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Class 1 Device Recall IPM Wound Gel

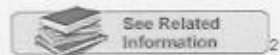


510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³|Inspections¹⁴
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Class 1 Recall IPM Wound Gel



Date Posted	July 29, 2014
Recall Status¹	Open
Recall Number	Z-2112-2014
Recall Event ID	68556 ²²
Product Classification	Dressing, Wound, Drug ²³ - Product Code FRO ²⁴
Product	IPM Wound Gel Rx Wound Dressing IPM Wound Gel is indicated for the management of wound healing.
Code Information	Lot #3P3446
Recalling Firm/ Manufacturer	Wellspring Pharmaceutical Corporation 5911 N Honore Ave Ste 211 Sarasota, Florida 34243-2612
Manufacturer Reason for Recall	Potential for microbial contamination of the product.
Action	WellSpring Pharmaceutical Corporation notified customers on March 25, 2014 via e-mail. The notification identified the affected product, the problem, and directed consignees to return all products.
Quantity in Commerce	3,135 cartons of 4/10g tubes
Distribution	Worldwide Distribution -- USA, including the states of Alabama, Arkansas, Georgia, Illinois, Kentucky, Louisiana, Missouri, Mississippi, New Jersey, South Carolina, Tennessee, Texas, and Virginia; and the country of Canada.
Total Product Life Cycle	TPLC Device Report ²⁵

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)²⁶

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