Xellia Pharmaceuticals Issues Voluntary Recall of Micafungin for Injection (50 mg and 100 mg lyophilized vials) in the US due to product package insert error

Buffalo Grove, IL, USA, 05 August 2021 - Xellia Pharmaceuticals ('Xellia'), USA, LLC, is voluntarily recalling the following batches of its Micafungin for Injection, 50 mg and 100 mg lyophilized vial product, in the US:

Product	NDC No.	Batch No.	Expiration Date	Configuration
Micafungin for Injection, 50 mg vials	70594-036-01	467111	01/2023	Single vials in individual cartons; 32 vials/case
Micafungin for Injection, 100 mg vials	70594-037-01	467129	01/2023	

This recall is being performed due to the omission of certain safety information from the product package insert. This missing information includes aspects of Adverse Reactions, Drug Interactions and Use in Specific Populations. There are no issues with the drug product.

While there are no issues with the quality of the drug product, complete prescribing information is required for safe and effective use of this injectable prescription product. Xellia takes quality seriously and is conducting a recall in accordance with strict quality control procedures and 21 CFR Part 7. The correct, complete prescribing information is available on DailyMed.

We performed a Health Hazard Evaluation, which concluded that the likelihood and degree of the missing information being a health hazard to patients is considerably low. To date, Xellia has not received reports of any adverse events associated with this recall.

This recall is being performed to the retail/pharmacy level in the United States only, for products which were shipped by Xellia between June 8, 2021 and July 20, 2021.

Xellia is directly notifying direct customers and arranging for return of all recalled products. Wholesalers/ distributors will notify their customers to implement the recall to the hospital/ pharmacy level. Those affected are required by 21 CFR §7.49 (d) to follow the instructions for this recall, and to respond to recall notifications even if not in possession of the recalled product. Recalled products should be returned to the original source – Xellia or your wholesale/distributor who will arrange for product return and reimbursement.

Customers should immediately examine their inventory, discontinue distribution or dispensing of affected batches, quarantine and return the product as directed. If patients have already received the product, there is no cause for concern as the drug product itself is unaffected. Any remaining product should be returned.

Customers with questions about this recall can contact **Xellia Customer Service** at **1-833-295-6953 or at XelliaPharmaReturns@icsconnect.com or the wholesaler who has supplied the product.**

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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.

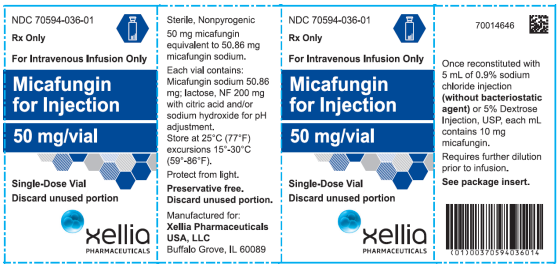
- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

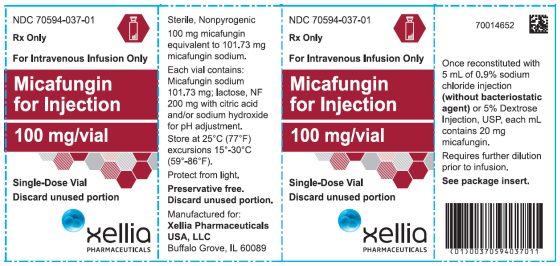
Xellia is committed to quality and excellence and takes pride in providing a consistent supply of quality products and services for its customers. We apologize for any inconvenience this voluntary recall may cause and are working to correct this issue and resume the supply of this product as quickly as possible.

How to identify Micafungin for Injection, 50 mg and 100 mg lyophilized vial batches subject to this recall

See product labels below for ease in identifying the product at the pharmacy level. The affected products were shipped by Xellia between June 8, 2021 and July 20, 2021.

BOX:





VIAL LABEL: