NRx Pharmaceuticals (Nasdaq:NRXP) Announces FDA Labeling Alignment for NRx's Preservative-Free Ketamine Application

April 6, 2026

- NRx has received a letter from the FDA Office of Generic Drugs indicating preliminary alignment on labeling for NRx's preservative-free ketamine product. Labeling remains subject to final supervisory review.
- NRx previously received a preliminary determination of bioequivalence for this product.
- The Company continues to anticipate a decision on approval under the Generic Drug User Fee Act (GDUFA) in Summer 2026.

WILMINGTON, Del., April 06, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, today announced that it has received a letter from the Labeling Program of the FDA Office of Generic Drugs whose only comments were limited to minor formatting changes to the proposed label for the Company's preservative-free ketamine product. The Company expects to submit the final label this month. The determination is deemed preliminary until final supervisory review of NRx's Abbreviated New Drug Application with anticipated approval in Summer 2026.

This determination by FDA is meaningful in that NRx's product has the potential to substantially augment the supply of US manufactured ketamine at a time when multiple suppliers of ketamine are advising the medical community that they are on backorder. NRx's preservative free product is manufactured in the United States at a time when the FDA has deemed ketamine to be a highly strategic product and recently awarded a Commissioner's National Priority Voucher for a new US manufacturing source of ketamine drug ingredient. A key administration focus has been the "re-shoring" of critical elements of the US drug supply.

"We deeply appreciate the FDA's timely review of the proposed labeling for our generic drug application and look forward to an ongoing collaborative relationship," said Dr. Jonathan C. Javitt, MD, MPH, NRx's CEO and Chairman."

In addition to the pending ANDA application for Preservative Free Ketamine, NRx (as announced yesterday) is preparing a New Drug Application under Fast Track Designation to expand the use of intravenous ketamine to treat patients with severe depression, who may have suicidal ideation.

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.

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