This recall is being initiated because out of specification results were observed during shelf-life testing of Dodex® Injectable, Cyanocobalamin Injection, USP 1000 mcg/mL at 24 months. The out of specification results were observed on the assay conducted on lot R2200476 of Dodex® Injectable, Cyanocobalamin Injection USP 1000 mcg/mL. The assay content of Cyanocobalamin Injection for this lot was observed to be 94.8%, which is outside of the specification range of 95.0% to 115.0 % of label claim. This means that the observed level of active ingredient in the product was below the approved specification when tested at 24 months, presenting a risk that the injection may deliver a subtherapeutic dosage of the active ingredient. A subtherapeutic dosage may result in longer treatment duration or recovery time for patients that are being treated for vitamin **B**12 deficiency. An impact assessment on other manufactured batches was conducted and in an abundance of caution, Accord Healthcare is voluntarily recalling all unexpired lots ofDodex®Injectable, Cyanocobalamin Injection, USP 1000 mcg/mL that have been released into the US market.

Please examine your inventory of Accord Healthcare's Dodex® Injectable Cyanocobalamin Injection, USP 1000 mcg/mL for the below listed lots carefully.

Item description	**NDC#**	**Lot#**	**Mfg. Date**	**Exp. Date**
Dodex® Injectable Cyanocobalamin Injection, USP 1000 mcg/mL	16729-533-08	R2200834	07/2022	06/2024
		R2200835	07/2022	06/2024
		R2200841	07/2022	06/2024
		R2200958	07/2022	06/2024
		R2201044	08/2022	07/2024
		R2201045	08/2022	07/2024
		R2201046	08/2022	07/2024
		R2201047	08/2022	07/2024
		R2201095	08/2022	07/2024
		R2201142	08/2022	07/2024
		R2201143	08/2022	07/2024
		R2201144	08/2022	07/2024
		M2215870	11/2022	10/2024
		M2215918	11/2022	10/2024