CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216142Orig1s000

OTHER REVIEW(S)

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: August 17, 2023

To: Sheel Shah, Regulatory Project Manager,
Division of Anti-Infectives Products (DAIP)

Leslie Ball, Clinical Reviewer, DAIP

Abimbola Adebowale, Associate Director for Labeling, DAIP

From: Qumerunnisa Syed, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Wendy Lubarsky, Regulatory Review Officer, OPDP
Sam Skariah, Team Leader, OPDP

Subject: OPDP Labeling Comments for MICAFUNGIN IN SODIUM CHLORIDE injection, for intravenous use

NDA: 216142

In response to DAIP's consult request dated August 04, 2023, OPDP has reviewed the proposed Prescribing Information (PI) and carton and container labeling for the original NDA submission for Micafungin in Sodium Chloride Injection, for intravenous use.

PI:
OPDP's review of the proposed PI is based on the draft labeling emailed to OPDP on August 11, 2023, and our comments are provided below.

Carton and Container Labeling:
OPDP's review of the proposed carton and container labeling is based on the draft labeling submitted by the sponsor to the electronic document room on June 16, 2023, and we do not have any comments at this time.

Thank you for your consult. If you have any questions, please contact Qumerunnisa Syed at 301-796-8897 or qumerunnisa.syed@fda.hhs.gov.

42 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

---

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

QUMERUNNISA B SYED
08/17/2023 11:46:59 AM

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING
Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	June 20, 2023
Requesting Office or Division:	Division of Anti-Infectives (DAI)
Application Type and Number:	NDA 216142
Product Name, Dosage Form, and Strength:	Micafungin in 0.9% Sodium Chloride Injection, in Galaxy Plastic Container, 50 mg/50 mL (1 mg/mL), 100 mg/100 mL (1 mg/mL), and 150 mg/150 mL (1 mg/mL)
Applicant/Sponsor Name:	Baxter Healthcare Corporation (Baxter)
TTT ID #:	2023-2923-1
DMEPA 1 Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD

1 PURPOSE OF MEMORANDUM

Baxter submitted revised container labels and carton labeling received on June 16, 2023 for Micafungin in 0.9% Sodium Chloride Injection. The Division of Anti-Infectives (DAI) requested that we review the revised container labels and carton labeling for Micafungin in 0.9% Sodium Chloride Injection (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 DISCUSSION

Baxter provided their response to our labeling recommendations as part of their June 6, 2023, submission.[b] Included in this response Baxter notes that their shipper carton labeling contains our recommended 2D data matrix barcode to comply with the Drug Supply Chain Security Act

[a] Myers, D. Label and Labeling Review for Micafungin (NDA 216142). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 MAY 17. TTT ID No.: 2023-2923.
[b] Baxter Healthcare Corporation. Labeling History: Response to Labeling Questions Received May 23 2023 for Micafungin in 0.9% Sodium Chloride Injection (NDA 216142). Deerfield (IL): Baxter; 2023 JUN 16. Available from: \\CDSESUB1\EVSPROD\nda216142\0011\m1\us\labeling-history-ir-comments-dated-2023may25-responses.pdf.

(DSCSA). As this shipper carton is tertiary packaging it was not previously submitted for our review. Baxter provided an example of the proposed 2D data matrix barcode and the location of the 1D barcode which is included in Figure 1 below. We find this inclusion of the 2D data matrix barcode to comply with the DSCSA and its proposed location acceptable from a medication error perspective.

