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Generic Name (Trade Name) Company

July 9, 2018

Ferric subsulfate 20% solution

(Monsel's Solution—BioDiagnostics International, MedGyn Products)

FDA advises health professionals not to use MedGyn Products' ferric subsulfate 20% solution

Uses/Notes

[FDA advises](#) health professionals not to use any ferric subsulfate 20% solution manufactured by BioDiagnostics International, Brea, CA, and distributed by MedGyn Products, Addison, IL. During FDA's recent inspection of the BioDiagnostics facility, investigators observed insanitary conditions and manufacturing practices that could result in contamination and decreased quality of the solution.

BioDiagnostics notified MedGyn of the recall of all lots of the solution on June 11, 2018. However, MedGyn has not yet notified its customers to remove any distributed drug product from the market.

The solution is used to stop bleeding after medical procedures, such as a colposcopy and a biopsy. It is sold in a carton containing 12 single-application vials and 12 applicators, 8 mL each, NDC 42721-112-08. Health professionals should immediately check their medical supplies, quarantine any of the solution, and not administer it to patients.

To date, FDA is not aware of any reports of adverse events associated with drug products manufactured by BioDiagnostics. Patients who have received drug products manufactured by MedGyn or BioDiagnostics and have concerns should contact their health professional.

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