CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215841Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

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:	February 24, 2022
Requesting Office or Division:	Division of Medical Imaging and Radiation Medicine (DMIRM)
Application Type and Number:	NDA 215841
Product Name and Strength:	Lometz (kit for the preparation of gallium Ga 68 gozetotide injection), 25 mcg/vial
Applicant/Sponsor Name:	Advanced Accelerator Applications
OSE RCM #:	2021-1563-2
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD

1 PURPOSE OF MEMORANDUM

Advanced Accelerator Applications submitted revised Lometz vial container label, carton labeling, diagnostic activity label, and syringe label received on February 23, 2022 for Lometz (kit for the preparation of gallium Ga 68 gozetotide injection) under NDA 215841. We reviewed the revised vial container label, carton labeling, diagnostic activity label, and syringe label for Lometz (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 CONCLUSION

Advanced Accelerator Applications implemented all of our recommendations and we have no additional recommendations at this time.

[a] Kane, D. Label and Labeling Review for Lometz (NDA 215841). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 JAN 28. RCM No.: 2021-1563-1.

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DEVIN R KANE
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HINA S MEHTA
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FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

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

Memorandum

Date: February 15, 2022

To: Gang Niu, M.D.
Division of Imaging and Radiation Medicine (DIRM)

Frank Lutterodt, Regulatory Project Manager, DIRM

Younsook Kim, Associate Director for Labeling, DIRM

From: David Foss, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Jim Dvorsky, Team Leader, OPDP

Subject: OPDP Labeling Comments for LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection), for intravenous use

NDA: 215841

In response to DIRM's consult request dated August 16, 2021, OPDP has reviewed the proposed product labeling (PI) and carton and container labeling for the original NDA submission for Locametz.

Labeling: OPDP's comments on the proposed labeling are based on the draft labeling received by electronic mail from DIRM on February 9, 2022, and are provided below.

Carton and Container Labeling: OPDP has reviewed the attached proposed carton and container labeling received by electronic mail from DIRM on February 11, 2022, and we do not have any comments.

Thank you for your consult. If you have any questions, please contact David Foss at (240) 402-7112 or david.foss@fda.hhs.gov.

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DAVID F FOSS
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MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

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:	January 28, 2022
Requesting Office or Division:	Division of Medical Imaging and Radiation Medicine (DMIRM)
Application Type and Number:	NDA 215841
Product Name and Strength:	Locametz (kit for the preparation of gallium Ga 68 gozetotide injection), 25 mcg/vial
Applicant/Sponsor Name:	Advanced Accelerator Applications
OSE RCM #:	2021-1563-1
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Hine Mehta, PharmD

1 PURPOSE OF MEMORANDUM

Advanced Accelerator Applications submitted revised Locametz vial container label, carton labeling, diagnostic activity label, and syringe label received on January 25, 2022 for Locametz (kit for the preparation of gallium Ga 68 gozetotide injection) under NDA 215841. We reviewed the revised vial container label, carton labeling, diagnostic activity label, and syringe label for Locametz (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations made during a previous label and labeling review.[a]

2 CONCLUSION

The revised Locametz vial container label, carton labeling, diagnostic activity label, and syringe label are unacceptable from a medication error perspective. We recommend revising the storage temperature ranges and beyond use time on the carton and container labels to align with the information provided in the prescribing information. Additionally, we recommend

[a] Kane, D. Label and Labeling Review for Locametz (NDA 215841). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2021 OCT 22. RCM No.: 2021-1563.

revising “25 mcg per vial” to read “25 mcg per vial gozetotide”. We provide our recommendations below.