Additionally, Baxter also included in their response to our labeling recommendations confirmation that they have revised the package code (last two digits of the national drug code (NDC)) such that the unit pack immediate paperboard carton containing one (1) Single-Dose GALAXY container and the 12 count (i.e., 50 mg/50 mL and 100 mg/100 mL) and 10 count (i.e., 150 mg/150 mL) will be different from the shipper cartons. The revised NDCs are listed in the table below:

Code	NDC
2G3434	Bag: NDC 0338-9051-01 Unit Pack: NDC 0338-9051-01 Shipper: NDC 0338-9051-12
2G3435	Bag: NDC 0338-9053-01 Unit Pack: NDC 0338-9053-01 Shipper: NDC 0338-9053-12
2G3433	Bag: NDC 0338-9055-01
	Unit Pack: NDC 0338-9055-01 Shipper: NDC 0338-9055-10
Unit Pack: immediate paperboard carton containing 1 Single-Dose GALAXY container/bag Shipper: a case containing either 10 or 12 unit packs	

Furthermore, they revised the last two digits of the NDC for the 150 mg/150 mL product, at the shipper level from (b) (4) to '-10', is also included in Section 16 *How Supplied/Storage* of the revised prescribing information, available at the following link: \\CDSESUB1\EVSPROD\nda216142\0011\m1\us\pi-draft-labeling-text-original-draft-v2.pdf.

We find the aforementioned revised package codes (last two digits of the NDC) acceptable from a medication error perspective.

Moreover, we note that the submitted revised labeling also includes revisions based on recommendations made by the Office of Pharmaceutical Quality (OPQ). Thus, we defer to OPQ to determine if these revisions are acceptable.

3 CONCLUSION

The Applicant implemented all of our carton labeling recommendations and we have no additional recommendations at this time. Additionally, we defer to OPQ to determine if, based on their recommendations, the submitted revised container labels and carton labeling are acceptable.

3 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

---

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DEBORAH E MYERS
06/20/2023 03:07:08 PM

VALERIE S VAUGHAN
06/20/2023 03:20:42 PM

LABEL AND LABELING REVIEW
Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	May 17, 2023
Requesting Office or Division:	Division of Anti-Infectives (DAI)
Application Type and Number:	NDA 216142
Product Name, Dosage Form, and Strength:	Micafungin in 0.9% Sodium Chloride Injection, in Galaxy Plastic Container, 50 mg/50 mL (1 mg/mL), 100 mg/100 mL (1 mg/mL), and 150 mg/150 mL (1 mg/mL)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Baxter Healthcare Corporation (Baxter)
FDA Received Date:	November 30, 2022 and February 28, 2023
TTT ID #:	2023-2923
DMEPA 1 Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD

1 REASON FOR REVIEW

As part of the approval process for Micafungin in 0.9% Sodium Chloride Injection, the Division of Anti-Infectives (DAI) requested that we review the proposed Micafungin prescribing information (PI), container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUND/REGULATORY HISTORY

NDA 216142 is a 505(b)(2) NDA and the listed drug product is Mycamine, NDA 021506, held by Astella Pharma US, Inc.

On November 30, 2022, Baxter submitted their Original New Drug Application for Micafungin in 0.9% Sodium Chloride Injection.[a]

On December 9, 2022, in an email exchange with Office of Surveillance and Epidemiology (OSE) Baxter confirmed that they intend to market this proposed product under its generic name, "Micafungin in 0.9% Sodium Chloride Injection.[b]

On February 9, 2023, the Agency issued a Filing Communication Letter that included no filing review issues identified. However, noted that Baxter did not provide a review and summary of the available clinical information to support the proposed language in the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of the labeling and thus, requested that Baxter resubmit labeling that addresses these issues by February 28, 2023.[c]

On February 28, 2023, Baxter submitted an Amendment in response to Labeling comments and questions in the Filling Communication which included the requested revised labeling.[d]

---

[a] Baxter Healthcare Corporation. Original New Drug Application Cover Letter for Micafungin in 0.9% Sodium Chloride Injection (NDA 216142). Deerfield (IL): Baxter; 2022 NOV 30. Available from: \\CDSESUB1\EVSPROD\nda216142\0001\m1\us\cover-letter-2022nov30.pdf.

[b] Chung, A. FDA Correspondence Via Email (09-DEC-2022): Email from OSE Re: NDA 216142 Micafungin in 0.9% Sodium Chloride Injection Request for Proprietary Name Review. Silver Spring (MD): FDA, CDER, OSE (US); 2023 DEC 09. NDA 216142. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af806a12df.

