Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

FDA

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, and consistent with R.A. No. 6675, known as the Generics Act of 1988, and R.A. No. 9711, otherwise known as the Food and Drug Administration Act of 2009, the product described hereunder has been found to conform with the requirements and standards for marketing authorization of pharmaceutical products per existing regulations in force as of date hereof.

Registration Number	: **DR-XY46921**
Generic Name	: Budesonide
Brand Name	: Budexa
Dosage Strength & Form	: 250 mcg/ mL (500 mcg/2 mL) Suspension for Nebulization
Pharmacologic Category	: Corticosteroid
Classification	: Prescription (Rx) Drug
Approved Shelf-life	: 24 Months
Storage Condition	: Store at temperatures not exceeding 30°C. Protect from light. Do not refrigerate or freeze.
Packaging	: LDPE Plastic respule x 2 mL in strip of 5's with aluminum pouch (Box of 20's)
Manufacturer	: AXA Parenterals Ltd. Plot No. 936, 937, & 939, Kishanpur, Jamalpur, Roorkee Distt., Haridawar 247667, Uttarakhand, India
Importer/Distributor	: S.M.H.P. Marketing & Consultancy G/F Manor Bldg., 2629 Taft Ave., Malate, Manila

The marketing authorization shall be valid until **24 June 2025** subject to the conditions listed on the reverse side. No change in the formulation, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This marketing authorization is subject to suspension, cancellation or recall should any violation of R.A. No. 3720, R.A. No. 6675 and R.A. No. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this **24 June 2020**

By Authority of the Director General
Per FDA Order No. 2016-005

JESUSA JOYCE N. CIRUNAY, RPh
Director IV
Center for Drug Regulation and Research

CONSIDER THIS DATE

: Initial

FDA-0496034