FDA-20207P1HC4ZDZ5MJYX8DA82E

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

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	:	**DRP-8861**
Generic Name	:	Cetirizine dihydrochloride
Brand Name	:	Ceticit
Dosage Strength & Form	:	10 mg Film-Coated Tablet
Pharmacologic Category	:	Antihistamines
Classification	:	Over-the-Counter (OTC) Drug
Approved Shelf-life	:	36 months
Storage Condition	:	Store at temperatures not exceeding 30°C
Packaging	:	Alu-PVC Blister Pack x 10 (Box of 30's)
Manufacturer	:	Fredun Pharmaceuticals Ltd. 14, 15, 16 Zorabian Industrial Complex, Vevoor, Palghar – 401404, Maharashtra State, India
Importer/Distributor	:	AMB HK Enterprises Inc. No. 6 Felipe Pike St., Bagong Ilog, Pasig City

The marketing authorization shall be valid until **18 May 2023** 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 **18 May 2020**.

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

RHODA LAINE D. MANALOTO, RPh, MGM
Officer-in-Charge
Center for Drug Regulation and Research

REG. STATUS : **Initial [OTC]**
AMOUNT : **Php 15,660; Php 510**
OR NUMBER : **01261352; 01261352**
DATE : **02 April 2020; 22 April 2020**
BAR CODE / DOC TRACK : 2020040116304

FDA-0458860

Registration Number : DRP-8861

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that Registrant has the right or privilege to the use of the name or brand so registered; Registrant hereby agrees and affirms to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property right arising from the registration of the product.

	A	This is subject to batch notification.
	B	This is subject to lot release certification.
	C	This is subject to compliance with the requirements under FDA Circular No. 2013-004 for Monitored Release (MR) drug products.
X	D	Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O No. 2016-0008 for drug products for human use and A.O. No. 105 s. 1991 for veterinary drug products.
	E	Submit a satisfactory Bioequivalence Study Report or Biowaiver (whichever is applicable) within the validity of this CPR in accordance with FDA Circular No. 2016-019.
	F	Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.
	G	Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a personalized ordinary prescription. It is a habit-forming drug.
	H	Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.
X	I	Submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity of this CPR in accordance with A. O. 2013-0022 and FDA Circular 2014-016.
	J	Review of the submitted Bioequivalence Study Report or Biowaiver, whichever is applicable, shall be completed by the FDA within the validity of this CPR; correspondingly, this CPR shall be revoked if product interchangeability has not been established.
	K	Subject to satisfactory compliance to the post-approval commitments detailed in the letter accompanying this CPR.

REMARKS:

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
PHILIPPINES

NOTIFICATION FOR MINOR VARIATION/S OF REGISTERED PHARMACEUTICAL PRODUCT

Date: 03 June 2020

NOTIFICATION NUMBER	
	2020-01876
DTN:	202006171408O6
TO BE FILLED OUT BY FDA	
Received by:	GLVI
Signature	
Date	22 June 2020
PAYMENT DETAILS	
Amount Paid:	Php 1020.00
OR No.:	1277011
OR Date Issued:	03 June 2020

FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Sir/Madam:

In accordance with Administrative Order No. 2013-0021 and related issuances, we wish to apply and notify FDA of our intention to make Minor Variation/s to our pharmaceutical product described below:

PRODUCT PARTICULARS

Generic Name: Cetirizine dihydrochloride
Dosage Strength/Form: 10 mg Film-coatedTablet
Brand Name Ceticit

Approved Shelf-life: 36 Months
Storage Condition: Store at temperatures not exceeding 30C.
Packaging/Presentation: Alu-PVC Blister Pack x 10 (Box of 30's)

FDA Registration No.: DRP-8861 **Validity:** 18 May 2023
Registration Status: Initial (OTC)

COMPANY PARTICULARS

Manufacturer: Fredun Pharmaceuticals ltd.
14, 15, 16 Zorabian Industrial Complex, Vevoor, Palghar - 401404, Maharashtra State, India
Trader : N/A

Importer: AMB HK Enterprises Inc.
No. 6 Felipe Pike St., Bagong Ilog, Pasig City
Distributor: AMB HK Enterprises Inc.
No. 6 Felipe Pike St., Bagong Ilog, Pasig City
Packer / Repacker: N/A

