CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218711Orig1s000

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)

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Date of This Review:	October 9, 2024
Requesting Office or Division:	Division of Oncology 1 (DO1)
Application Type and Number:	NDA 218711
Product Name, Dosage Form, and Strength:	Beizray (docetaxel) Injection, 80 mg/4 mL (20 mg/mL)
Applicant Name:	Zhuhai Beihai Biotech Co., Ltd.
FDA Received Date:	September 13, 2024 and October 1, 2024
TTT ID #:	2023-6702-1
DMEPA 2 Team Leader:	Tingting Gao, PharmD

1 PURPOSE OF MEMORANDUM

Zhuhai Beihai Biotech Co., Ltd. submitted revised container label and carton labeling received on September 13, 2024 and October 1, 2024 for Beizray. The Division of Oncology 1 (DO1) requested that we review the revised container label and carton labeling for Beizray (Appendix A and Apppendix B) 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

The proposed sticker for the IV Solution Stabilizer is acceptable from a medication error perspective.

However, the revised the container label and carton labeling are unacceptable from a medication error perspective. We provided the following recommendations for the container labels and carton labeling to improve readability. DO1 communicated our recommendations below to Zhuhai Beihai Biotech Co., Ltd. on September 25, 2024[b].

A. General Comments (Container Label(s) and Carton Labeling)
    1. Amend the established name from [redacted] (b) (4) to "(docetaxel) injection" on container and carton labels.

B. Container label
    1. Consider un-bold the package type term "4 mL Single-dose Vial Discard Unused Portion" to reduce prominence.
    2. On the principal display panel, ensure there is sufficient white space between each statement to improve readability. For example:

C. Carton Labeling
    1. As currently presented on the principal display panel, the "Discard unused portion" statement is presented in a large and bold font and competes in prominence with other important information (e.g., route of administration). We recommend presenting the "Discard unused portion" statement using the same font type and font size as the "Each Kit Contains:" statement to reduce prominence.

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[a] Gao, T. Label and Labeling Review for Beizray (NDA 218711). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Sept 9. TTT ID: 2023-6702.

[b] Lee, C. FDA Communication: NDA 218711 - 9/25/24 C&C IR. Silver Spring (MD): FDA, CDER, OND, DO1 (US); 2024 SEPT 25. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af80770267.

Zhuhai Beihai Biotech Co., Ltd. submitted revised Beizray container label and carton labeling on October 1, 2024 in response to our recommendations above. Zhuhai Beihai Biotech Co., Ltd. also provided an updated mockup of Beizray tray.

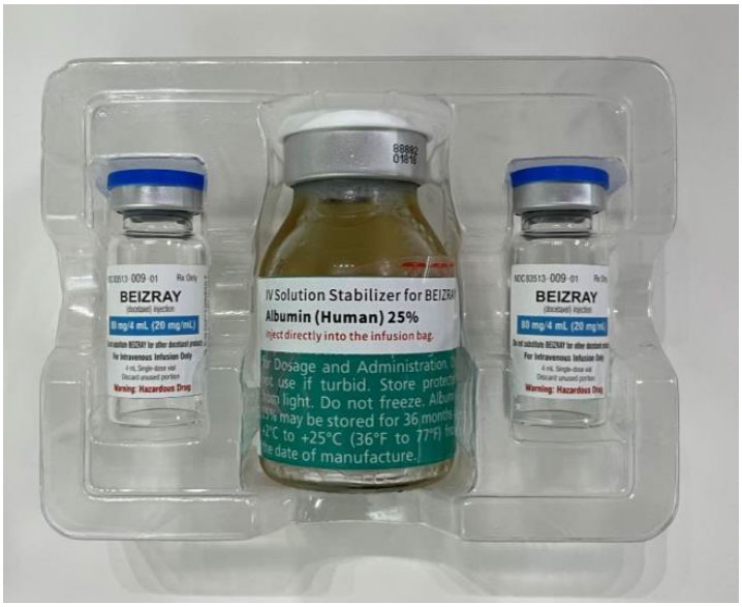

Figure 1. Beizray Kit containing two BEizray vials and one Albumin (Human) 25% vial labeled with a "IV Solution Stabilizer for Beizray" sticker.

We found the revised Beizray container label and carton labeling acceptable from a medication error perspective.

3 CONCLUSION

The October 1, 2024 Beizray container label and carton labeling, and the September 13, 2024 IV Solution Stabilizer container label are acceptable from a medication error perspective. We have no further recommendations at this time.