[c] Shah, S. FDA Communication: Filing Communication – No Filing Review Issues Identified Micafungin in 09% Sodium Chloride Injection (NDA 216142). Silver Spring (MD): FDA, CDER, OND, DAI (US); 2023 FEB 09. NDA 216142. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af806b13af.

[d] Baxter Healthcare Corporation. Cover Letter: Response to Labeling Comments and Questions in the Filing Communication – No Filing Issues Identified Letter for Micafungin in 0.9% Sodium Chloride Injection (NDA 216142). Deerfield (IL): Baxter; 2023 FEB 28. Available from: \\CDSESUB1\EVSPROD\nda216142\0005\m1\us\cover-letter-2023feb28.pdf.

2 MATERIALS REVIEWED

Table 1. Materials Considered for this Label and Labeling Review	
Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B
ISMP Newsletters*	C – N/A
FDA Adverse Event Reporting System (FAERS)*	D – N/A
Other	E – N/A
Labels and Labeling	F

N/A=not applicable for this review
*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

3 CONCLUSION AND RECOMMENDATIONS

The proposed prescribing information (PI), container labels, and carton labeling may be improved to promote the safe use of this product from a medication error perspective. We provide the identified medication error issues, our rationale for concern, and our proposed recommendations to minimize the risk for medication error in Section 4 for the Division and in Section 5 for Baxter Healthcare Corporation.

4 RECOMMEDATIONS FOR DIVISION OF ANTI-INFECTIVES (DAI)

Table 2. Identified Issues and Recommendations for Division of Anti-Infectives (DAI)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Full Prescribing Information – Section 2 *Dosage and Administration*			
1.	As currently presented, it is not clear that the premixed Galaxy bags are intended to be administered in total.	Wrong dose errors (e.g., overdose) could occur if the premixed Galaxy bags are used to administer doses less than 50 mg, 100 mg, and 150 mg, respectively.	Insert a new subsection 2.1, *Important Administration Instructions*, which includes the text "If a dose of Micafungin is required that does not equal 50 mg, 100 mg, or 150 mg, Micafungin in 0.9% Sodium Chloride Injection in GALAXY Containers is not

Table 2. Identified Issues and Recommendations for Division of Anti-Infectives (DAI)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			recommended for use and an alternative formulation of Micafungin should be considered." Additionally, we recommend adding a footnote following the title of Table 2 *Micafungin in 0.9% Sodium Chloride Injection Dosage in Pediatric Patients (4 Months of Age and Older)* referring to the key text "If a dose of Micafungin is required that does not equal 50 mg, 100 mg, or 150 mg, Micafungin in 0.9% Sodium Chloride Injection in GALAXY Containers is not recommended for use and an alternative formulation of Micafungin should be considered." With the inclusion of a new 2.1 subsection, we additionally recommend revising the title of the current subsection 2.4, [redacted] (b) (4) " to "*Directions for Use of Micafungin Injection."* Furthermore, under the current subsection 2.3, "*Dosage for Pediatric Patients Younger than 4 Months of Age*" we recommend adding the statement, "If a dose of Micafungin is required that does not equal 50 mg, 100 mg, or 150 mg, Micafungin in 0.9% Sodium Chloride Injection in GALAXY Containers is not

Table 2. Identified Issues and Recommendations for Division of Anti-Infectives (DAI)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			recommended for use and an alternative formulation of Micafungin should be considered."
Full Prescribing Information – Section 3 *Dosage Forms and Strengths*			
1.	A description of the dosage form is not provided (e.g., colorless solution).	A description of identifying characteristics of the dosage form is required per Section 3 cite 21 CFR 201.57(c)(4)(ii).	Provide a description of identifying characteristics of the injection in accordance with 21 CFR 201.57(c)(4)(ii).
Full Prescribing Information – Section 16 *How Supplied/Storage and Handling*			
1.	A description of the dosage form is not provided (e.g., colorless solution).	A description of identifying characteristics of the dosage form is required per 21 CFR 201.57(c)(17)(iii).	Provide a description of identifying characteristics of the injection in accordance with 21 CFR 201.57(c)(17)(iii).

