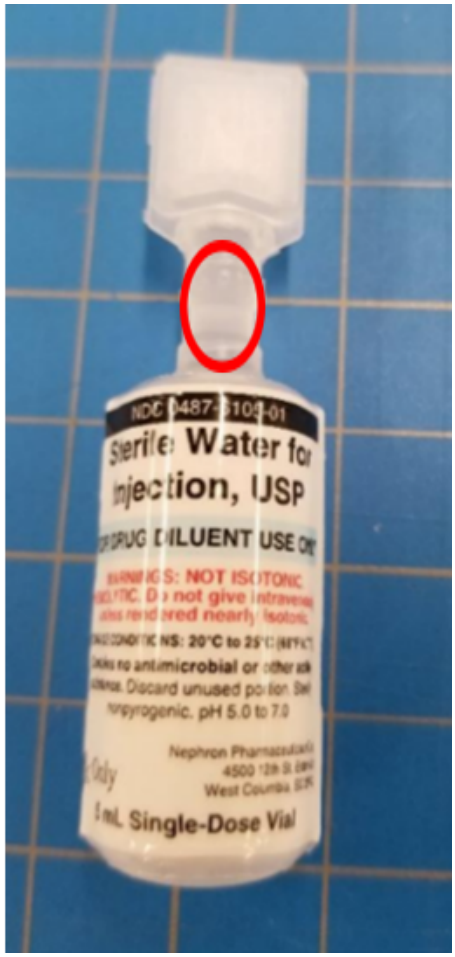
FDA Completes First-Cycle Review of Preservative-Free Ketamine ANDA with No Drug Related Major Deficiencies; Final Packaging Certification Requested for Approval

August 7, 2026

- FDA identified no major deficiencies related to the ketamine drug product, ingredients, proposed labeling, CMC, or other drug-related review matters.
- Remaining item relates to manufacturer certification for a luer lock vial already used in three FDA-approved ANDA products with 11.9 million units shipped over the past 12 months without complaints, returns, adverse events, or recalls.
- No new clinical, safety, efficacy, or drug-related data are required for ANDA approval.
- Following an August 6, 2026 clarification meeting attended by senior FDA leadership, FDA committed to reviewing the requested certification in the shortest possible review cycle.
- NRX believes completion of first-cycle ANDA review with no drug-related major deficiencies substantially de-risks the path to approval and commercialization.
- NRx will host a conference call and Q&A session on Monday, August 10, 2026, at 8:30 a.m. ET to discuss the regulatory update, launch readiness, and other corporate developments.

Figure 1



Medication vial and luer lock tip

MIAMI, Aug. 07, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) today announced that the FDA has completed first-cycle review of the Company's ANDA for its preservative-free ketamine, with no major deficiencies related to the drug product, ingredients, proposed labeling, Chemistry, Manufacturing and Controls, or other drug-related review matters. No new clinical, safety, efficacy, or drug-related data are required for ANDA approval. Following receipt of the FDA comments, the Company held a clarification meeting with FDA on August 6, 2026 to confirm the remaining information required to support approval. The meeting was attended by leadership of the FDA Center for Drug Evaluation and Research (CDER) and the Office of Generic Drugs.

FDA identified a remaining question related to evidence that the luer lock tip of the medication vial would perform properly when connected to a syringe by a licensed health professional. Because the question related to the product's container closure system, it was classified by FDA as a Major Deficiency. Importantly, this remaining item is packaging-related and does not relate to the ketamine drug product itself, its ingredients, proposed labeling, CMC, or other drug-related review matters.

The luer lock medication vial is used in three currently-approved ANDA products that collectively shipped 11.9 million doses of medication in the US over the past 12 months, without complaints, returns, recalls, or adverse events. NRx included testing data in its ANDA on more than 3,500 vials from seven manufactured lots of its ketamine product, with no observed failures in operation of the luer lock tip. At the August 6 meeting, FDA requested that NRx provide a manufacturer attestation confirming that the product is manufactured on the same manufacturing lines with the same methods as the currently approved products, together with an attestation of the above complaint-free history. The company is providing this attestation to FDA for immediate review and FDA committed to reviewing the requested certification in the shortest possible review cycle, while providing a clear path to resolution.