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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: **October 3, 2024**

To: Christal Lee, Regulatory Project Manager, DO1

William Pierce, Associate Director for Labeling, DO1

From: Mispa Ajua-Alemanji, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Rachael Conklin, Team Leader, OPDP

Subject: OPDP Labeling Comments for BEIZRAY (docetaxel) injection, for intravenous use

NDA: 218711

Background:
In response to DO1's consult request dated October 24, 2023, OPDP has reviewed the proposed Prescribing Information (PI), Patient Package Insert (PPI) and Carton and Container labeling for BEIZRAY (docetaxel) injection, for intravenous use. Pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR 314.50, the sponsor proposes a New Drug Application for BEIZRAY (BH009), docetaxel Injection (Albumin solubilized), 80 mg/4 mL for the treatment of similar indications as the reference product Taxotere® (NDA 020449), Docetaxel Injection, 80 mg/4 mL.

PI:
OPDP's comments on the proposed labeling are based on the draft PI and PPI received by electronic mail from DO1 on September 20, 2024, and we have no comments.

PPI:
A combined OPDP and Division of Medical Policy Programs (DMPP) review was completed and comments on the proposed PPI were sent under separate cover on September 30, 2024.

Carton and Container Labeling:
OPDP has reviewed the proposed carton and container labeling submitted by the Sponsor to the electronic document room on September 13, 2024, and we have no comments.

Thank you for your consult. If you have any questions, please contact Mispa Ajua-Alemanji at Mispa.Ajua-Alemanji@fda.hhs.gov.

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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 27, 2024
To:	Christal Lee, PharmD Regulatory Project Manager **Division of Oncology I (DO1)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** Barbara Fuller, RN, MSN, CWOCN Team Leader, Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Helen Young, MSN, MPH, CRRN, PHN, RN Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Mispa Ajua-Alemanji, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	BEIZRAY (docetaxel)
Dosage Form and Route:	injection, for intravenous use
Application Type/Number:	NDA 218711
Applicant:	Zhuhai Beihai Biotech Co., Ltd.c/o Conjugation Healthcare

1 INTRODUCTION

On October 6, 2023, Zhuhai Beihai Biotech Co., Ltd. c/o of Conjugation Healthcare submitted for the Agency's review an original 505(b)(2) New Drug Application (NDA) 218711 for BEIZRAY (docetaxel) injection**.** The Referenced Listed Drug (RLD) is TAXOTERE (docetaxel) injection NDA 020449. The Applicant seeks approval for the following proposed indications for the treatments of patients with:

- Breast Cancer (BC): single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC
- Non-small Cell Lung Cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC
- Castration-Resistant Prostate Cancer (CRPC): with prednisone in metastatic castration-resistant prostate cancer
- Gastric Adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction
- Squamous Cell Carcinoma of the Head and Neck (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN

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 I (DOI) on October 24, 2023, for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for BEIZRAY (docetaxel) injection.

2 MATERIAL REVIEWED

- Draft BEIZRAY (docetaxel) injection PPI received on October 6, 2023, and received by DMPP and OPDP on September 20, 2024.
- Draft BEIZRAY (docetaxel) injection Prescribing Information (PI) received on October 6, 2023, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on September 20, 2024.
- Approved TAXOTERE (docetaxel) injection labeling dated January 18, 2023.

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 PI
- 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)
- ensured that the PPI is consistent with the approved comparator labeling where applicable.

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 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)

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

Date of This Review:	September 9, 2024
Requesting Office or Division:	Division of Oncology 1 (DO1)
Application Type and Number:	NDA 218711
Product Name, Dosage Form, and Strength:	Beizray (docetaxel) Injection, 80 mg/4 mL (20 mg/mL)
Product Type:	Combination Product (Drug-Biologic copackage)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Zhuhai Beihai Biotech Co., Ltd.
FDA Received Date:	March 6, 2024 and May 17, 2024
TTT ID #:	2023-6702
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 REASON FOR REVIEW

As part of the approval process for Beizray (docetaxel) Injection, the Division of Oncology 1 (DO1) requested that we review the proposed Beizray prescribing information (PI), container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUND

Beizray (docetaxel) is a proposed 505(b)(2) drug product and the Listed Drug (LD) is Taxotere (docetaxel), NDA 020449.

