CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761171Orig1s000

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:	October 27, 2020
Requesting Office or Division:	Division of Oncology 2 (DO2)
Application Type and Number:	BLA 761171
Product Name and Strength:	Danyelza (naxitamab) Injection, 40 mg/10 mL
Applicant/Sponsor Name:	Y-mAbs Therapeutics, Inc.
OSE RCM #:	2020-665-1
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader:	Ashleigh Lowery, PharmD, BCCCP

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised container label and carton labeling received on October 23, 2020 for Danyelza. Division of Oncology 2 (DO2) requested that we review the revised container label and carton labeling for Danyelza (Appendix A) to determine if it is 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 CONCLUSION

The Applicant implemented all of our recommendations and we have no additional recommendations at this time.

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[a] Stewart J. Label and Labeling Review for Danyelza (BLA 761171). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 AUG 21. RCM No.: 2020-665.

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JANINE A STEWART
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ASHLEIGH V LOWERY
10/28/2020 03:09:05 PM

Clinical Inspection Summary

Date	9/23/2020
From	Michele Fedowitz, MD Karen Bleich, MD Kassa Ayalew, MD, MPH Good Clinical Practice Assessment Branch (GCPAB) Division of Clinical Compliance Evaluation (DCCE) Office of Scientific Investigations (OSI)
To	Diana Bradford, MD Amy Barone, MD Harpreet Singh, MD Division of Oncology 2 (DO2) Office of Oncologic Diseases (OOD)
BLA #	761171
Applicant	Y-mAbs Therapeutics, Inc.
Drug	Naxitamab
NME (Yes/No)	Yes
Therapeutic Classification	Humanized monoclonal antibody
Proposed Indication	Refractory and relapsed neuroblastoma
Consultation Request Date	June 1, 2020
Summary Goal Date	September 30, 2020
Action Goal Date	October 30, 2020
PDUFA Date	November 30, 2020

I. OVERALL ASSESSMENT OF FINDINGS AND RECOMMENDATIONS

Clinical data from two studies, Study 201 and Study 12-230, were submitted to the Agency in support of a Biologics Licensing Application (BLA 761171) for naxitamab for the above proposed indication. The clinical investigator Dr. Brian Kushner was selected for clinical inspections of both studies.

The inspection revealed no significant findings. The studies appear to have been conducted adequately. There was no evidence of underreporting of serious adverse events or significant protocol deviations. Based on the inspection, the data generated by the inspected clinical investigator appear to be acceptable in support of the BLA.

II. BACKGROUND

Y-mAbs Therapeutics Inc. seeks approval of naxitamab for use in patients with high-risk refractory or relapsed neuroblastoma. The study drug was initially developed by investigators at Memorial Sloan Kettering (MSK). In 2015, Y-mAbs acquired the rights to naxitamab from

MSK. In support of the BLA, the Applicant submitted clinical data from two studies: **Study 12-230**, an MSK-sponsored study, titled "Phase I/II Study of Combination Therapy of Antibody hu3F8 with Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) in Patients with Relapsed/Refractory High-Risk Neuroblastoma" and **Study 201**, a Y-mAbs-sponsored study, titled "A Pivotal Phase 2 Trial of Antibody Naxitamab (hu3F8) and Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) in High-Risk Neuroblastoma Patients with Primary Refractory Disease or incomplete Response to Salvage Treatment in Bone and/or Bone Marrow."

Study 12-230 (NCT01757626) is a Phase 1 followed by Phase 2 study. Both phases of the study were single-center, single-arm, open-label studies. The inclusion criteria for both phases included subjects with high-risk, refractory or relapsed neuroblastoma (NB) and resistant to standard therapy, who were older than 1 year and had been off of chemotherapy and immunotherapy for a minimum of three weeks.

Phase 1 assessed escalating doses of intravenous naxitamab in combination with subcutaneous GM-CSF using a 3 + 3 dose-escalation design. The recommended Phase 2 dose was determined to be naxitamab at 9.0 mg/kg per cycle (3 mg/kg/dose) given on days 1, 3, and 5 of each cycle.

Phase 2 evaluated the efficacy of naxitamab combined with GM-CSF in 3 groups of neuroblastoma subjects:

- *Group 1* - patients have primary refractory disease (no prior relapse but incomplete response to treatment) in bone marrow as documented by histology and/or ^{123}I-MIBG scan.
- *Group 2* - patients are in second or greater Complete Response (CR) and at high risk for another relapse.
- *Group 3* - patients have secondary refractory disease (prior relapse and incomplete response to retrieval therapy) in bone marrow as documented by histology and/or ^{123}I-MIBG scan.

