

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208744Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis (DMEPA)
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: November 1, 2017
Requesting Office or Division: Division of Anti-Infective Products (DAIP)
Application Type and Number: NDA 208744
Product Name and Strength: Tigecycline for Injection USP, 50 mg per vial
Applicant/Sponsor Name: Accord Healthcare, Inc.
Submission Date: October 27, 2017
OSE RCM #: 2015-2200-4
DMEPA Safety Evaluator: Deborah Myers, RPh, MBA
DMEPA Team Leader: Otto L. Townsend, PharmD

1 PURPOSE OF MEMO

The Division of Anti-Infective Products (DAIP) requested that we review the revised container label and carton labeling for Tigecycline for Injection, USP, 50 mg per vial, submitted on October 27, 2017, (Appendix A) to determine if it is acceptable from a medication error perspective.

The Applicant submitted revised labeling in response to the Agency's October 19, 2017 Information Request (IR) asking that they change the proposed content statement [REDACTED] (b) (4) [REDACTED] " on the side panel to instead state "Contains 100 mg maltose monohydrate: see Boxed Warning" as well as increase the prominence of the statement by highlighting or boxing

2 CONCLUSION

The revised container label and carton labeling for Tigecycline for Injection, USP, 50 mg per vial are acceptable from a medication error perspective. Again, we defer^{a,b} to the Office of Pharmaceutical Quality (OPQ) for their assessment and to determine if it is appropriate to change the package type term [REDACTED] ^{(b) (4)} to “Single Dose.” We have no further recommendations at this time.

^a Myers, D. Label and Labeling Review for Tigecycline for Injection USP (NDA 208744). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 MAR 22. 12 p. OSE RCM No.: 2015-2200.

^b Myers, D. Label and Labeling Memo for Tigecycline for Injection USP (NDA 208744). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2017 SEP 14. 3 p. OSE RCM No.: 2015-2200-3.

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/s/

DEBORAH E MYERS
11/01/2017

OTTO L TOWNSEND
11/01/2017

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis (DMEPA)
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: September 14, 2017
Requesting Office or Division: Division of Anti-Infective Products (DAIP)
Application Type and Number: NDA 208744
Product Name and Strength: Tigecycline for Injection USP, 50 mg per vial
Applicant/Sponsor Name: Accord Healthcare, Inc.
Information Request Response Date: September 8, 2017
Labeling Submission Date: May 26, 2016
OSE RCM #: 2015-2200-3
DMEPA Safety Evaluator: Deborah Myers, RPh, MBA
DMEPA Team Leader: Otto L. Townsend, PharmD

1 PURPOSE OF MEMO

The Division of Anti-Infective Products (DAIP) requested that we review the container label and carton labeling for Tigecycline for Injection, USP, 50 mg per vial, submitted on September 8, 2017, to determine if they are acceptable from a medication error perspective.

The container label and carton labeling were not included in the Applicant's July 18, 2017 Class 2 Resubmission. As a result, The Agency sent a Labeling Information Request, dated September 6, 2017, to Accord for their latest Package Insert (PI), container label, and carton labeling. Within Accord's September 8, 2017 response they reference the container label and carton labeling submitted on May 26, 2016, which we previously reviewed and found acceptable^a.

^a Myers, D. Label and Labeling Review Memorandum for Tigecycline for Injection USP (NDA 208744). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 JUN 22. 5 p. OSE RCM No.: 2015-2200-1.

2 CONCLUSION

As stated in our previous reviews^{a,b}, we find the revised container label and carton labeling acceptable from a medication error perspective and defer^c to the Office of Pharmaceutical Quality (OPQ) for their assessment and determination of the appropriate package type term of (b) (4) vs. "Single Dose." We have no further recommendations at this time.

^b Myers, D. Label and Labeling Review Memorandum for Tigecycline for Injection USP (NDA 208744). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2017 SEP 05. 2 p. OSE RCM No.: 2015-2200-2.