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
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B
Labels and Labeling	C
DMEPA 2 recommendations for proposed Beizray Prescribing Information	D

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We note the proposed Beizray (docetaxel) Injection product has the same active ingredient, indications, dosage form, frequency, and route of administration as the listed drug, Taxotere. Furthermore, Beizray is available only in one strength, 80 mg/4 mL (20 mg/mL) whereas Taxotere is available in three strengths 20 mg/mL, 80 mg/4 mL, and 160 mg/8 mL. Beizray is also co-packaged with a 50 mL of 25% Human Albumin solution (See Figure 1).[a]

However, unlike other docetaxel products, Beizray does not contain (b) (4) polysorbate 80) in its formulation. Thus, its preparation differs from other docetaxel products in that the 25% Human Albumin solution must first be added to the 0.9% Sodium Chloride intravenous infusion bag before adding Beizray to the intravenous bag. If the 25% Human Albumin is not used, Beizray will precipitate in the intravenous bag. Therefore, Beizray cannot be substituted for or with other docetaxel formulations.

[a] Zhuhai Beihai Biotech Co., Ltd. proposes to co-package Beizray with a FDA/CBER approved 25% Human Albumin product.

Figure 1. Beizray Kit containing two Beizray vials and one Human Albumin vial in a tray.

We evaluated the proposed Beizray Patient Package Insert (PPI) and determined that it is acceptable from a medication error perspective.

However, the proposed Beizray prescribing information (PI), container label, carton labeling, and container label for 25% Human Albumin may be improved to promote the safe use of this product from a medication error perspective. We provided the identified medication error issues, our rationale for concern, and our proposed recommendations to minimize the risk for medication error for the Division of Oncology 1 (DO1) in Section 4.1 and Apppendix D and for Zhuhai Beihai Biotech Co., Ltd. in Section 4.2.

4 CONCLUSION & RECOMMENDATIONS

The proposed Beizray Prescribing Information (PI), container labels, and carton labeling may be improved to promote 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 for the Division of Oncology 1 (DO1) in Section 4.1 and Appendix D and for Zhuhai Beihai Biotech Co., Ltd. in Section 4.2.

4.1 RECOMMENDATIONS FOR DIVISION OF ONCOLOGY 1 (DO1)

Please see Appendix D for specific recommendations for the Dosage and Administration section of the proposed Beizray PI.

4.2 RECOMMENDATIONS FOR ZHUHAI BEIHAI BIOTECH CO., LTD.

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

A. General Comments for Beizray Container label and Carton Labeling

1. As currently presented on the principal display panel (PDP), the statement (b) (4) is inconsistent with the current labeling terminology. Thus, revise the statement to "Warning: Hazardous Drug".
2. As currently presented, the Beizray container label and carton labeling does not indicate that Beizray is not substitutable with other docetaxel products. Inadvertent substitution can lead to medication errors such as, but not limited to, wrong drug errors or wrong dose errors due to errors in preparation and administration. We recommend adding the statement "**Do not substitute BEIZRAY for other docetaxel products**" on the PDP for both Beizray container label and carton labeling. Remove the statement (b) (4) (b) (4) on the container label and the carton labeling to allow sufficient space to add the Do not substitute statement on the PDP.
3. Revise the storage information to be consistent with the storage information in the Prescribing Information. For example, "Store at 20°C to 25°C (68°F to 77°F). Excursions permitted from 15°C to 30°C (59°F to 86°F). [see USP controlled room temperature]. Retain in the original package to protect from light. Protect from freezing."

B. Beizray Container Label

1. On the PDP, title case the word "Only" so that the route of administration statement reads "For Intravenous Infusion Only".
2. Relocate the net quantity statement "4 mL Single-dose vial" to the PDP so that it reads:

   4 mL Single-dose vial
   Discard unused portion
3. On the side panel, Revise the storage information from (b) (4) (b) (4) to (b) (4) (b) (4) Protect from light. Protect from freezing." to be consistent with the storage information provided in Section 16 How Supplied/Storage and Handling of the Beizray Prescribing Information.
4. On the side panel, add the statement of dosage "**Recommended Dosage:** see Prescribing Information" in accordance with 21 CFR 201.55, if space permits.

C. Container label for Albumin (Human) 25%

1. As currently presented, the Albumin (Human) container label does not identify that this is intended to be used for Beizray. This may lead to wrong preparation errors where the user did not inject Albumin (Human) into the 0.9% Sodium

Chloride Injection infusion bag prior to injecting Beizray. Consider add the statement "IV Solution Stabilizer for BEIZRAY" on the principal display panel so that it is the most prominent statement on the label similar to the following:

IV Solution Stabilizer for BEIZRAY

Albumin (Human) 25%

Inject directly into the infusion bag.