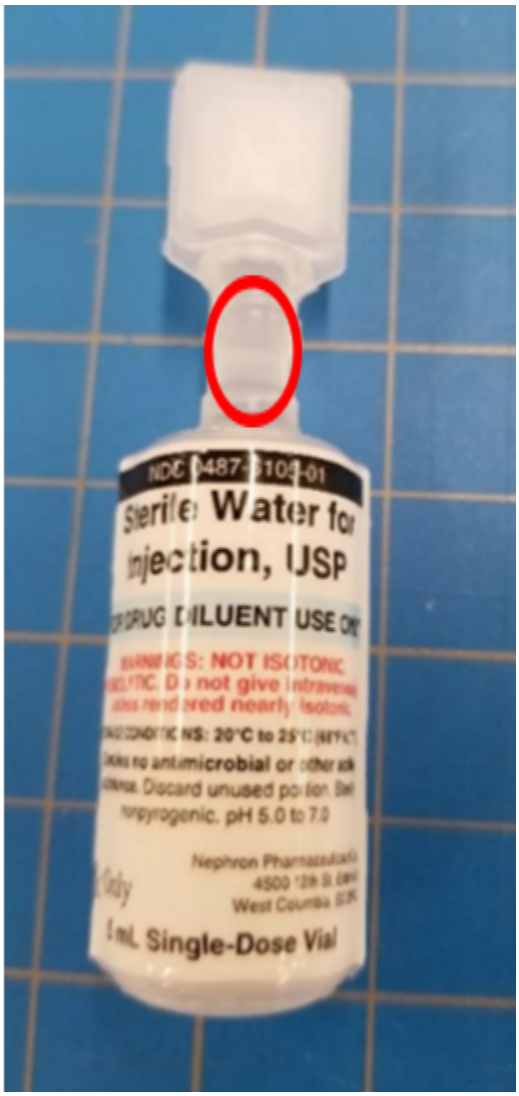
Current industry statistics suggest only 14% to 18% of ANDA products are approved during first cycle review. NRx believes that completion of this first review cycle with no drug-related major deficiencies and only a packaging-related certification remaining represents a meaningful regulatory milestone and substantially de-risks the path to commercialization.

The Company believes prompt review of the remaining certification would be consistent with ongoing public health efforts to address the current ketamine shortage, strengthen U.S.-based supply of strategic medicines, and support the objectives of the April 20, 2026 Presidential Executive Order aimed at advancing breakthrough mental health treatments for veterans and other

patients in need. Currently, the Company believes the vast majority of ketamine for sale in the United States is manufactured outside the U.S. at a time when demand for ketamine continues to increase. Additionally, all other forms of IV ketamine contain a preservative that is no longer permitted by FDA in new drugs, hand cleansers or topical antiseptics.

“We believe this outcome meaningfully de-risks the path to approval because the remaining issue is not related to the ketamine drug product, but to certification of a vial system already used in approved commercial products. We appreciate FDA’s proactive engagement in clarifying the path to approval for our preservative-free ketamine at a time when ketamine remains listed on the FDA drug shortage list and has been identified as a strategically important drug by the Secretary of Health and the FDA Commissioner” said Jonathan Javitt, MD, MPH, Founder and Chief Executive Officer of NRx Pharmaceuticals. “Importantly, FDA identified no major deficiencies related to the drug product, ingredients, proposed labeling, CMC, or other drug-related review matters, which is a highly encouraging outcome on first-cycle ANDA review. Importantly, the August 6 meeting provided a clear and defined path to resolution of the remaining FDA question. We are encouraged by FDA’s commitment at the meeting to review this remaining information in the shortest-possible review cycle and remain focused on advancing our ANDA toward approval and commercialization.”

Figure 1: Medication vial and luer lock tip



The medication vial and luer lock tip configuration currently used in an approved product are shown above for illustrative purposes.

Conference Call Information

NRx management will host a conference call and webcast on Monday, August 10, 2026, at 8:30 a.m. Eastern Time to discuss the FDA meeting, path to approval and future commercialization plans.

Date: Monday, August 10, 2026
Time: 8:30 a.m. ET

Webcast: Events | NRx Pharmaceuticals, Inc.

A replay of the webcast will be available on the Company's website following the event.

About NRx Pharmaceuticals, Inc.
NRx Pharmaceuticals, Inc. (**www.nrxpharma.com**), is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal depression, chronic pain, and PTSD. The Company is developing NRX-100 (preservative-free intravenous ketamine) and NRX-101, (oral D-cycloserine/lurasidone). NRX-100 has been awarded Fast Track Designation for the treatment of suicidal ideation in depression, including bipolar depression. NRX-101 has been awarded Breakthrough Therapy Designation for the treatment of suicidal bipolar depression. NRx has filed an Abbreviated New Drug Application (ANDA), and initiated a New Drug Application filing for NRX-100 with an application for the Commissioner's National Priority Voucher Program for the treatment of suicidal ideation in patients with depression, including bipolar depression.

Notice Regarding Forward-Looking Statements
The information contained herein includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "look forward," and other similar expressions among others. These statements relate to future events or to the Company's future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. The Company has reported regulatory milestones as they have been achieved but has not predicted the outcome of any future regulatory determination. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond the Company's control and which could, and likely will, materially affect actual results, levels of activity, performance or achievements. Any forward-looking statement reflects the Company's current views with respect to future events and is subject to these and other risks, including uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy, and, among other things, liquidity. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's most recent Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. Investors and security holders are urged to read these documents free of charge on the SEC's website at **http://www.sec.gov**. Except as may be required by applicable law, the Company assumes no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, whether as a result of new information, future events or otherwise.

For further information:
Brian Korb
Managing Partner, astr partners
(917) 653-5122
brian.korb@astrpartners.com

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/dc62450a-3cf6-489b-8a3a-9767d551e5c2