The primary endpoint was the objective response rate (ORR), either complete response (CR) or partial response (PR), during the naxitamab treatment period, centrally assessed according to the International Neuroblastoma Response Criteria (INRC) modified with ^{123}I-MIBG criteria and following the use of ^{18}F FDG-PET for MIBG non-avid lesions.

A treatment cycle consisted of 3 doses of naxitamab and 10 days of GM-CSF, with all subjects receiving naxitamab 9.0 mg/kg per cycle (3.0 mg/kg per infusion) on days 1, 3, and 5 co-administered with 10 days of GM-CSF subcutaneously starting on day -4 through day 5. Cycles were repeated monthly through 5 cycles. Group 1 and Group 3 patients could continue to receive cycles every 1-2 months for up to 24 months from study enrollment or until they received 5 cycles after they achieved a response (CR or PR), whichever came first.

Imaging was performed by CT, MRI, MIBG and/or PET approximately every 3 months for 24 months from first treatment or until the subject was off the study, whichever came earlier. Bone marrow (BM) studies were done every 3 months for subjects without history of BM involvement. For subjects with NB in the BM in the past year, BM studies were performed

before cycle 3 and after cycle 4 and then approximately every 3 months for 24 months from the first treatment or until the subject was off the study, whichever came earlier.

From December 20, 2012 through January 15, 2018, the study had 131 enrollments with 117 unique subjects enrolling in the trial. The efficacy data cut-off is May 15, 2018 and safety data cut-off is December 17, 2018. Enrollment in Trial 12-230 is ongoing at the time of the submission.

Study 201 (NCT03363373) is a single arm, open-label phase 2 study evaluating the safety and efficacy of naxitamab and GM-CSF. Inclusion criteria included subjects with high-risk neuroblastoma, with primary refractory disease or incomplete response to salvage treatment in bone and/or bone marrow.

The primary endpoint was overall response rate (proportion of subjects obtaining an overall response) to naxitamab and GM-CSF, centrally assessed according to the International Neuroblastoma Response Criteria (INRC).

All subjects received intravenous naxitamab 9.0 mg/kg per cycle (3.0 mg/kg per infusion) on days 1, 3, and 5 co-administered with 10 days of subcutaneous GM-CSF 250 $\mu g/m^2$ per day on days –4 to 0, and 500 $\mu g/m^2$ per day on days 1 to 5. The frequency for the first 5 treatment cycles was every 4 weeks (±1 week). At week 21 (5 cycles for the standard dosing regimen) the frequency decreased to every 8 weeks (±2 weeks) through a total of 101 weeks.

To evaluate the overall response rate, imaging was performed by CT, MRI, MIBG and/or PET and centrally assessed according to the International NB Response Criteria (INRC) modified with ^{123}I-MIBG criteria and allowing the use of ^{18}F FDG-PET for MIBG non-avid lesions. Bone Marrow sampling was performed at week 6 (after cycle 2) and then at varying intervals depending on disease response.

From April 3, 2018 through June 12, 2019 (the data cut-off date) 23 subjects had enrolled and received one infusion of naxitamab; the study is ongoing at the time of the submission.

Dr Kushner was chosen for inspection for the primary supportive study, Study 12-203, as all patients were enrolled at MSK. Dr. Kushner was additionally chosen for inspection of Study 201, the study that is intended to confirm clinical benefit, because of high domestic enrollment.

III. RESULTS

1. **Dr. Brian Kushner**
   Memorial Sloan Kettering Cancer Center
   New York, NY 10065

   This clinical investigator was inspected on July 27-31, 2020 as a data audit for Studies 12-230 and 201. This was the first FDA inspection for this investigator.

Study 12-230 (Site 01, single center study)
At the data cut-off date, the clinical investigator had 131 enrollments of 117 unique subjects; 57 enrollments in Phase 1 and 74 in Phase 2. The Phase 2 enrollments included Group 1 (18), Group 2 (27), and Group 3 (28); one subject was not treated. Of the 131 enrollments, there were 4 subjects active on study treatment at the time of data cut-off and 128 off study. There were 56 who completed study and 74 subjects were discontinued as follows: 56 subjects (PD), 5 subjects (PI discretion), 5 subjects (adverse events), 4 subjects (withdrew consent), 1 subject (not treated) and 3 subjects (human anti-human antibody positive).