3 RECOMMENDATIONS FOR ADVANCED ACCELERATOR APPLICATIONS

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

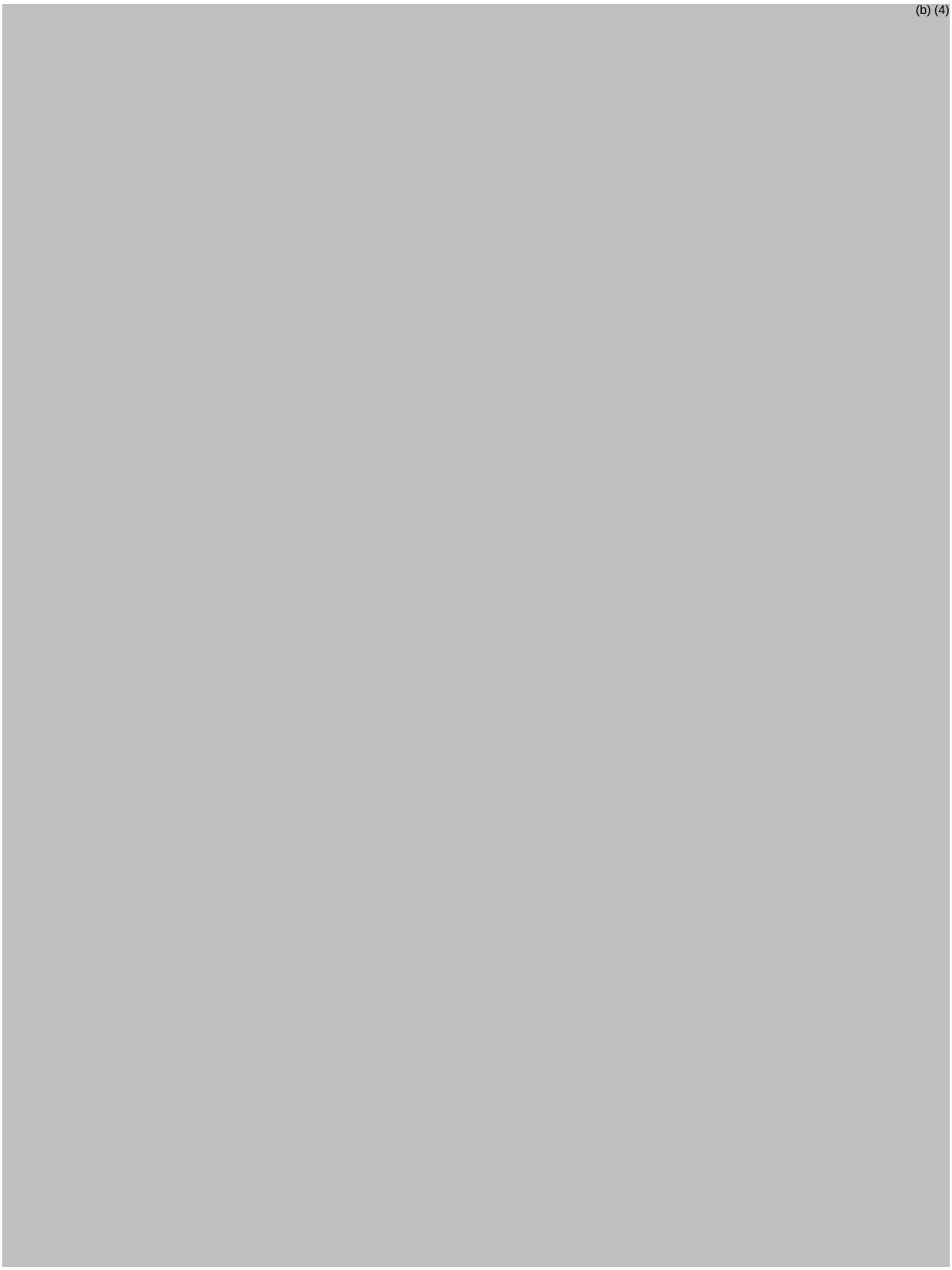
A. Carton Labeling and Vial Container Labels
    1. As currently presented, the proposed vial container label displays the strength as “25 mcg per vial”. We recommend revising this statement to read “25 mcg per vial gozetotide”.