D. Beizray Carton Labeling

1. As currently presented, the healthcare providers may not understand what [redacted] means. Thus, we recommend replacing this statement with the statement "Must be diluted before use in a prepared Albumin (Human) in 0.9% Sodium Chloride Injection solution" in red font to increase the prominence of this important information. Place this new statement below the route of administration statement. For example:

80 mg/4 mL (20 mg/mL)

For Intravenous Infusion Only

Must be diluted before use in a prepared Albumin (Human) in 0.9% Sodium Chloride Injection solution

2. On the PDP, remove the statement [redacted] since this may be misinterpreted as [redacted]
3. On the PDP, consider adding the net quantity of the single dose vials so that the net quantity statement reads:

   Each Kit Contains:

   -Two 4 mL Single-dose vials of Beizray (docetaxel) Injection

   -One 50 mL Single-dose vial of IV Solution Stabilizer (Human Albumin 25%)

4. On the back panel, revise [redacted] to "Each IV Solution Stabilizer vial contains 12.5 grams Albumin (Human) in aqueous solution."
5. On the back panel, revise [redacted] to "Prescribing Information" for consistency with the current labeling terminology.
6. On the back panel, remove the statement [redacted] since this statement is already stated on the PDP.
7. On the back panel, revise the statement of dosage [redacted] to "**Recommended Dosage:** see Prescribing Information".

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Beizray received on Mahy 17, 2024 from Zhuhai Beihai Biotech Co., Ltd., and the listed drug (LD).

Table 2. Relevant Product Information for Beizray and the Listed Drug

Product Name	**Beizray**	**Taxotere (NDA 020449)[b]**
Initial Approval Date	N/A	5/14/1996
Active Ingredient	docetaxel	docetaxel
Indication	Breast Cancer (BC): single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC Non-small Cell Lung Cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC Castration-Resistant Prostate Cancer (CRPC): with prednisone in metastatic castration-resistant prostate cancer Gastric Adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction Squamous Cell Carcinoma of the Head and Neck (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN	
Dosage Form	Injection	Injection
Strength	80 mg/4 mL (20 mg/mL)	20 mg/mL, 80 mg/4 mL, and 160 mg/8 mL
Route of Administration	Intravenous	intravenous
Dose and Frequency	BC locally advanced or metastatic: 60 mg/m^2 to 100 mg/m^2 single agent BC adjuvant: 75 mg/m^2 administered 1 hour after doxorubicin 50 mg/m^2 and cyclophosphamide 500 mg/m^2 every 3 weeks for 6 cycles NSCLC: after platinum therapy failure: 75 mg/m^2 single agent NSCLC: chemotherapy naive: 75 mg/m^2 followed by cisplatin 75 mg/m^2 HRPC: 75 mg/m^2 with 5 mg prednisone twice a day continuously (2.3) GC: 75 mg/m^2 followed by cisplatin 75 mg/m^2 (both on day 1 only) followed by fluorouracil 750 mg/m^2 per day as a 24-hr IV (days 1-5), starting at end of cisplatin infusion SCCHN: 75 mg/m^2 followed by cisplatin 75 mg/m^2 IV (day 1), followed by fluorouracil 750 mg/m^2 per day as a 24-hr IV (days 1-5), starting at end of cisplatin infusion; for 4 cycles SCCHN: 75 mg/m^2 followed by cisplatin 100 mg/m^2 IV (day 1), followed by fluorouracil 1000 mg/m^2 per day as a 24-hr IV (days 1-4); for 3 cycles	

[b] Taxotere [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2023 Jan. [cited 2024 Feb 8]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020449s086lbl.pdf.

Table 2. Relevant Product Information for Beizray and the Listed Drug		
Product Name	**Beizray**	**Taxotere (NDA 020449)[b]**
How Supplied	Beizray Kit with Albutein® 25% • Two single-dose vials of BEIZRAY Injection: 80 mg/4 mL • One single-dose vial of 50 mL of 25% Human Albumin solution for infusion	Carton of one single-dose vial
Storage	BEIZRAY Injection and 25% Human Albumin: [redacted] (b) (4) Retain in the original package to protect from light. Protect from freezing.	Store between 2°C and 25°C (36°F and 77°F). Retain in the original package to protect from light. Freezing does not adversely affect the product.
Container Closure	Single dose vial	Single-dose vial

APPENDIX B. PREVIOUS DMEPA REVIEWS

On July 24, 2024, we searched for previous DMEPA reviews relevant to this current review using the terms, docetaxel. Our search identified numerous previous reviews within the last 5 years, and we considered our previous recommendations to see if they are applicable for this current review.