For the inspection, 31 unique subject source records were comprehensively reviewed and compared to the data listings for source data verification. The reviewed records included eligibility (including group allocation), informed consent, patient electronic medical records, imaging results, bone marrow biopsy results, toxicity gradings, medication administration records, adverse events, concomitant medications, and local disease assessments. Additionally, 10 unique subject records were spot-checked for source data verification.

The inspection also reviewed the documents related to the conduct and oversight of this study at the site, including signed FDA Form 1572s, financial disclosures, IRB approval of the study protocol/amendments and informed consent form, delegation log, study drug accountability records, protocol deviations, training, monitoring reports, and screening and enrollment logs.

The primary endpoint of objective response rate (ORR) by blinded central imaging could not be verified with the source data as Dr. Kushner did not have access to the (b) (4) ORR results, as specified in the protocol.

From 2012 – 2018, Memorial Sloan Kettering (MSK) provided oversight and monitoring for Study 12-230 according to MSK policy "Data Safety and Monitor Plans" for the conduct of investigator-initiated clinical trials. In August 2015, Y-mAbs Therapeutics (Y-mAbs) obtained the rights for commercialization of naxitamab from MSK and obtained access to the study data. Since 2018, the study has been monitored by (b) (4) who is also conducting retrospective monitoring and data verification from 2012-2017. The ongoing and retrospective monitoring performed by (b) (4) were reviewed during the inspection. There is no evidence of inadequate study oversight.

The study conduct appeared adequate and no regulatory violations were identified. The submitted data listings were verified with the source records with no evidence of underreporting of protocol deviations or adverse events.

Study 201 (Site 10)
At the time of data cut-off, 11 subjects had been screened and 8 enrolled by Dr. Kushner. At the time of the inspection, one subject had died (b) (6) six subjects were on follow-up (b) (6) and one was off

treatment (b) (6) All 11 source records were reviewed and compared to the data listings. The reviewed records included eligibility, informed consent, electronic medical records, ECG, MRI reports, MIBG reports, bone marrow biopsy reports, lab reports, vital signs, protocol outcome forms, pain assessment forms, research blood collection forms, medication administration history, toxicity gradings, and adverse events.

The inspection also reviewed the documents related to the conduct and oversight of this study at the site, including signed FDA Form 1572s, financial disclosures, IRB's approval of the study protocol/amendments and informed consent form, delegation log, study drug accountability records, protocol deviations, training, monitoring plans and logs, and screening and enrollment logs.

There were discrepancies between the submitted data listings and the source documentation as follows:

1. Two pain assessments were missing in the source documents for Subject (b) (6) (Cycle 2, Infusion 2, dated (b) (6)). The submitted data listings indicate that the pain assessment was "0" for both missing assessments as shown in Table 1.

Table 1: Subject (b) (6) Pain Assessments

Date	Time Point	Submitted Data Listing of Pain Assessment*	Source Data at the CI Inspection
(b) (6)	Prior to naxitamab	0	0
	Prior to discharge	0	0
	Prior to naxitamab	0	*missing*
	Prior to discharge	0	*missing*
	Prior to naxitamab	0	0
	Prior to discharge	0	0

**From 16.2.8.5 Data Listing of Pain Assessment*

2. Two pain assessments were transposed in the data listings (as compared to the source data) for Subject (b) (6) (Cycle 3, Infusion 2, dated (b) (6) as shown in Table 2.

Table 2: Subject (b) (6) Pain Assessments

Date	Time Point	Submitted Data Listing of Pain Assessment*	Source Data at the CI Inspection
(b) (6)	Prior to naxitamab	0	0
	During infusion	6	5**
	15 min after infusion	5	6**
	Prior to discharge	0	0

**From 16.2.8.5 Data Listing of Pain Assessment*
***These data points were changed in the Electronic Data Capture (EDC) at the time of the inspection.*

3. Subject (b) (6) received 60 mg of naxitamab on (b) (6) (Cycle 3) according to the source documents, not 50 mg as is written in the data listings (16.2.5.1 Listing of Naxitamab Administration).

Reviewer's Comments: The data discrepancy errors are minor and do not appear to affect subject safety or data reliability. No repeated or systemic data discrepancies were identified.

The primary endpoint of overall response rate by blinded central imaging could not be verified with source data, because Dr. Kushner did not have access to the result of the independent scan reviewer, (b) (4), as specified in the protocol.