^c Myers, D. Label and Labeling Review for Tigecycline for Injection USP (NDA 208744). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 MAR 22. 12 p. OSE RCM No.: 2015-2200.

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/s/

DEBORAH E MYERS
09/14/2017

OTTO L TOWNSEND
09/14/2017

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis (DMEPA)
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: September 5, 2017
Requesting Office or Division: Division of Anti-Infective Products (DAIP)
Application Type and Number: NDA 208744
Product Name and Strength: Tigecycline for Injection USP, 50 mg per vial
Applicant/Sponsor Name: Accord Healthcare, Inc.
Submission Date: May 26, 2017
OSE RCM #: 2015-2200-2
DMEPA Safety Evaluator: Deborah Myers, RPh, MBA
DMEPA Team Leader: Otto L. Townsend, PharmD

1 PURPOSE OF MEMO

The Division of Anti-Infective Products (DAIP) requested that we review the revised prescribing information (PI)^a included in the Class 2 resubmission of this 505 b2 application for Tigecycline for Injection, USP, 50 mg per vial, submitted on May 26, 2017, to determine if it is acceptable from a medication error perspective. The revisions are in response to recommendations that we made during previous label and labeling reviews.^b

2 CONCLUSION

We reviewed the revised prescribing information^a for Tigecycline for Injection, USP, 50 mg per vial and note that our previous recommendations^b have been implemented. Therefore, we find the revised prescribing information acceptable from a medication error perspective. We have no further recommendations at this time.

^a <\\cdsesub1\evsprod\nda208744\0016\m1\us\spl\tigecycline.xml>

^b Myers, D. Label and Labeling Review for Tigecycline for Injection USP (NDA 208744). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 MAR 22. 12 p. OSE RCM No.: 2015-2200.

As the Applicant did not include container label and carton labeling as part of their May 26, 2017 resubmission, we maintain our acceptance of the container label and carton labeling submitted on June 3, 2016^c.

^c Myers, D. Label and Labeling Review Memorandum for Tigecycline for Injection USP (NDA 208744). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 JUN 22. 5 p. OSE RCM No.: 2015-2200-1.

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/s/

DEBORAH E MYERS
09/05/2017

OTTO L TOWNSEND
09/05/2017

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis (DMEPA)
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 22, 2016
Requesting Office or Division: Division of Anti-Infective Products (DAIP)
Application Type and Number: NDA 208744
Product Name and Strength: Tigecycline for Injection USP, 50 mg per vial
Submission Date: June 3, 2016
Applicant/Sponsor Name: Accord Healthcare, Inc.
OSE RCM #: 2015-2200-1
DMEPA Primary Reviewer: Deborah Myers, RPh, MBA
DMEPA Team Leader: Vicky Borders-Hemphill, PharmD

1 PURPOSE OF MEMO

The Division of Anti-Infective Products (DAIP) requested that we review the revised container label and carton labeling for Tigecycline for Injection, USP, 50 mg per vial (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.¹ The Applicant provided clarification in the cover letter dated May 26, 2016 describing the location of the lot number and expiration date on the container label and carton labeling and we find this adequate (Appendix B).

In addition, we note that the DAIP has requested additional information and data from the Applicant in an IR request dated June 22, 2016, regarding DMEPA's previously stated safety concerns due to this product containing maltose and the potential for this to result in false

¹ Myers, D. Label and Labeling Review for Tigecycline for Injection USP (NDA 208744). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 MAR 22. 12 p. OSE RCM No.: 2015-2200.

glucose readings. If the Applicant provides data showing clinical implications related to the product containing maltose then DMEPA will provide recommendations regarding risk for medication error when these data become available.

2 CONCLUSION

The revised container labels and carton labeling are acceptable from a medication error perspective.

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

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/s/

DEBORAH E MYERS
06/22/2016

BRENDA V BORDERS-HEMPHILL
06/22/2016