B. Carton Labeling
    1. We note the back panel of the proposed carton labeling lists the inactive ingredients contained in each vial but does not provide the quantity of each inactive ingredient. We recommend revising the back panel of the carton labeling to include the quantity for each of the inactive ingredients.
    2. We note the storage temperatures presented on the carton labeling are not consistent with the storage temperatures provided in the Locametz PI. We recommend revising the storage temperatures on the carton labeling to align with the storage temperatures presented in the Locametz PI. Revise to read “Before reconstitution, store at 2°C to 25°C (36°F to 77°F). Do not freeze. After radiolabeling, store upright with an appropriate lead shielding to protect from radiation, (b) (4)
    3. As currently presented, the proposed carton labeling includes the statement “After radiolabeling, use within (b) (4) hours”. However, we note the proposed PI defines the beyond use time as 4 hours. We recommend revising this statement on the proposed carton labeling to read “After radiolabeling, use up to 4 hours”.

C. Diagnostic Activity Label
    1. We note the storage temperatures presented on the diagnostic activity label are not consistent with the storage temperatures provided in the Locametz PI. We recommend revising the storage temperatures on the diagnostic activity label to align with the storage temperatures presented in the Locametz PI. Revise to read “After radiolabeling, store upright with an appropriate lead shielding to protect from radiation, (b) (4)
    2. As currently presented, the proposed diagnostic activity label includes the statement “After radiolabeling, use within (b) (4) hours”. However, we note the proposed PI defines the beyond use time a 4 hours. We recommend revising this statement on the proposed diagnostic activity label to read “After radiolabeling, use up to 4 hours”.

D. Syringe Label
    1. As currently presented, the proposed syringe label includes the statement “Use within (b) (4) hours after radiolabeling”. However, we note the proposed PI defines the beyond use time as 4 hours. We recommend revising this statement on the proposed syringe label to read “Use up to 4 hours after radiolabeling”.

APPENDIX A. IMAGES OF LABEL AND LABELING RECEIVED ON JANUARY 25, 2022



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/s/

DEVIN R KANE
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HINA S MEHTA
01/31/2022 01:06:20 PM

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:	October 22, 2021
Requesting Office or Division:	Division of Medical Imaging and Radiation Medicine (DIRM)
Application Type and Number:	NDA 215841
Product Name, Dosage Form, and Strength:	Locametz (kit for the preparation of gallium Ga 68 gozetotide injection) 25 mcg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Advanced Accelerator Applications
FDA Received Date:	July 29, 2021 and September 22, 2021
OSE RCM #:	2021-1563
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

1 REASON FOR REVIEW

Advanced Accelerator Applications submitted a 505(b)(2) application under NDA 215841 for Locametz (kit for the preparation of gallium Ga 68 gozetotide injection) on July 29, 2021. Locametz, after radiolabeling with gallium Ga 68, is a radioactive diagnostic agent proposed for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy, with suspected recurrence based on elevated serum prostate specific antigen (PSA) level, or for (b) (4) of patients with metastatic prostate cancer, for whom PSMA-targeted therapy is indicated. We evaluated the proposed Locametz prescribing information (PI), vial container labels, carton labeling, diagnostic activity label, and syringe label for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUND OR REGULATORY HISTORY

NDA 215841 relies upon the reference listed drug product gallium Ga 68 PSMA-11 injection which was approved under NDA 212642 and NDA 212643 on December 1, 2020. Both NDA 212642 and NDA 212643 are available as clear, colorless solution in a multiple-dose vial containing 18.5 MBq/mL to 185 MBq/mL (0.5 mCi/mL to 5 mCi/mL) Ga 68 PSMA-11 at calibration time. The drug product proposed under NDA 215841 would be supplied as a multiple-dose vial containing 25 mcg of gozetotide as a lyophilized powder and will require radiolabeling with gallium Ga 68 chloride prior to administration.

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 Label and Labeling 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

We note the proposed product, Locametz, shares the same recommended dose (3 mCi to 7 mCi) and route of administration (intravenous) as the reference listed drug products (RLD). Locametz also shares similarity in proposed indication to the RLD products, with an additional proposed indication for (b) (4) of patients with metastatic prostate cancer, for whom PSMA-targeted therapy is indicated. Additionally, we note the proposed drug product under NDA 215841 differs from the RLD in that it is proposed as a nonradioactive drug product with a strength of 25 mcg of gozetotide per vial and requires radiolabeling with gallium Ga 68 chloride prior to administration to the patient. The gallium Ga 68 chloride required for radiolabeling of the proposed drug product is not supplied as part of the proposed kit and would be obtained from either an Eckert & Ziegler GalliaPharm Ge 68/Ga 68 generator or an IRE ELiT Galli Eo (Ge 68/Ga 68) generator.

