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Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045



May 4, 2023

Notification of Emergency Date Extension for Solu-Cortef[®] (hydrocortisone sodium succinate for injection, USP) 100 mg/2 mL (50 mg/mL) ACT-O-VIAL[™] Single Dose Vial

Dear Customer,

Pfizer has received approval from the U.S. Food and Drug Administration (FDA) of our emergency request to extend the use date of 32 lots of **Solu-Cortef[®] (hydrocortisone sodium succinate for injection, USP) 100 mg/2 mL (50 mg/mL) ACT-O-VIAL[™] Single Dose Vial**, NDC 00009-0011-04, to mitigate a shortage of this medically necessary product.

The lots listed in the table included at the end of this letter have been extended by five months beyond the labeled 36-month expiry. The FDA is not requiring or recommending that the lots identified in the table be relabeled with new extended use dates. If replacement product becomes available during the extension period, customers are expected to replace and properly dispose of these affected lots as soon as possible. We anticipate that FDA's [website](#), which lists extended use dates to assist with drug shortages, will also be updated to reflect this information.

If you have any questions, please call our Customer Service Department at 1-844-646-4398.

Thank you,

Linna Wilkins
Director, Cardiovascular & Steroids
Pfizer Hospital U.S.

Emergency Extended Use Dating for 32 Lots of Solu-Cortef® (hydrocortisone sodium succinate for injection, USP) 100 mg/2 mL (50 mg/mL) ACT-O-VIAL™ Single Dose Vial

Unit of Sale NDC	Unit of Use NDC	Product Description	Lot Number	Labeled Extended Use Date	New Extended Use Date
00009-0011-04	00009-0011-03	Solu-Cortef® (hydrocortisone sodium succinate for injection, USP) 100 mg/2 mL (50 mg/mL) ACT-O-VIAL™ Single Dose Vial	EG4000	1/31/23	6/30/23
			DX9532	3/31/23	8/31/23
			EA7641 EA7642 EC9035 EC9036 ED7612 EK5929	4/30/23	9/30/23
			ED7613 EE2600 EE2603 EE6558	5/31/23	10/31/23
			EF0994 EF0995 EF0996 EF4252 EK5931 EF8716 EF8717	6/30/23	11/30/23
			EG3999 EG7018 EH3512 EJ6423	7/31/23	12/31/23
			EJ6424 EK0104 EK2371 EK2710 EL4877	8/31/23	1/31/24
			EK0105 EN0670 EN8907 EN8908	9/30/23	2/29/24