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Date: 30/07/2018

To,

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Subject: **Press Release - Twin USFDA approvals for Morepen's Bulk Drugs (API) Facilities**

Dear Sir,

Please find enclosed Company's press release on **"Twin USFDA approvals for Morepen's Bulk Drugs (API) Facilities".**

Kindly take it on your record.

Thanking you.
Yours faithfully,
For Morepen Laboratories Limited

Morepen Laboratories Ltd. New Delhi

(Thomas P. Joshua)
Company Secretary

Encl.: *As Above*

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Press Release

Twin USFDA approvals for Morepen Labs' Bulk Drugs (API) facilities

Baddi facility gets US FDA nod for bulk drug "Atorvastatin" and Masulkhana facility for "Montelukast"

Key Highlights:

- Baddi facility in Himachal Pradesh gets US FDA approval for cholesterol reducing bulk drug "Atorvastatin".
- Masulkhana facility, also in Himachal Pradesh, gets US FDA approval for an anti-asthma bulk drug "Montelukast Sodium".
- Both the US FDA approvals accorded without any adverse observation- "*Nil 483*".
- Company gets an opportunity to tap the combined market size of over Rs 7,000 Cr. for these two APIs in the US market.
- The above two APIs already contribute Rs. 150 Cr to Morepen's topline and have grown at a CAGR of 25% and 17% respectively. This is expected to rise significantly following the current US FDA approvals.

New Delhi, July 30, 2018: Morepen Laboratories Ltd. has received **US FDA** (*United States Food and Drug Administration*) approvals for both its bulk drugs manufacturing facilities situated in Himachal Pradesh. While the Baddi facility has got **US FDA** approval for the manufacture of bulk drug "**Atorvastatin Calcium**", a Cholesterol reducing drug, the Masulkhana facility has recently got the nod for manufacturing an anti-asthma bulk drug "**Montelukast Sodium**" for export to the US market.

It is significant to note here that **the US market size for these two bulk drugs viz. Atorvastatin Calcium and Montelukast Sodium is approximately Rs.5,000 crore and Rs. 2,000 crore respectively.** The two APIs collectively contributes around Rs. 150 crore annual revenue to the company's topline and constitutes 44 per cent of the company's total API business.

The main API facility situated at Baddi (Himachal Pradesh) houses multiple plants for manufacture of different drugs, including **Atorvastatin**, and is spread across an area of around 50 acres. The Masulkhana facility of Morepen Labs got its first **USFDA** approval for the manufacture of **'Loratadine'** in the year 1999, followed by another

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USFDA approval for **'Desloratadine'** in the year 2011. **Montelukast**" is the third API approved out of this plant.

Speaking on the development, **Mr. Sushil Suri, Chairman and Managing Director, Morepen Laboratories Ltd.** said, "History has repeated itself with the company once again securing twin USFDA approvals, without any adverse remarks from the US regulator. With this development in place, **the company is set to expand its foothold in the combined Rs. 7,000 crore US market for Atorvastatin and Montelukast.** The two APIs will also strengthen company's existing APIs portfolio comprising Loratadine and Desloratadine in the US market."

Morepen Labs got an initial US FDA clearance for Montelukast Sodium in December 2017, based upon approval of customer's ANDA which triggered an inspection of its **Masulkhana facility** in 2018. The facility had gone for regular inspection for all the three products manufactured therein viz. **Loratadine, Desloratadine (already approved) and Montelukast (new approval).** Similarly, the **Baddi plant** was also inspected by US FDA for the first time, triggered by a US customer for supply of **Atorvastatin** to the US markets. The inspection got concluded this month itself. This plant mainly manufactures Atorvastatin amongst other APIs. Following this inspection, both the facilities of Masulkhana and Baddi have been approved without any deficiency and US FDA has not given any adverse remark/ observation (i.e. **no Form 483 has been issued**), besides a complete approval of the two plants' quality parameters has been accorded

Mr. Suri further pointed out that, "with the help of our experienced and dedicated team, we are fully committed to service the regulated markets and fulfil the compliance requirements for US, European and other global customers. **We are continuously working on scaling up our R&D efforts to become a niche player in the global API markets.** R&D team of the company is working relentlessly for churning out new technologies and innovative processes towards cost reduction and also towards process simplification."

Atorvastatin and Montelukast have shown great growth potential during last 5 years, with a CAGR of 25% and 17% respectively. The company expects decent incremental revenues with more US business coming to company's kitty in the coming years.

The **Masulkhana plant was also inspected and approved by the Therapeutic Goods Agency (TGA), Australia in 2015**; minor improvements were made in keeping with the TGA requirements. In addition, **the plant has received an EU-GMP**

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certification following an inspection by the Slovenian drug regulatory authorities in 2013.

This apart, Morepen also supplies the APIs for Canada and the European Union since 1999, and intermediates for Loratadine for the Japanese market. Its application for marketing of API (known as DMF or Drug Master File) is under consideration of the Japanese authority.

The company has a **very strong regulatory department** and has filed 45 Drug Master Files for all APIs with international documentation and validation data. It has been granted six Certificate of Suitability (COS) applicable in 28 European countries.

About Morepen Laboratories Ltd.

Morepen Laboratories Ltd. is a 34-year old, Rs. 600 Cr. pharmaceutical and healthcare products company. The company went public in the year 1993 and is currently listed at both the Bombay Stock Exchange as well as the National Stock Exchange.

Morepen is engaged in the manufacturing and sale of APIs/ Bulk Drugs, Home Diagnostics, Formulations and OTC products. The company's state-of-the-art manufacturing facility at Baddi (Himachal Pradesh) comprises a scientifically integrated complex of 10 plants, each with a specific product profile.

The USFDA approved plant at Masulkhana is for manufacture of Loratadine, an anti-allergy drug – internationally known as Claritin. Desloratadine and the new blockbuster drug Montelukast is also manufactured at this FDA approved site. The large and spread out manufacturing facility at Baddi has EU GMP & WHO GMP Standards and manufactures latest and much in demand APIs like Atorvastatin, Rosuvastatin, Fexofenadine and others for regulated markets of Europe, USA and also for non-regulated markets across the globe.

Morepen markets over 100 branded formulations under six major therapeutic segments in the domestic market. The company's manufacturing facilities are backed by a strong dedicated team of research and development (R&D) professionals who ensure stringent quality standards. In Home - Diagnostics business, Morepen has a formidable presence in Blood Glucose Monitors and Blood Pressure Monitors, in the domestic markets. The company's OTC brands are being promoted under its wholly owned subsidiary Dr. Morepen Limited. Dr. Morepen's famous OTC product line, including Burnol, Lemolate, Sat-Isabgol, Pain-X and others, has a significant presence in the domestic market.

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