5 RECOMMENDATIONS FOR BAXTER HEALTHCARE CORPORATION

Table 3. Identified Issues and Recommendations for Baxter Healthcare Corporation (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Carton Labeling			
1.	As currently presented, the human-readable and machine-readable (2D data matrix barcode) product identifier is missing.	In June 2021, FDA finalized the Guidance for Industry on product identifiers required under the Drug Supply Chain Security Act (DSCSA). The Act requires manufacturers and re-packagers to affix or imprint a product identifier to each package and homogenous	We recommend that you review the guidance to determine if the product identifier requirements apply to your product's labeling. See Guidance for Industry: *Product Identifiers under the Drug Supply Chain Security Act - Questions and Answers* (July 2021).[e]

[e] Guidance for Industry: Product Identifiers Under the Drug Supply Chain Security Act - Questions and Answers. 2021. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-identifiers-under-drug-supply-chain-security-act-questions-and-answers.

Table 3. Identified Issues and Recommendations for Baxter Healthcare Corporation (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
		case of a product intended to be introduced in a transaction in(to) commerce. The product identifier includes the NDC, serial number, lot number, and expiration date in both a human-readable form and machine-readable (2D data matrix barcode) format.	If you determine that the product identifier requirements apply to your product's labeling, we request you add a place holder to the carton labeling. Additionally, we recommend you ensure there is sufficient white space between the linear barcode and 2-D matrix barcode to allow barcode scanners the ability to correctly read each barcode.
2.	As currently presented, the national drug code (NDC) package codes (last two digits of the NDC) on the unit pack immediate paperboard carton containing 1 Single-Dose GALAXY container (i.e., "-12" for the 50 mg/50 mL and 100 mg/100 mL, as well as (b) (4) " for the 150 mg/150 mL) is the same as those included in the proposed prescribing information for the 12 count 50 mg/50 mL and 100 mg/100 mL cartons, as well as the 10 count 150 mg/150 mL carton.	The NDC assigned to a carton containing more than one unit should have a different package code (last 2 digits) than that of the individual containers within the carton.	We ask that you confirm that the package code (last two digits of the NDC) will be different between the unit pack immediate paperboard carton containing 1 Single-Dose GALAXY container and the 12 count (i.e., 50 mg/50 mL and 100 mg/100 mL) and 10 count (i.e., 150 mg/150 mL) cartons.

APPEARS THIS WAY ON ORIGINAL

APPENDICES: METHODS & RESULTS FOR EACH MATERIAL REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table presents relevant product information for Micafungin that Baxter Healthcare Corporation submitted on November 30, 2022, and the listed drug (LD), Mycamine.[f]

Table 4. Relevant Product Information for Listed Drug and Micafungin		
Product Name	Mycamine	Micafungin
Application Type and Number (Applicant)	NDA 021516 (Astellas)	NDA 216142 (Baxter)
Initial Approval Date	March 16, 2005	N/A
Active Ingredient	micafungin	
Indication	Indicated in adult and pediatric patient for: • Treatment of Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses in adult and pediatric patients 4 months of age and older. • Treatment of Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses ***without*** meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age. • Treatment of Esophageal Candidiasis in adult and pediatric	Indicated in adult and pediatric patient for: • Treatment of Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses in adult and pediatric patients 4 months of age and older for whom appropriate dosing with this formulation can be achieved. • Treatment of Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses ***without*** meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age for whom appropriate dosing with

[f] Mycamine [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. DEC 2019 [Cited 2023 APR 20]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021506s023lbl.pdf.

