FDA-2018QD1V3YSSSU1TLN2E1CC7

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

Registration Status : RENEWAL
FDA Registration No. : MDR-05405
Classification :

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs. Device and Cosmetics Act, the product described hereunder has been found to conform with the requirements and standards for registration of medical devices per existing regulations in force as of date hereof.

Name of Product : SERASEAL® INJECTABLE HEMOSTATIC AGENT
Size/Code: 1.5mL vial, 3mL vial, 5mL vial

Manufacturer : Wortham Laboratories, Inc. - TN, USA

Trader :

Importer : GX International, Inc. - 8F Alpap Building Trade St. cor. Investment Drive, Madrigal Business Park, Ayala, Alabang, Muntinlupa City

Distributor : GX International, Inc. - 8F Alpap Building Trade St. cor. Investment Drive, Madrigal Business Park, Ayala, Alabang, Muntinlupa City

Approved Use : Intended use to be applied on a wound to stop bleeding on contact.

Claimed Shelf-Life : 3 years

This registration shall be valid for five year(s) and shall expire on 11 April 2023 subject to the conditions listed on the reverse side.

No change in the information, labelling and commercial presentation of this product shall be made during the effectivity of this registration without approval of this Office.

This registration is subject to suspension, cancellation or recall should violation of any provisions of R.A. 3720, as amended, and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this 11th day of July, 2018.

BY AUTHORITY OF THE DIRECTOR GENERAL

ENGR. BAYANI C. SAN JUAN, MSc, MNSA, CESE
Director IV

DSN :20180201083359
O.R. No :0958047 / 0990053
Amount :P 5,050.00 / P 1,010.00
Date Issued :1 February 2018 / 17 April 2018
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FDA-0340564

MANDATORY REQUIREMENT:

1. This product must be available only in drugstores, hospitals and other legal outlets.
2. The labelling of each device must state:
   a) The date (month/year) within which to use said device, whenever applicable.
   b) The lot or batch number, whenever applicable.
   c) Product registration number.
   d) Name and address of local distributor/importer.

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 privilege to the use of the name or brand so registered; Registrant hereby agree and affirm to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or industrial design rights arising from the registration of the product(s) listed on the other side hereof.

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 March 2022

MS. MARIA LUISA P. BUNAGAN
Company Pharmacist
Buergli Pharma Inc.
Unit 204, 2nd Flr., One Corporate Plaza
845 Arnaiz Ave., Legaspi Village
Makati City

This refers to your application for Certificate of Product Registration (CPR) variation filed on **15 November 2021** with the following post approved change:

Present	Proposed
Manufacturer: Wortham Laboratories Inc. – TN, USA Importer/Distributor: GX International Inc. 8F Alpap Building Trade. St. cor. Investment Drive, Madrigal Business Park, Ayala, Alabang, Muntinlupa City EU Representative: Wortham Laboratories London 11 Dershingham Rd, NW21SN UK Instruction for Use: Issued: 9/1/2008 Revised : 01/09/19 Rev 7	**Manufacturer:** **Wellesta Holding Pte. Ltd. – 360 Orchard Road, Unit 12-03 International Building Singapore 238869 Mfd By: Wortham Laboratories Inc. – Oaks Drive, Chattanooga, TN 37416 USA** **Importer/Distributor:** **Buergli Pharma Inc.** **204, 2nd Flr., One Corporate Plaza, 845 Arnaiz Ave., Brgy. Lorenzo, Legaspi Villae, Makati, Metro Manila** **EU Representative:** **InterV Nordic AB, Sportvagen 28 S-191 43 Sollentuna, Sweden** **Instruction for Use:** **Issued: 9/1/2008** **Revised : 11/27/2017 Rev 6**

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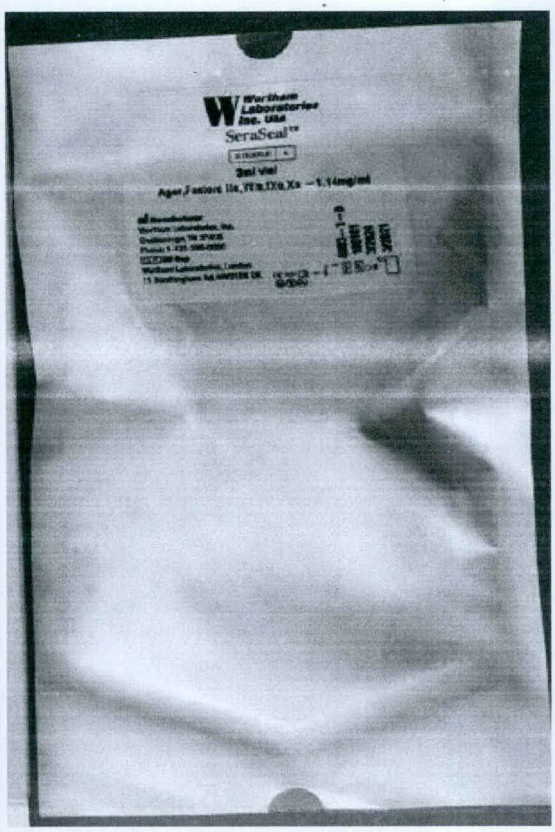
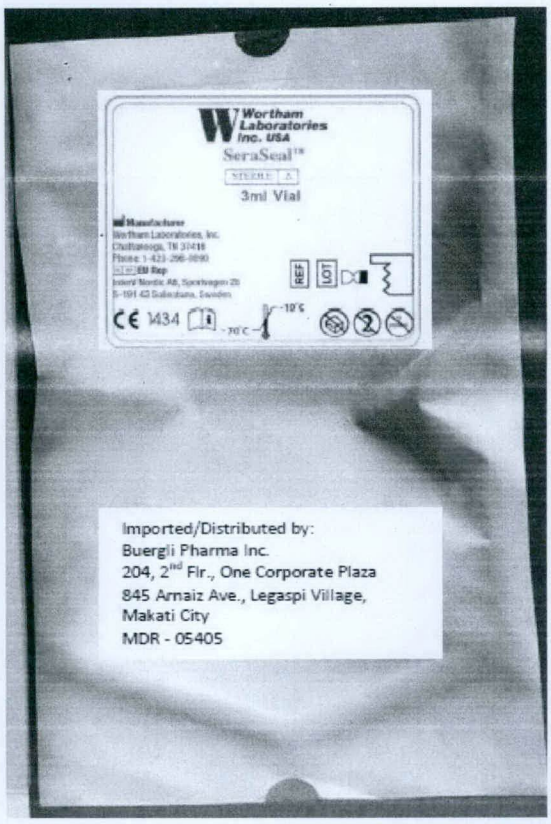
Product Label:	**Product Label:**
	

We are pleased to inform you that your application is approved for ***Seraseal® Injectable Hemostatic Agent*** with Product Registration No. **MDR-05405** valid until **11 April 2023.**

This letter of approval should be attached to the aforementioned CPR. All changes will be reflected in the CPR during its renewal.

All existing inventories of the previous labeling will be given until 30 September 2022 to exhaust all products. No further extension will be granted.

Very truly yours,

MARIA CECILIA C. MATIENZO
Director IV
Center for Device Regulation, Radiation Health, and Research
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O.R No.: SEQ# 111221357713 / SEQ# 12022381611 / SEQ# 31822408368
Date: 12 Nov 2021/ 20 Jan 2022 / 18 Mar 2022
Amount: PhP 510 / PhP 510 / PhP 1,020

DTN: 20211111144902