

Date: 9th May, 2024

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla
Complex, Bandra (E), Mumbai – 400 051
NSE Symbol: APLLTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals Limited receives various US Food & Drug Administration (USFDA) (Tentative or Final) product approvals.

This is to inform the exchanges that the Company has received various US Food & Drug Administration (USFDA) (Tentative or Final) Product Approvals.

The summary statement giving brief of all product approvals received from 1st April, 2024 till 8th May, 2024 is enclosed for your information and records.

Alembic has a cumulative total of 201 ANDA approvals (173 final approvals and 28 tentative approvals) from USFDA.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,

For Alembic Pharmaceuticals Limited

Manisha Saraf
Company Secretary

Encl.: A/a.

ALEMBIC PHARMACEUTICALS LIMITED

Annexure

Summarized Product Approval received 1st April, 2024 till 8th May, 2024.

Product Name	Approval Final/Tentative	Innovator Name	Brand name	Indication*
Diazepam Injection USP, 10 mg/2 mL (5 mg/mL), Single-Dose Prefilled Syringe	Final	Hoffmann LA Roche Inc	Valium® (Diazepam) Injection	Diazepam Injection USP Diazepam is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety.
Selexipag Tablets 1,000 mcg and 1,200 mcg.	Tentative	Actelion Pharmaceuticals Inc.	Uptravi	Selexipag tablets are indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.
Binimetinib	Tentative	Array Biopharm	Mektovi	Binimetinib tablet is a kinase inhibitor indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.
Tretinoin Cream USP, 0.1%,	Final	Bausch Health US, LLC., USA	Retin-A	Tretinoin Cream is indicated for topical application in the treatment of acne vulgaris.
Clindamycin Phosphate Topical Gel USP 1%	Final	Pharmacia & Upjohn	Cleocin T	Clindamycin phosphate gel is indicated in the treatment of acne vulgaris

*Refer label for full indication

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE: ALEMBIC ROAD, VADODARA - 390 003. • TEL: (0265) 2280550, 2280880 • FAX: (0265) 2281229
Website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN : L24230GJ2010PLC061123