	patients 4 months of age and older. • Prophylaxis of *Candida* Infections in adult and pediatric patients 4 months of age and older undergoing Hematopoietic Stem Cell Transplantation (HSCT). <u>Limitations of Use</u> • The safety and effectiveness of MYCAMINE have not been established for the treatment of candidemia ***<u>with</u>*** meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age as a higher dose may be needed. • MYCAMINE has not been adequately studied in patients with endocarditis, osteomyelitis or meningoencephalitis due to *Candida*. • The efficacy of MYCAMINE against infections caused by fungi other than *Candida* has not been established.	this formulation can be achieved. • Treatment of Esophageal Candidiasis in adult and pediatric patients 4 months of age and older for whom appropriate dosing with this formulation can be achieved. • Prophylaxis of *Candida* Infections in adult and pediatric patients 4 months of age and older undergoing Hematopoietic Stem Cell Transplantation (HSCT) for whom appropriate dosing with this formulation can be achieved. <u>Limitations of Use</u> • The safety and effectiveness of Micafungin in 0.9% Sodium Chloride Injection have not been established for the treatment of candidemia ***<u>with</u>*** meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age as a higher dose may be needed. • Micafungin in 0.9% Sodium Chloride Injection has not been adequately studied in patients with endocarditis,

<table>
<tr><td></td><td></td><td>osteomyelitis or meningoencephalitis due to Candida.
• The efficacy of Micafungin in 0.9% Sodium Chloride Injection against infections caused by fungi other than Candida has not been established.</td></tr>
<tr><td>Route of Administration</td><td colspan="2">Intravenous infusion</td></tr>
<tr><td>Dosage Form</td><td>for Injection</td><td>in 0.9% Sodium Chloride Injection, in Galaxy Plastic Container</td></tr>
<tr><td>Strength</td><td>50 mg/vial
100 mg/vial</td><td>50 mg/50 mL (1 mg/mL)
100 mg/100 mL (1 mg/mL)
150 mg/150 mL (1 mg/mL)</td></tr>
<tr><td>Dose and Frequency</td><td colspan="2"><table>
<tr><th>Adult</th><th>Pediatric Patients 4 Months and Older 30 kg or less</th><th>Pediatric Patients 4 Months and Older greater than 30 kg</th><th>Pediatric Patients Younger than 4 Months of Age</th></tr>
<tr><td colspan="4">Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses</td></tr>
<tr><td>100 mg daily</td><td colspan="2">2 mg/kg/day (maximum 100 mg daily)</td><td>See below</td></tr>
<tr><td colspan="4">Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses without Meningoencephalitis and/or Ocular Dissemination</td></tr>
<tr><td>See above</td><td colspan="2">See above</td><td>4 mg/kg/day</td></tr>
<tr><td colspan="4">Treatment of Esophageal Candidiasis</td></tr>
<tr><td>150 mg daily</td><td>3 mg/kg/day</td><td>2.5 mg/kg/day (maximum 150 mg daily)</td><td>Not approved</td></tr>
<tr><td colspan="4">Prophylaxis of Candida Infections in HSCT Recipients</td></tr>
<tr><td>50 mg daily</td><td colspan="2">1 mg/kg/day (maximum 50 mg daily)</td><td>Not approved</td></tr>
</table></td></tr>
<tr><td>How Supplied</td><td>cartons of 10 individually packaged 50 mg single-dose vials with a blue flip-off cap
cartons of 10 individually packaged 100 mg single-dose vials with a red flip-off cap</td><td>12 count of 50 mg/50 mL (1 mg/mL) GALAXY containers
12 count of 100 mg/100 mL (1 mg/mL) GALAXY containers
10 count of 150 mg/150 mL (1 mg/mL) GALAXY containers</td></tr>
<tr><td>Storage</td><td>Unopened vials of lyophilized material must be stored at room temperature, 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see</td><td>Store Micafungin in 0.9% Sodium Chloride Injection in the refrigerator (36°F to 46°F [2°C to 8°C]) in the original carton to protect from light. Do not use after the expiration</td></tr>
</table>

	USP Controlled Room Temperature]. Protect from light.	date printed on the carton and container label. If needed, Micafungin in 0.9% Sodium Chloride Injection may be stored at room temperature up to 77°F (25°C) for up to 30 days in the original carton. Once stored at room temperature, do not place back in the refrigerator. Discard Micafungin in 0.9% Sodium Chloride Injection after 30 days if stored at room temperature. Do not freeze and do not use Micafungin in 0.9% Sodium Chloride Injection if it has been frozen.