Villanueva. Ruby
06/17/2020

NOTIFICATION NUMBER	
	2020-61876
Received by:	

POST-APPROVAL CHANGES PARTICULARS

Table of Changes		
Current	**Proposed Changes**	**Specific Type of Minor Variation**
Product Labeling: **Old Packaging Design**	**Product Labeling:** **New Packaging Design**	**MiV-PH-N1** **Change of Product Labeling (New Packaging Design)**
Outer Carton Pack Size/s: **Box of 30's**	**Outer Carton Pack Size/s:** **Box of 30's** **Box of 100's**	**MiV-PA31** **Change of outer carton pack sizes for a drug product**
Nothing Follows	**Nothing Follows**	**Nothing Follows**

Villanueva, Ruby
04/17/2020

NOTIFICATION NUMBER	
Received by:	

DECLARATION

In support of our notification, I, the undersigned, hereby declare under oath that:

1. I am duly authorized to bind the establishment I represent pursuant to the authority attached to this Notification for Minor Variation Form (Board Resolution in case of corporation and Special Power of Attorney in all other cases both of which should be duly notarized);
2. In behalf of my company, the pharmaceutical product identified in the notification meets all the legal requirements, and conforms to existing standards and specification requirements applicable to the said product;
3. The particulars given in this notification are true and all data and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies;
4. I agree that the grant of acceptance shall be automatically revoked by FDA in the event that there is subsequent findings of misrepresentation in any of the data indicated in the required documents or any of the said documents is subsequently found to be falsified of fraudulently filed; and/or in case the samples of the identified pharmaceutical product collected through post marketing surveillance shall be found not to conform to the product's registered specifications or approved labeling.
5. The company I represent shall automatically cease and desist from further distributing the identified pharmaceutical product subject of revocation upon receipt of the notice of revocation and pending any administrative proceeding until further notice from FDA.
6. I, or my company undertake to:
   a) Ensure the identified pharmaceutical product's technical and safety information is made readily available to FDA anytime when requested, and to keep records of the distribution of the products for product recall purposes;
   b) Notify FDA of any adverse events consistent with the requirements of pharmacovigilance;
   c) Respond to and cooperate fully with Food-Drug Regulation Officers with regard to any subsequent post-marketing activity initiated by FDA.
   d) Exhaust the remaining stocks **of labeling materials and products** bearing the old product information up to a maximum of one (1) year from the date of receipt of the notification, at the manufacturing level.
   e) Submit a commercial sample of the first batch of manufacturing/importation/packaging/repackaging of the subject product, for all pack sizes, including the package insert or patient information leaflet (whichever is applicable) reflecting the notified change, as soon as available.
7. I understand that our company or establishment cannot place reliance on the acceptance of the notification by FDA in any legal proceedings concerning the above product, in the event that the identified product has failed to conform to any standards or specifications previously declared to FDA.

Villanueva, Ruby
06/17/2020

NOTIFICATION NUMBER	
	2020-61876
Received by:	

COMPANY PHARMACIST

Signature: _____
Name: ROBIN OBLEA, RPH
Designation: REGULATORY PHARMACIST
Date: 03 JUNE 2020

SUBSCRIBED AND SWORN TO BEFORE ME this JUN 16 2020 personally appeared the following:

Name	Residence Certificate	Date Issued	Place Issued
ROBIN OBLEA	**14500131**	**13 January 2020**	**Pasig City**
PERLINA NENETTE T. IBRAHIM	**14500940**	**18 January 2020**	**Pasig City**

Known to me and to me known to be the same persons who executed the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed.

WITNESS MY HAND AND SEAL on the date and place first above written.

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Book No. 92
Series of 2020

ATTY. CONCEPCION P. VILLAREÑA
Notary Public for Quezon City
Until December 31, 2021
PTR No. 9296041 – 1-2-2020/ QC
IBP No. 093586 – 10-22-2019/ QC
Roll No. 30457 – 05-09-80
MCLE VI – 0030379
Adm. Matter No. NP-001(2020-2021)
TIN No. 131-942-754

Villanueva, Ruby
06/17/2020