

January 17, 2025

BSE Limited

Department of Corporate Relationship
1st Floor, New Trade Ring, Rotunda Building
Phiroze Jeejeebhoy Towers
Dalal Street, Mumbai- 400001
Scrip Code: 524742

National Stock Exchange of India Ltd

Department of Corporate Services
Exchange Plaza, 5th Floor,
C-1, Block G, Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
Scrip Code: CAPLIPOINT.

Dear Sir/Madam,

Sub: Press Release – Receipt of USFDA Approval

Attaching herewith a Press Release regarding receipt of final approval by our Subsidiary Caplin Steriles Limited from the United States Food and Drug Administration (USFDA) for the Abbreviated New Drug Application (ANDA) Levetiracetam in Sodium Chloride Injection, 500mg/100mL, 1000mg/100mL and 1500mg/100mL infusion bags (Large Volume Parenteral), a generic therapeutic equivalent version of the Reference Listed Drug (RLD), from HQ Speciality Pharma Corp. Request you to take the same on record.

Thanking You,

Sincerely Yours
For Caplin Point Laboratories Limited

Venkatram G
General Counsel & Company Secretary
Membership No. A23989
Encl: A/a

CAPLIN STERILES GETS USFDA APPROVAL FOR LEVETIRACETAM IN SODIUM CHLORIDE INJECTION, INFUSION BAGS

Chennai, Jan 17, 2025: Caplin Steriles Limited (Caplin), a Subsidiary Company of Caplin Point Laboratories Limited (BSE: CAPPL (524742), NSE: CAPLIPOINT), has been granted final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Levetiracetam in Sodium Chloride Injection, 500mg/100mL, 1000mg/100mL and 1500mg/100mL infusion bags (Large Volume Parenteral), a generic therapeutic equivalent version of the Reference Listed Drug (RLD), from HQ Speciality Pharma Corp. This is the second Ready-To-Use Infusion bag (RTU Bags) ANDA drug product approved for Caplin Steriles, with a further 6 products under review with FDA for RTU Bags segment.

Levetiracetam in Sodium Chloride Injection is an antiepileptic drug indicated for adjunctive therapy – i) in the treatment of partial-onset seizures in adults with epilepsy, ii) in the treatment of myoclonic seizures in adults with juvenile myoclonic epilepsy and iii) in the treatment of primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy. According to IQVIA™ (IMS Health), Levetiracetam in Sodium Chloride Injection had US sales of approximately \$19 million for the 12-month period ending November 2024.

About Caplin Steriles Limited

Caplin Steriles Limited, a Subsidiary of Caplin Point Laboratories Limited, is a fast growing sterile product manufacturing company that is approved by several regulatory agencies such as US FDA, EU-GMP, ANVISA and INVIMA. Caplin Steriles Limited, has developed and filed 45 ANDAs in USA on its own and with partners, with 32 approvals so far. The Company is also working on a portfolio of 40+ simple and complex Injectable and Ophthalmic products, that it intends to file over the next 4 years. The company also has multiple products filed with several approvals in non-US markets such as Mexico, Australia, Canada, South Africa etc.

About Caplin Point Laboratories Limited

Caplin Point Laboratories Limited is a fast-growing pharmaceutical company with a unique business model catering predominantly to Emerging Markets of Latin America and a growing presence in the Regulated Markets such as USA. The Company has state of the art manufacturing facilities that cater to a complete range of finished dosage forms. Caplin Point is one of the few companies to show consistent high-quality growth in cashflows, Profitability and Revenues over the last 15 years.

Caplin Point has appeared on **Forbes “Asia’s 200 Best Under a Billion”** list for an unprecedented 7 times in the last 10 years, and was awarded “The Emerging Company of 2018” and “Business Excellence Award for 2019” by Economic Times.

CAUTIONARY STATEMENT:

This press release contains certain forward-looking statements. Any forward-looking statement applies only on the date of this press release. By their nature, forward-looking statements are subject to a number of known and unknown risks and uncertainties that may or may not occur in the future and as a result of which the actual results and performance may differ substantially from the expected future results or performance expressed or implied in the forward-looking statements. No warranties or representations are made as to the accuracy, achievement or reasonableness of such statements, estimates or projections, and Caplin Point has no obligation to update any such information or to correct any inaccuracies herein or omission here from which may become apparent.

For details, please contact:

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