The study conduct appeared adequate and no regulatory violations were identified. There was no evidence of underreporting of protocol deviations or adverse events.

No Form FDA 483 was issued to Dr. Kushner at the conclusion of the inspection.

{See appended electronic signature page}

Michele Fedowitz, M.D.
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	September 17, 2020
To:	Rebecca Cohen, RN, MPH, OCN Regulatory Health Project Manager **Division of Oncology 2 (DO2)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** Morgan Walker, PharmD, MBA, CPH Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)**
From:	Jessica Chung, PharmD, MS Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Robert Nguyen, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	DANYELZA (naxitamab-xxxx)
Dosage Form and Route:	injection, for intravenous use
Application Type/Number:	BLA 761171
Applicant:	Y-mAbs Therapeutics

1 INTRODUCTION

On March 31, 2020, Y-mAbs Therapeutics submitted for the Agency's review an original Biologics License Application (BLA) 761171 for DANYELZA (naxitamab-xxxx) injection. The proposed indication for DANYELZA (naxitamab-xxxx) injection is the treatment of refractory or relapsed high-risk neuroblastoma in bone (b) (4) or bone marrow in combination with GM-CSF.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Oncology 2 (DO2) on April 27, 2020, for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for DANYELZA (naxitamab-xxxx) injection.

2 MATERIAL REVIEWED

- Draft DANYELZA (naxitamab-xxxx) injection PPI received on August 24, 2020, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on September 8, 2020.
- Draft DANYELZA (naxitamab-xxxx) injection Prescribing Information (PI) received on March 31, 2020, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on September 8, 2020.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We reformatted the PPI document using the Arial font, size 10.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the Prescribing Information (PI)
- rearranged information due to conversion of the PI to Physicians Labeling Rule
- removed unnecessary or redundant information
- ensured that the PPI is free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The PPI is acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the PPI is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the PPI.

Please let us know if you have any questions.

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LABEL AND LABELING REVIEW
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)

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

Date of This Review:	August 21, 2020
Requesting Office or Division:	Division of Oncology 2 (DO2)
Application Type and Number:	BLA 761171
Product Name, Dosage Form, and Strength:	Danyelza (naxitamab) Injection, 40 mg/10 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Y-mAbs Therapeutics, Inc.
FDA Received Date:	March 31, 2020
OSE RCM #:	2020-665
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader (Acting):	Ashleigh Lowery, PharmD, BCCCP

1 REASON FOR REVIEW

As part of the review process for this BLA, this review evaluates the proposed Danyelza Prescribing Information (PI), Patient Package Insert (PPI), container label, and carton labeling for areas of vulnerability that may lead to medication errors.

2 MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

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

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 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

Our review of materials found that the proposed Danyelza PI, container label, and carton labeling may be improved to promote safe use of this product. Thus, we provide related recommendations below in Section 4.

We note the use of the term (b) (4) in the labels and labeling and we communicated this to OPQ. We defer to OPQ to determine the appropriate package type term for this product.

4 CONCLUSION & RECOMMENDATIONS

We conclude that the proposed Danyelza PI, container label, and carton labeling can be improved to increase the clarity, and to promote the safe use of the product. We provide recommendations for DO2 in Section 4.1 and recommendations for Y-mAbs Therapeutics, Inc. in Section 4.2 below.

4.1 RECOMMENDATIONS FOR DIVISION OF ONCOLOGY 2 (DO2)

A. Prescribing Information

1. Dosage and Administration Section

a. Consider revising the title and the presentation of the information in Table 4 for improved clarity of the preparation information as follows:

Table 1. Preparation of DANYELZA (b) (4)

DANYELZA dose (mg)	DANYELZA volume (mL)	Volume of 5% Albumin (Human), USP (mL)	Total infusion volume (b) (4) by adding sufficient 0.9% Sodium Chloride Injection, USP (mL)	Final concentration of prepared DANYELZA infusion (mg/mL)
≤ 80	≤ 20	10	50	≤ 1.6
81-120	> 20 - 30	15	75	1.1 – 1.6
121-160	> 30 - 40	20	100	1.2 – 1.6
161-200	> 40 - 50	25	125	1.3 – 1.6
201-240	> 50 - 60	30	150	1.3 – 1.6
241-280	> 60 - 70	35	175	1.4 – 1.6

b. (b) (4)

2. Dosage Forms and Strengths

a. Consider revising the presentation of information in Section 3: Dosage Forms and Strengths to include the description of the dosage form and to improve readability; for example, as follows:

Injection: 40 mg/10 mL (4 mg/mL) clear to slightly opalescent and colorless to slightly yellow solution in a single-dose vial.