We performed a risk assessment of the proposed prescribing information (PI), vial container labels, carton labeling, diagnostic activity label, and syringe label for Locametz to determine whether there are deficiencies that may lead to medication errors and other areas of improvement. We note the second page of the proposed vial container label is blank. On September 15, 2021 we sent an information request (IR) to Advanced Accelerator Applications to confirm whether or not the second page of the proposed vial container label was intentionally left blank. Advanced Accelerator Applications provided a response on September 22, 2021 and stated "We confirm that the proposed vial container label is 3 pages, and the second page is intentionally left blank. This is a multilayered label due to the amount of content required and to meet readability standards. Therefore, page 1 is the top layer that will be visible first, page 2 is the backside of page 1 as it is flipped up, and page 3 is directly under page 1 and visible when page 1 is flipped up. Page 3 is the part of the multilayered label that is adhered to the vial."

Our evaluation of the proposed PI, vial container labels, carton labeling, diagnostic activity label, and syringe label for Locametz identified areas of vulnerability that may lead to medication errors. For the Division we recommend including the strength following radiolabeling, replacing symbols with their intended meaning, including units after all numeric values presented in the PI, removing trailing zeros, and presenting all storage temperatures in terms of degrees Celsius with the Fahrenheit equivalent values in parenthesis. For the Applicant we recommend removing the use of the placeholder "Tradename" and replacing it with the conditionally acceptable proprietary name "Locametz", defining the proposed format for the expiration, and replacing the use of "multi-dose (b) (4)" with "multiple-dose vial". We provide our recommendations below.

4 CONCLUSION & RECOMMENDATIONS

Our evaluation of the proposed Locametz prescribing information (PI), vial container labels, carton labeling, diagnostic activity label, and syringe label identified areas of vulnerability that may lead to medication errors. Below, we have provided recommendations in Section 4.1 for

the Division and Section 4.2 for the Applicant. We ask that the Division convey Section 4.2 in its entirety to Advanced Accelerator Applications so that recommendations are implemented prior to approval of this NDA.

4.1 RECOMMENDATIONS FOR DIVISION OF MEDICAL IMAGING AND RADIATION MEDICINE (DIRM)

A. General Comments (Highlights of Prescribing Information and Full Prescribing Information)

1. We recommend removing the use of the placeholder "Tradename" and replacing it with the conditionally acceptable proprietary name "Locametz".
2. We note the use of the symbol "-" used to represent the word "to" in multiple sections of the label. We recommend removing the use of the symbol and replacing it with its intended meaning of "to".
3. As currently presented, there are numeric values presented in multiple sections of the label that are not followed by their respective units. We recommend including the appropriate units after all numeric values in order to avoid any confusion.
4. We note the use of the language "reconstitution" used throughout the prescribing information to refer to the process of adding the gallium Ga 68 to the vial of gozetotide. We recommend revising this language to "radiolabeling" throughout the PI to accurately define the addition of the radioactive gallium Ga 68.

B. Highlights of Prescribing Information

1. Dosage Forms and Strengths

a. As currently presented this section is missing important information such as the strength. We recommend revising to read "Locametz is supplied as a multiple-dose vial containing 25 mcg of gozetotide as a white lyophilized powder. After radiolabeling with Ga 68, the vial contains a sterile solution of Ga 68 gozetotide at a strength up to (b) (4)

C. Prescribing Information

1. Section 2: Dosage and Administration

a. We note in Section 2.4 Drug Preparation in bullet 'a' under Step 2: Incubation that the room temperature range is presented in terms of degrees Fahrenheit without the Celsius equivalent values. We recommend revising this bullet to read "Incubate the Locametz vial (b) (4) between 20° and 30°C (68° to 86°F) for at least 5 minutes without agitation or stirring.".

b. As currently presented, bullet 'd' in Section 2.4 Drug Preparation under Step 2: Incubation provides the storage temperature value in terms degrees Fahrenheit without the Celsius equivalent value. We recommend revising bullet 'd' to read "Store the Locametz vial containing gallium Ga 68 gozetotide injection upright in a lead shielded container below 30°C (86°F) until use.".

