

Date: 3rd July, 2023

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 receives various US Food & Drug Administration (USFDA) (Tentative or Final) product approvals during the quarter ended 30th June, 2023.

With reference to our earlier communication dated 17th April, 2023 and the captioned subject, this is to inform the exchange that the Company has received various US Food & Drug Administration (USFDA) (Tentative or Final) Product Approvals during the quarter ended 30th June, 2023.

The summary statement giving brief of all product approvals received during the quarter ended 30th June, 2023 is enclosed for your information and records.

Alembic has a cumulative total of 184 ANDA approvals (159 final approvals and 25 tentative approvals) from USFDA.

We request you to kindly take the above on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited

Manisha Saraf
Company Secretary

Encl: A/a.

ALEMBIC PHARMACEUTICALS LIMITED

Annexure

Summarised Product Approval received during the quarter ended 30th June, 2023.

Product Name	Approval Final/Tentative	Innovator Name	Brand name	Indication*
Bepotastine Besilate Ophthalmic Solution, 1.5%.	Final	Bausch & Lomb Incorporated	Bepreve Ophthalmic Solution	Bepotastine besilate ophthalmic solution 1.5% is a histamine H ₁ receptor antagonist indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis.
Doxycycline Capsules, 40 mg,	Tentative	Galderma Laboratories, L.P.	Oracea Capsules	Doxycycline capsules are indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. No meaningful effect was demonstrated for generalized erythema (redness) of rosacea.
Nadolol Tablets USP, 20 mg, 40 mg, and 80 mg.	Final	USWM, LLC	Corgard Tablets	Nadolol tablets are indicated for the long-term management of patients with angina pectoris and for the treatment of hypertension, to lower blood pressure.
Carboprost Tromethamine Injection USP, 250 mcg/mL Single-Dose Vials.	Final	Pfizer, Inc.	Hemabate Injection	Carboprost tromethamine injection, USP sterile solution is indicated for aborting pregnancy between the 13th and 20th weeks of gestation. It is also indicated for the treatment of postpartum hemorrhage due to uterine atony which has not responded to conventional methods of management.

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Product Name	Approval Final/Tentative	Innovator Name	Brand name	Indication*
Doxercalciferol Injection, 4 mcg/2 mL (2 mcg/mL) Multiple-Dose Vials.	Final	Genzyme Corporation	Hectorol Injection	Doxercalciferol Injection is indicated for the treatment of secondary hyperparathyroidism in adult patients with CKD on dialysis

*Refer label for full indication.

ALEMBIC PHARMACEUTICALS LIMITED

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