NRx Pharmaceuticals Reports Positive FDA Office of Generic Drugs Feedback on Preservative-Free Ketamine Program

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- NRx has received a positive review letter (Discipline Review Letter) addressing Drug Quality requesting only “Minor” administrative changes
- NRx conducted a meeting with leadership of the FDA Office of Generic Drugs in which support was voiced for the potential approval of the Abbreviated New Drug Application within the current review cycle.
- Ketamine is identified as medically necessary by the US Department of Veterans Affairs for the treatment of suicidality and treatment-resistant depression.
- In addition to the current ANDA, NRx is in the process of submitting a New Drug Application to align the labeling of ketamine with its use in treating depression and suicidality
- The President’s April 16, 2026 Executive Order directs rapid approval for drugs that may be used to treat severe depression, suicidality, and PTSD

WILMINGTON, Del., April 22, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a biopharmaceutical company that focuses on neuroplastic therapies for depression, PTSD, and related conditions, today announces the receipt of a positive Discipline Review Letter from the FDA Office of Generic Drugs and the completion of a supportive meeting with Generic Drug Leadership. The Discipline Review Letter entitled “Quality” covers the areas of Drug Substance, Drug Product, Manufacturing, and Microbiology. The letter requests only administrative changes and updates to prior stability data, all of which are identified as “Minor.” This positive review letter follows the previously announced favorable bioequivalence determination from the FDA Office of Generic Drugs on March 17, 2026, and represents a separate review discipline within the ANDA process.

NRx additionally conducted a meeting with leadership of the FDA Office of Generic Drugs in which the national priority around expediting approval of ketamine, now documented in the President’s April 16, 2026 Executive Order, was recognized by FDA leadership. The Executive Order -- ACCELERATING MEDICAL TREATMENTS FOR SERIOUS MENTAL ILLNESS calls for expedited approval of drugs to treat severe depression and suicidality. The approval of the preservative-free ketamine ANDA is particularly important because of supply shortages documented by physicians who seek to obtain ketamine for use in the clinic setting. FDA leadership expressed support for addressing the remaining aspects of the current ANDA application within the current review cycle that targets approval in Summer 2026.

NRx’s presentation of ketamine differs from existing products in that it does not contain a known toxic preservative, Benzethonium Chloride. This preservative is no longer allowed to be included in new drugs and according to FDA policy cannot even be included in hand cleansers and topical antiseptics.

“NRx thanks the President, Secretary Kennedy, Commissioner Makary, and FDA leadership for recognizing the extraordinary need faced by Americans with severe depression and suicidality.” Said Dr. Jonathan C. Javitt, MD, MPH, NRx’s CEO and Chairman. “Every 11 minutes an American dies from suicide. Every day we lose 20 or more Veterans and Soldiers, along with countless first responders. We are committed to working with FDA to bring lifesaving treatments to patients who need them.”

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 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.

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