c. We note throughout Section 2 Dosage and Administration that the prepared drug product is referred to as "(b) (4) ". We recommend presenting the prepared drug product as "gallium Ga 68 gozetotide injection".

d. As currently presented, bullet 'c' in Section 2.6 Administration contains improper nomenclature for the diluents. We recommend revising "water for injection" to "Sterile Water for Injection, USP" and "sodium chloride 9 mg/ml (0.9%) solution" to "0.9% Sodium Chloride Injection, USP".

e. As currently presented, Section 2.9 Radiation Dosimetry contains numeric values that are presented with the use of trailing zeros. We recommend removing the use of trailing zeros in order to avoid misinterpretation of the important values.

2. Section 3: Dosage Forms and Strengths

a. We recommend revising Section 3: Dosage Forms and Strengths to read

(b) (4)

3. Section 16: How Supplied/Storage and Handling

a. We recommend revising Section 16.1 How Supplied to read (b) (4)

(b) (4)

b. As currently presented, Section 16.2 provides the storage temperature requirements in terms of degrees Fahrenheit without the Celsius equivalent values. We recommend provided all temperatures in terms of degrees Celsius with the Fahrenheit equivalent values in parenthesis.

c. We note that Section 16.2 does not contains information regarding the storage of the radiolabeled product in appropriate lead shielding to protect from radiation. We recommend revising the second statement of Section 16.2 Storage and Handling under Storage to read "After radiolabeling, store upright with an appropriate lead shielding to protect from radiation, below 30°C (86°F).".

4.2 RECOMMENDATIONS FOR ADVANCED ACCELERATOR APPLICATIONS

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

A. General Comments (Vial Container Labels, Carton Labeling, Diagnostic Activity Label, and Syringe Label)

1. We recommend removing the use of the placeholder "Tradename" on the vial container labels, carton labeling, diagnostic activity label, and syringe label and replacing it with the conditionally acceptable proprietary name "Locametz".

B. Container Labels

1. We note the first page of the proposed vial container label lacks the statement "Rx Only". We recommend including the statement "Rx Only" on the first page of the proposed vial container label.
2. As currently presented, the first page of the proposed Locametz vial container label defines the established name as "(b) (4) . We recommend revising the established name to read "kit for the preparation of gallium Ga 68 gozetotide injection".
3. We note the first and third pages of the vial container label state "25 mcg" in the upper right corner. We recommend revising this statement to read "25 mcg per vial or 25 mcg/vial" and placing it below the established name to prevent misinterpretation.
4. We note the first page of the vial container label states "(b) (4) ". We recommend revising this statement to read:

   "For Intravenous Use Only.

   Radiolabel with gallium Ga 68 chloride before use.".
5. As currently presented, the container type is not defined on the proposed vial container label. We recommend defining the container type on the first page of the vial container label and displaying the statement "Multiple-Dose Vial".

6. We note the vial container label contains a placeholder for the expiration date and does not contain the proposed format for the expiration date. We recommend that the expiration date appears in YYYY-MM-DD format is only numerical characters are used or in YYYY-MMM-DD is alphabetical characters are used to represent the month.

7. We note the first page of the proposed vial container label contains a placeholder for the [(b) (4)]". We recommend revising this placeholder to read "Lot".

8. As currently presented, the third page of the proposed vial container label contains the statement "[(b) (4)]". We recommend revising this statement to read "[(b) (4)] See Prescribing Information".

C. Carton Labeling

1. We note the top panel of the proposed carton labeling contains the statement "multi-dose [(b) (4)] for radiopharmaceutical preparation containing one vial of....". We recommend revising this statement to read

   "Locametz

   (kit for the preparation of gallium Ga 68 gozetotide injection)

   25 mcg per vial

   [(b) (4)]."

2. As currently presented, the side panel of the proposed carton labeling for Locametz contains the statement "[(b) (4)]". We recommend revising this statement to read "See Prescribing Information for preparation and administration instructions."