3. How Supplied/Storage and Handling Section

    a. Consider revising the presentation of information in Section 16: How Supplied/Storage and Handling to improve readability; for example, as follows:

4.2 RECOMMENDATIONS FOR Y-MABS THERAPEUTICS, INC.

We recommend the following be implemented prior to approval of this BLA:

A. General Comments (Container labels & Carton Labeling)

1. In September 2018, FDA released draft guidance on product identifiers required under the Drug Supply Chain Security Act.[1] The Act requires manufacturers and repackagers, respectively, to affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction in(to) commerce beginning November 27, 2017, and November 27, 2018, respectively. We recommend that you review the draft guidance to determine if the product identifier requirements apply to your product's labeling.

    [1]The draft guidance is available from: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm621044.pdf

2. Revise the (b) (4) statement to read "Recommended Dosage: See prescribing information." for consistent terminology with the Prescribing Information.

B. Container Labels

1. Decrease the prominence of the NDC number as this information appears more prominent than other important information (e.g. established name, route of administration) on the principal display panel (PDP).

2. As currently presented, information commonly reserved for the side panel (i.e. storage information and manufacturer information) appears more prominent than the product identifying information (i.e., proprietary name, established name) which is featured on the PDP. Revise the container label so that the PDP information is presented with greater prominence than the side panel information.

3. The linear barcode is missing on the immediate container label. The drug barcode is often used as an additional verification before drug administration in the hospital setting; therefore, it is an important safety feature that should be part of the label whenever possible. Therefore, we request you add the product's linear barcode to each individual container label as required per 21CFR 201.25(c)(2).

4. Bold the storage information on the side panel so it reads "Store refrigerated at 2°C to 8°C (36°F to 46°F). Keep vial in outer carton protect from light." We recommend this to increase the prominence of this important information and to minimize the risk of the storage information being overlooked.

5. As currently presented, the format for the expiration date is not defined. To minimize confusion and reduce the risk for deteriorated drug medication errors, identify the format you intend to use. FDA recommends that the human-readable expiration date on the drug package label include a year, month, and non-zero day. FDA recommends that the expiration date appear in YYYY-MM-DD format if only numerical characters are used or in YYYY-MMM-DD if alphabetical characters are used to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, to be expressed as: YYYY-MM if only numerical characters are used or YYYY-MMM if alphabetical characters are used to represent the month. FDA recommends that a hyphen or a space be used to separate the portions of the expiration date.

C. Carton Labeling

1. To increase the prominence of the important information which appears below the product name, consider increasing the font size of the important product information statements (i.e., strength and the statements below such as "For intravenous infusion…", etc.).

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Danyelza received on March 31, 2020 from Y-mAbs Therapeutics, Inc.

Table 2. Relevant Product Information for Danyelza	
Initial Approval Date	N/A
Nonproprietary Name	naxitamab
Indication	For the treatment of refractory or relapsed high-risk neuroblastoma in bone (b) (4) or bone marrow in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF)
Route of Administration	Intravenous infusion
Dosage Form	Injection
Strength	40 mg/10 mL
Dose and Frequency	3 mg/kg on Day 1, 3 mg/kg on Day 3, and 3 mg/kg on Day 5 of a cycle, infused over at least 60 minutes for the initial infusion; at least 30 minutes for subsequent infusions. Treatment cycles are repeated every 4 weeks (b) (4) until a complete or partial response is achieved, followed by five additional cycles every 4 weeks (b) (4) Subsequent cycles can be repeated every 8 weeks (b) (4) (b) (4)
How Supplied	Cartons containing 1 single-dose vial
Storage	Store refrigerated at 2°C to 8°C (36°F to 46°F) until time of use. Keep the vial in the outer carton to protect from light
Container Closure	(b) (4) glass vial with a (b) (4) stopper and an aluminum seal

APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[a] along with postmarket medication error data, we reviewed the following Danyelza labels and labeling submitted by Y-mAbs Therapeutics, Inc..

- Container label received on March 31, 2020
- Carton labeling received on March 31, 2020
- Prescribing Information (Image not shown) received on March 31, 2020, available from \\cdsesub1\evsprod\bla761171\0004\m1\us\114-labeling\draft\labeling\draft-labeling-text-word.docx

G.2 Label and Labeling Images

(b) (4)

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

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