APPENDIX B. PREVIOUS DMEPA REVIEWS

On April 20, 2023, we searched for previous DMEPA reviews relevant to this current review using the terms, "micafungin." Our search identified thirteen previous reviews[g,h,i,j,k,l,m,n,o,p,q,r,s], and we considered our previous recommendations to see if they are applicable for this current review.

---

[g] Myers, D. Suitability Petition Review for Micafungin sodium for injection, proposing 150 mg/vial). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021-JUL 06. OSE RCM No.: 2021-673.

[h] Myers, D. Label and Labeling Review Memo for Micafungin Sodium for Injection (NDA 212125). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUN 25. OSE RCM No.: 2021-1192.

[i] Myers, D. Label and Labeling Review Memo for Micafungin for Injection (212156). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 MAR 15. OSE RCM No.: 2021-446.

[j] Myers, D. Label and Labeling Review Memo for Micafungin Sodium for Injection (NDA 212125). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUL 01. OSE RCM No.: 2018-1726-2.

[k] Myers, D. Label and Labeling Review Memo for Micafungin for Injection (NDA 212156). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 APR 22. OSE RCM No.: 2018-1529-2.

[l] Myers, D. Label and Labeling Review Memo for Micafungin for Injection (NDA 212156). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 APR 09. OSE RCM No.: 2018-2529-1.

[m] Myers, D. Label and Labeling Review for Micafungin for Injection (NDA 212156). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 MAR 25. OSE RCM No.: 2018-2529.

[n] Myers, D. Label and Labeling Review Memo for Mycamine (NDA 021506/S-023). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 SEP 30. RCM No.: 2019-1283-1.

[o] Myers, D. Label and Labeling Review for Mycamine (NDA 021506/S-023). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUL 10. RCM No.: 2019-1283.

[p] Myers, D. Label and Labeling Review Memo for Micafungin Sodium for Injection (NDA 212125). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUL 08. RCM No.: 2018-1726-1.

[q] Myers, D. Label and Labeling Review for Micafungin Sodium for Injection (NDA 212125). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 12. RCM No.: 2018-1726.

[r] Kolejian, S. Label and Labeling Review Memo for Mycamine (NDA 021506/S-019). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 AUG 18. RCM No.: 2016-1843.

[s] Winiarski, A. Label and Labeling Review for Mycamine (NDA 021506/S-015). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2013 APR 04. RCM No.: 2013-680.

APPENDIX F. LABELS AND LABELING

F.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[t] along with postmarket medication error data, we reviewed the following Micafungin labels and labeling submitted by Baxter Healthcare Corporation.

- Container labels received on November 30, 2022
- Carton labeling received on November 30, 2022
- Annotated container labels received on November 30, 2022
- Annotated carton labeling received on November 30, 2022
- Prescribing Information (Images not shown)
    - Cleaned proposed (Draft) PI received on November 30, 2022, available at the following link: \\CDSESUB1\EVSPROD\nda216142\0001\m1\us\pi-draft-labeling-text-original-draft-v1-c.docx.
    - Annotated comparison with Listed Drug, Mycamine, received on February 28, 2023, available at the following link: \\CDSESUB1\EVSPROD\nda216142\0005\m1\us\annotated-comparison-pi-astellas-mycamine-v2-2023feb28.pdf.

[t] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

9 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

---

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DEBORAH E MYERS
05/17/2023 11:15:46 AM

VALERIE S VAUGHAN
05/17/2023 01:28:59 PM