3. We note the side panel of the proposed carton labeling contains the statement "To be reconstituted with gallium Ga 68 chloride...". We recommend revising this statement to read "To be radiolabeled with gallium Ga 69 chloride...".

4. As currently presented, the storage information on the proposed carton labeling states "Before reconstitution, [(b) (4)]". We recommend revising the storage information language to align with the storage information presented in Section 16 of the prescribing information. Revise the storage information to read "Before [(b) (4)] After radiolabeling, store upright, below 30°C (86°F) [(b) (4)] After radiolabeling, use within [(b) (4)] hours."

5. We note the placeholder for the "[(b) (4)]" at the bottom left corner of the principal display panel. We recommend revising this placeholder to read "Lot" and moving this information to the side panel or the back panel.

6. As currently presented, the proposed carton labeling contains a placeholder for the expiration but the format for the expiration is not defined. We recommend that the expiration date appears in YYYY-MM-DD format is only numerical characters are used or in YYYY-MMM-DD is alphabetical characters are used to represent the month. Additionally, we recommend moving the expiration to the side panel or back panel with the lot number.

7. We note the principal display panel of the proposed carton labeling contains the statement "(b) (4) . We recommend revising this statement to read "kit for the preparation of gallium Ga 68 gozetotide injection".

8. As currently presented, the principal display panel displays the strength as "(b) (4) ". We recommend revising the strength to 25 mcg/vial or 25 mcg per vial" and placing below the established name to prevent misinterpretation.

9. As currently presented, the principal display panel of the proposed carton labeling contains the statement "(b) (4)". We recommend revising this statement to read:

   "For Intravenous Use Only

   Radiolabel with gallium Ga 68 chloride before use.".

D. Diagnostic Activity Label

1. As currently presented, we note the proposed diagnostic activity label states (b) (4) We recommend revising this statement to read "For Intravenous Use Only".

2. As currently presented, the proposed activity label for Locametz contains the vial strength of "25 mcg". We recommend removing this strength from the proposed syringe label as it reflects the amount of gozetotide in the vial and may be confused for the concentration of the radiolabeled drug product.
3. We note the proposed label states (b) (4) . We recommend revising this statement to read "See Prescribing Information for dosage and administration instructions".
4. As currently presented, the storage requirements following radiolabeling are not provided on the proposed diagnostic activity label. We recommend including the statement "Store upright (b) (4) lead (b) (4) . After radiolabeling, use within (b) (4) hours.".
5. We note the placeholder line for (b) (4). We recommend revisin this line to read "Discard After: _____Time _____Date".
6. We note the placeholder line for "(b) (4)". We recommend revising this line to read "Calibration: _____ Time _____Date".
7. As currently presented, the "Rx Only" statement blends in with the radioactive material cautionary statement. We recommend presenting the "Rx Only" statement on its own line outside of the caution yellow box.

8. We note the proposed diagnostic activity label only contains placeholders for the strength in terms of megabecquerels (MBq). We recommend including the total activity in terms of megabecquerels (MBq) and millicuries (mCi). Additionally, we note the proposed diagnostic activity label does not contain a line for the overall concentration. We recommend including a line for the concentration at calibration time in terms of MBq/mL and mCi/mL.

9. As currently presented, the proposed diagnostic activity label lacks a warning statement regarding the safe handling of the radiolabeled product. We recommend including the warning statement "Warning: Only licensed healthcare professionals who are qualified by specific training in the safe use and handling of radionuclides should use radiopharmaceuticals." We recommend including this statement in the bottom left corner of the proposed diagnostic activity label.

E. Syringe Label

1. We note that Locametz must be used within (b) (4) hours of radiolabeling. We recommend including this information on the syringe label. Revise the syringe label to include the statement "Use within (b) (4) hours after radiolabeling".
2. As currently presented, the "Rx Only" statement blends in with the radioactive material cautionary statement. We recommend presenting the "Rx Only" statement on its own line outside of the caution yellow box.
3. We note the statement "(b) (4)" currently presented on the proposed syringe label. We recommend revising this statement to read "See Prescribing Information before use".
4. We note the placeholder for the (b) (4)" number. We recommend revising this placeholder to read "Lot".
5. As currently presented, the proposed syringe label for Locametz contains the vial strength of "25 mcg". We recommend removing this strength from the proposed syringe label as it reflects the amount of gozetotide in the vial and may be confused for the strength of the dose drawn into the syringe.

