GFA Production (Xiamen) Co., Ltd. Issues Voluntary Nationwide Recall of Easy Care First Aid® Burn Cream and First Aid kits due to Microbial Contamination

Company Contact:
Registrar Corp, US Agent for FDA communications
Tel: +1-757-224-0177, ext. 414
Fax: +1-757-224-0179
Email: sgurganus@registrarcorp.com

FOR IMMEDIATE RELEASE – December. 23, 2022 – Xiamen, Fujian, GFA Production (Xiamen) Co., Ltd. is voluntarily recalling one lot of **Easy Care first aid® AfterBurn® Cream**, 0.9 g single-use packets. The single use packets are sold in boxes of 10 or packaged in certain First Aid kits. This recall is to the consumer level. FDA analysis found the product to be contaminated with *Bacillus licheniformis*, and *Bacillus sonorensis*.

Risk Statement: In immunocompromised patients, the topical use of the contaminated Easy Care® AfterBurn® Cream 0.9g single-use packets could potentially result in severe or life-threatening adverse events such as bacteremia, sepsis, and peritonitis. In non-immunocompromised patients, the population most likely to use the product, the use of the defective product may result in infectious complications, for instance skin infections, but in this population the infections are expected to be less severe and more readily responsive to treatment. To date, GFA Production (Xiamen) Co., Ltd. has not received any reports of adverse events related to this recall.

The Easy Care first aid® AfterBurn® Cream 0.9 g single-use packet, is used as an over the counter first-aid treatment for minor burns. The single use packets bear lot number W06I28 and are packaged in boxes of ten or included in the certain First Aid kits named below. The lot number of the single use packet can be found on the back of the packet. The lot number for the First Aid Kit that contains the single use packet can be found on each kit, either on the product hang-tag or on the bottom of the kit. The product was distributed nationwide to retailers from March 4, 2022 through December 12, 2022. Refer to the images below for guidance on where to find the lot code details. If your product does not have a lot code that is listed in the below table then it is **not** part of this recall and can be used as intended.

Package	Product Number	Product Description	Lot number	Expiration
Box of 10	9999-1515	EasyCare First Aid® AfterBurn® Cream, 0.9g single-use packet	W06I28	09/28/2024
First Aid Kit	1015-0150	Adventure® Marine 150	W06I20	09/20/2024
	0120-0213	Adventure® First Aid 1.0	W06C05 W06F10 W06H15	03/05/2024 06/10/2024 08/15/2024
	0120-0212	Adventure® First Aid 1.5	W06H15	08/15/2024
	9999-2129	Easy Care First Aid® 25 Person 2009 ANSI	W05L28	12/28/2023
	9999-2128	Easy Care First Aid® 10 Person 2009 ANSI	W05L28 W06F10 W06H15	12/28/2023 06/10/2024 08/15/2021
	9999-2150	Easy Care First Aid® Class A ANSI 25 Person	W06C05 W06H15	03/05/2024 08/15/2024
	9999-2132	Easy Care First Aid® 25 Person 2009 ANSI	W06H15	08/15/2024
	2980-0700	CVS® First Aid Home	W06H15	08/15/2024
	9999-2132	Easy Care First Aid® 25 Person 2009 ANSI	W06H15	08/15/2024
	9999-2131	Easy Care First Aid® 10 Person 2009 ANSI	W06H15	08/15/2024

Product Photos

Single-Use Burn Cream Packet

Lot W06I28

Adventure® Marine 150

Lot W06I28

Adventure® First Aid 1.5

Lot W06H15

Adventure® First Aid 1.0

Lot W06C05
Lot W06F10
Lot W06H16

Product Photos

Easy Care First Aid® 10 Person ANSI

Lot W05L28
Lot W06F10
Lot W06H15

Easy Care First Aid® 25 Person ANSI

Lot W05L28
Lot W06H15

Easy Care First Aid® Class A ANSI

Lot W06C05
Lot W06H15

CVS® First Aid Home

Lot W06H15

GFA Production (Xiamen) Co., Ltd. is notifying its distributor by e-mail and is arranging for the return of all recalled Easy Care first aid® AfterBurn® Cream, .9g single-use packets and the certain First Aid kits that contain them. Retailers that have any 0.9 g single-use packets or the First Aid kit lots listed above should return them to their distributor. Consumers should stop using the Easy Care first aid® AfterBurn® Cream .9g single-use packet and discard it.

Consumers with questions regarding this recall can contact the U.S. distributor, Adventure Ready Brands, by email to regulatory@adventurereadybrands.com or telephone to 603-837-0285 on Monday to Friday from 9:00AM and 5:00PM, Eastern Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.