

April 20, 2018

## URGENT: DRUG RECALL - Boiron Calendula Cream 5th panel 2.5 oz

<Contact name or Dept.>
<Firm Name>
<Address>
<City/state/zip>

## Dear < >:

This is to inform you that Boiron USA is voluntarily recalling 54,284 units of its Calendula Cream 2.5 oz at the retail level. The product involved includes:

Product Name: Boiron Calendula Cream 5<sup>th</sup> panel 2.5 oz Product Code: CALENDCR70.5PNL.0217.US (.5YV)

Lots # and Expiry:

M7090711 EXP 09/2019 M7090712 EXP 09/2019 M7090713 EXP 09/2019 M7090709 EXP 09/2019 M7090807 EXP 09/2019 M7110589 EXP 11/2019

NDC: 0220-1109-63 UPC: 306969021569 Product Labeling Enclosed

This over-the-counter drug promotes the healing of common skin irritations (cuts, scrapes, chafing, minor burns and sunburn). The active ingredient of Calendula officinalis 1X HPUS is inaccurately stated as being 7% on the outer packaging label. The correct listing of 10% appears on the product tube contained within the box. This mislabeling issue applies to six lots with the expiration dates of either 09/2019 or 11/2019.

This recall will be carried out to the retail level and your assistance will be greatly appreciated. Our records show we shipped some of this product to you on date(s) and qty(s). Please examine your stocks immediately to determine if you are in possession of any of the lots listed above. If so, discontinue sales of these lots and promptly return units to:

Stericycle Expert Solutions, Attn: Event# 3814 2670 Executive Drive, Suite A Indianapolis, IN 46241

You will be reimbursed by check or credit memo for the returned goods and shipping.



Please return the enclosed card immediately providing the requested information.

This recall is being made with the knowledge of the Food and Drug Administration. Please follow instructions on the enclosed form. Should you have additional questions, please contact Stericycle Expert Solutions at:

Questions: 855-800-1094 Fax: 844-721-3050

Email: Boiron3814@stericycle.com

Sincerely,

Mark T. Land Vice President of Government and Regulatory Affairs Boiron USA

## **Product Image:**