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Locametz received on July 29, 2021 from Advanced Accelerator Applications, and the listed drugs (LD).

Table 2. Relevant Product Information for Locametz and the Listed Drugs			
Product Name	Locametz	Gallium Ga 68 PSMA-11[a] (NDA 212642)	Gallium Ga 68 PSMA-11[b] (NDA 212643)
Initial Approval Date	N/A	December 1, 2020	
Active Ingredient	kit for the preparation of gallium Ga 68 gozetotide injection	gallium Ga 68 PSMA-11	
Indication	Locametz, after radiolabeling with gallium-68, is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer: • with suspected metastasis who are candidates for initial definitive therapy. • with suspected recurrence based on elevated serum prostate specific antigen (PSA) level. • for (b) (4) of patients with metastatic	Ga 68 PSMA-11 Injection is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: • with suspected metastasis who are candidates for initial definitive therapy. • with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.	

[a] Gallium Ga 68 PSMA-11 [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2020 DEC 01. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212642s000lbl.pdf

[b] Gallium Ga 68 PSMA-11 [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2020 DEC 01. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212643s000lbl.pdf

	prostate cancer, for whom PSMA-targeted therapy is indicated.		
Route of Administration	Intravenous	Intravenous	
Dosage Form	For Injection	Injection	
Strength	25 mcg/vial	18.5 MBq/mL to 185 MBq/mL (0.5 mCi/mL to 5 mCi/mL) Ga 68 PSMA-11 at calibration time	
Dose and Frequency	The recommended dose is [redacted] (b) (4) 111 MBq (3 mCi) up to a maximum dose of 259 MBq (7 mCi).	The recommended adult dose is 111 MBq to 259 MBq (3 mCi to 7 mCi) as a bolus intravenous injection.	
How Supplied	Locametz is supplied as a multiple-dose vial for radiopharmaceutical preparation of gallium Ga 68 gozetotide solution for injection. Each vial contains 25 micrograms of gozetotide as white lyophilized powder (powder for solution for injection) in a 10 mL type I Plus glass vial closed with a rubber stopper and sealed with a flip-off cap.	Ga 68 PSMA-11 Injection (NDC 76394-2642-3) is a clear, colorless solution, supplied in a capped glass vial containing 18.5 MBq/mL to 185 MBq/mL (0.5 mCi/mL to 5 mCi/mL) of Ga 68 PSMA-11 at end of synthesis, in approximately 12 mL. The contents of each vial are sterile, pyrogen-free and preservative-free. The expiration date and time are provided on the container label.	Ga 68 PSMA-11 Injection (NDC 24275-0525-1) is a clear, colorless solution, supplied in a capped glass vial containing 18.5 MBq/mL to 185 MBq/mL (0.5 mCi/mL to 5 mCi/mL) of Ga 68 PSMA-11 at end of synthesis, in approximately 11 mL. The contents of each vial are sterile, pyrogen-free and preservative-free.
Storage	Before reconstitution, store [redacted] (b) (4)	Store Ga 68 PSMA-11 Injection upright in a lead shielded container at 25°C (77°F);	

	After [redacted] store upright, below 30°C (86°F) [redacted] After [redacted], use within [redacted] hours.	excursions are permitted from 15°C to 30°C (59°F to 86°F). Store Ga 68 PSMA-11 Injection within the original container in radiation shielding.

APPENDIX G.LABELS AND LABELING

G.1List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[c] along with postmarket medication error data, we reviewed the following Locametz labels and labeling submitted by Advanced Accelerator Applications.

- Vial Container Label received on July 29, 2021
- Carton Labeling received on July 29, 2021
- Diagnostic Activity Label received on July 29, 2021
- Syringe Label received on July 29, 2021
- Prescribing Information (Image not shown) received on July 29, 2021, available from \\CDSESUB1\evsprod\nda215841\0000\m1\us\annotated.pdf

G.2Label and Labeling Images

(b) (4)

[redacted]

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

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/s/

DEVIN R KANE
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