SyrSpend SF Cherry Recall Alert

Date of Notice: May 5, 2022

Brief Description of Recall Alert

Fagron Inc. is voluntarily recalling two (2) lots of SyrSpend SF Cherry out of an abundance of caution. The affected lots are potentially contaminated with *Burkholderia gladioli*.

Burkholderia gladioli commonly affects patients with respiratory diseases. Patients with compromised immune systems such as those with cystic fibrosis are at higher risk. *Burkholderia gladioli* can cause complications after transplants. Exposure to contaminated product could lead to adverse events, which could be severe for at-risk individuals.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
SyrSpend SF Cherry, 500 mL	51552-1123-5	A67185	08/31/2024
SyrSpend SF Cherry, 4 L	51551-1123-9	A67186	08/31/2024

Prescriber Information

Fagron has notified its distributors and customers by phone, e-mail, and/or letter and is arranging for return of all recalled product. Hospitals, pharmacies, and distributors that possess affected product should quarantine this material and await further instructions from Fagron or Fagron's recall coordinator. Please immediately discontinue use or distribution of the recalled product. Fagron has received three (3) complaints regarding an undesirable smell associated with the product. To date, Fagron has not received any reports of adverse events related to the product being recalled.

Fagron has contracted with Sedgwick to facilitate this recall. Healthcare providers with questions regarding this recall may contact Fagron Customer Service at 1-800-423-6967 from 9:00 a.m. to 5:00 p.m. CST, Monday through Friday, or by email at customer.service@fagron.us. Questions specific to the return of product should be directed to Sedgwick at 1-877-650-8362 or by email at fagron4043@sedgwick.com.

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.
- Regular Mail or Fax: Download form 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

Member Information

Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members with medical-related questions, who wish to report an adverse event or quality issues about the product being recalled, should contact Fagron Customer Service at 1-800-423-6967 from 9:00 a.m. to 5:00 p.m. CST, Monday through Friday, or by email at customer.service@fagron.us.

RxAdvance Response

Members should continue taking SyrSpend SF Cherry until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option is given. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.