Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-0352

19 FEB 2021

TO: **DRUG DISTRIBUTORS AND DRUG WHOLESALERS**

SUBJECT: **Product Recall of Specific Batches of Three (3) Dosage Forms of Deproteinized Calf Blood Extract (Solcoseryl)**

Drug distributors and drug wholesalers are hereby advised by the Food and Drug Administration (FDA) regarding the recall of the affected batches of the subject products. The details of the products are as follows:

DRUG PRODUCT (1)	**DEPROTEINIZED CALF BLOOD EXTRACT OINTMENT (SOLCOSERYL)**	
REGISTRATION NO.	**DR-81**	
BATCH NOS./EXP. DATES	**109728**	**31 January 2022**
	111974	**31 October 2022**
	113716	**31 December 2023**
	114241	**30 June 2024**
MANUFACTURER	**Legacy Pharmaceuticals Switzerland GmbH – Ruhrbergstrasse 21, CH-4127 Birsfelden, Switzerland**	
IMPORTER [MARKETING AUTHORIZATION HOLDER (MAH)]	**A. Menarini Philippines, Inc. – 4F W Building, 11th Ave. cor. 28th St., Bonifacio High St., Bonifacio Global City, Taguig City**	

DRUG PRODUCT (2)	**DEPROTEINIZED CALF BLOOD EXTRACT 2 g/20 g JELLY (SOLCOSERYL)**	
REGISTRATION NO.	**DR-82**	
BATCH NOS./EXP. DATES	**109080**	**31 October 2021**
	111564	**30 September 2022**
	113002	**31 May 2023**
	114045	**29 February 2024**
MANUFACTURER	**SAME AS ABOVE**	
IMPORTER (MAH)	**SAME AS ABOVE**	

DRUG PRODUCT (3)	**DEPROTEINIZED CALF BLOOD EXTRACT + POLIDOCANOL 2.125 mg/10 mg DENTAL PASTE (SOLCOSERYL)**	
REGISTRATION NO.	**DR-XY2063**	
BATCH NOS./EXP. DATES	**110340**	**31 March 2021**
	111565	**31 August 2021**
	112548	**31 May 2022**
	112728	**31 May 2022**

