

Elite Pharmaceuticals Files ANDA with US FDA to Market Opiate Analgesic Product

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NORTHVALE, NJ / ACCESSWIRE / September 25, 2023 / Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCQB:ELTP), a specialty pharmaceutical company engaged in the development, manufacture, and distribution of niche generic products, today announced that it filed an Abbreviated New Drug Application (ANDA) on August 17, 2023, and was accepted for review by the US Food and Drug Administration (FDA) on September 19, 2023 for an undisclosed generic drug product in a class of medications called *opiate analgesics*. IQVIA reported annual sales for the twelve months ending June 2023 of \$720 million for the brand and generic market for this product.

About Elite Pharmaceuticals, Inc.

Elite Pharmaceuticals, Inc. is a specialty pharmaceutical company that develops, manufactures, and distributes niche generic products. Elite's product lines consist of immediate-release and controlled-release, solid oral dose products, which are marketed under the Elite Laboratories label, as well as pursuant to licenses granted to third-party pharmaceutical marketing and distribution organizations. Elite operates a cGMP and DEA registered facility for research, development, and manufacturing located in Northvale, NJ. For more information, visit www.elitepharma.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, those related to the effects, if any, on future results, performance or other expectations that may have some correlation to the subject matter of this press release. Readers are cautioned that such forward-looking statements involve, without limitation, risks, uncertainties, and other factors not under the control of Elite, which may cause actual results, performance or achievements of Elite to be materially different from the results, performance or other expectations that may be implied by these forward-looking statements. These forward-looking statements may include statements regarding the expected timing of approval, if at all, of products by the FDA and the actions the FDA may require of Elite in order to obtain such approvals. These forward-looking statements are not guarantees of future action or performance. These risks and other factors are discussed, without limitation, in Elite's filings with the Securities and Exchange Commission, including its reports on forms 10-K, 10-Q, and 8-K. Elite is under no obligation to update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

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