	113717	30 June 2023
	114803	30 June 2023
MANUFACTURER	SAME AS ABOVE	
IMPORTER (MAH)	SAME AS ABOVE	

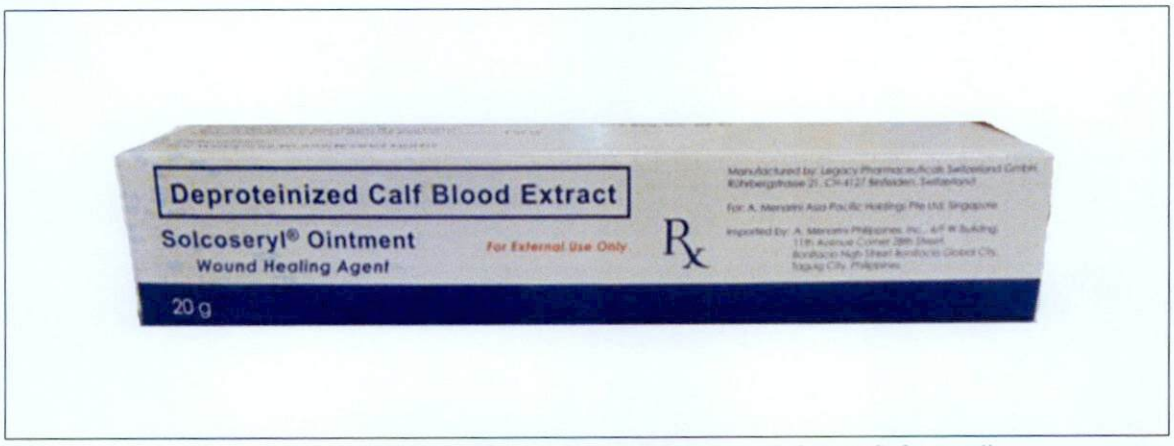

Figure 1. Deproteinized Calf Blood Extract Ointment (Solcoseryl) for recall

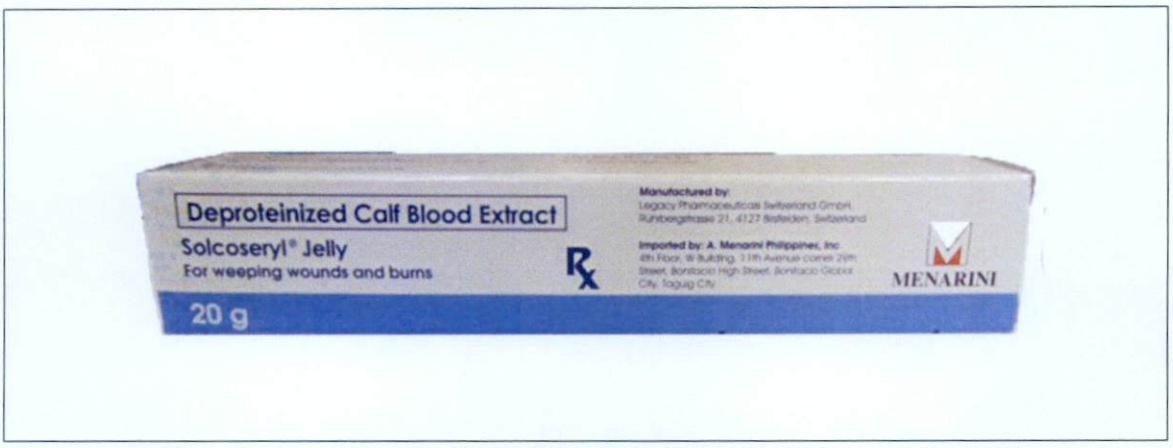

Figure 2. Deproteinized Calf Blood Extract 2 g/20 g Jelly (Solcoseryl) for recall

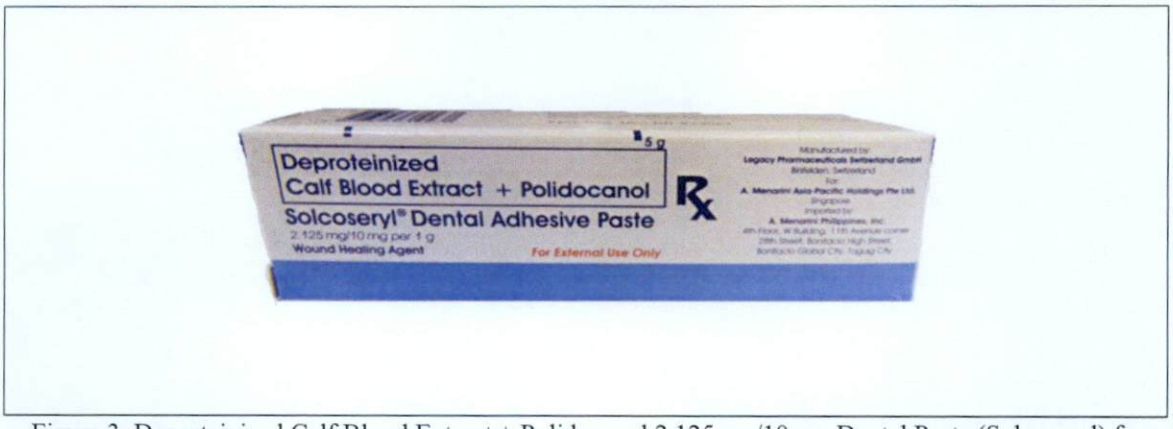

Figure 3. Deproteinized Calf Blood Extract + Polidocanol 2.125 mg/10 mg Dental Paste (Solcoseryl) for recall

The recall is pursued due to the rating of Swissmedic on its sterile license manufacturer as non-compliant to Good Manufacturing Practice (GMP). Sterile products in the Swiss market were ordered for recall except for critical products, including the subject products, due to its therapeutic use. After due evaluation and assessment, recall of the subject products in the Philippines is ordered until distributor level only.

Deproteinized Calf Blood Extract Jelly and Ointment are indicated for treating leg ulcers, pressure sores in bedridden patients, abrasions, and burns. Deproteinized Calf Blood Extract Dental Paste is used for painful and inflammatory affections of the oral mucosa, gums and lips, apththae, rhagades, herpes labialis, gingivitis, paradonitis, stomatitis, denture pressure sores, teething pains, dressing after scalding, curettage and dental extractions, and collocation of immediate dentures. The ointment and jelly are packed in a 20 g aluminum tube (Box of 1's); dental paste in a 5 g aluminum tube (Box of 1's).

Therefore, distributors that have the affected batches of the drug products are instructed to discontinue further distribution and may contact A. Menarini Philippines, Inc. at telephone numbers +(632) 333-3800 and +(632) 333-3888, or send an e-mail to **aaguinaldo@menariniapac.com** and/or **kristine.sagmon@menariniapac.com** for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product batches are not sold or made available by concerned distributors, after the issuance of this advisory, in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph.** To report continuous sale or distribution of the abovementioned, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. Any suspected adverse reaction experienced from the use of the product should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.


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Director General