Table 3. Docetaxel products

Application	Applicant	Strength	Status	OSE Review
NDA 020449 Taxotere (Docetaxel)	Sanofi-Aventis	Single dose vial: 20 mg/mL, 80 mg/4 mL, 160 mg/8 mL	Approved 5/14/1996	2019-46 2019-46-1
NDA 022234 Docetaxel Injection	Hospira	Single dose vial: 20 mg/mL Multiple dose vial: 80 mg/8 mL and 160 mg/16 mL	Approved 3/8/2011	2016-2940 2019-1603
NDA 201195 Docetaxel Injection	Accord	Multiple dose vial: 160 mg/8 mL, 80 mg/4 mL and 20 mg/mL	Approved 6/8/2011	2016-946 2019-40 2023-4982 2023-4982-1
NDA 201525 Docetaxel Injection	Sandoz	Multiple dose vial: 20 mg/2 mL, 80 mg/8 mL and 160 mg/16 mL	Approved 6/29/2011	2018-2457 2019-2462
NDA 022534 Docetaxel Injection	Sun Pharm	Single dose vial: 20 mg/mL, 80 mg/4 mL and 160 mg/8 mL	Approved 5/3/2011	2018-1813 2021-2103
NDA 203551 Docetaxel Injection	Actavis	Single dose vial: 20 mg/mL, 80 mg/4 mL, and 160 mg/8 mL	Approved 4/12/2013	2017-1749 2019-652 2019-652-1 2020-352 2024-9170
NDA 205934 Docetaxel Injection	Shilpa	Single dose vial: 20 mg/mL Multiple dose vial: 80 mg/4 mL and 160 mg/8 mL	Approved 12/22/2015	2021-624 2021-624-1 2021-624-2
NDA 215813 Docivyx (Docetaxel) Injection	Ingenus	Single-dose vial: 20 mg/2 mL, 80 mg/8 mL and 160 mg/16 mL	Approved 11/22/2022	2022-249 2022-249-1 2023-6902 2023-6902-1
NDA 218822 Beizray (Docetaxel) Injection	Zhuhai Beihai Biotech Co	Single-dose vial: 80 mg/4 mL, supplied with albumin (50 mL)	Subject of this review	2023-6702

APPENDIX C. LABELS AND LABELING

C.1 List 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 Beizray labels and labeling submitted by Zhuhai Beihai Biotech Co., Ltd..

- Beizray container label received on March 6, 2024
- Albumin container label received on May 17, 2024
- Beizray carton labeling received on May 17, 2024
- Prescribing Information (Image not shown) received on May 17, 2024, available from \\CDSESUB1\EVSPROD\nda218711\0019\m1\us\114-labeling\draft\labeling\11413-draft-prescribing-information-text-tracked-label.docx
- Patient Information (Image not shown) received on March 6, 2024, available from \\CDSESUB1\evsprod\NDA218711\0012\m1\us\114-labeling\draft\labeling\11413-draft-patient-information-text-tracked-label.docx

C.2 Label and Labeling Images

Container label – Beizray

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

APPENDIX D. DMEPA RECOMMENDATIONS FOR BEIZRAY PRESCRIBING INFORMATION

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 1/24/2024

TO: Division of Oncology I (DO I)
Office of Oncologic Diseases (OOD)

FROM: Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct an on-site inspection**

RE: NDA 218711

OSIS received an inspection request consult from the Division of Oncology I (DO I) on January 10, 2024, for the below sites. The requested review goal date is May 13, 2024.

Rationale

Inspections or remote regulatory assessments (RRAs) of the sites below are not able to be completed. Specifically, the requested review goal date of May 13, 2024, to meet the Action Goal Date of June 13, 2024 and the PDUFA date of August 6, 2024, does not provide sufficient time for an inspection or remote regulatory assessment (RRA) to be completed and for OSIS to submit a review to the review division.

We note OSIS's inspection history for the sites listed below.

Krishna Rajendra (KR) Hospital: The Office of Regulatory Affairs (ORA) inspected the clinical site in January 2023. The inspection was conducted under the following submission: NON-RESPONSIVE

The following objectionable conditions were observed:

- Two subjects did not meet protocol inclusion criteria
- Not all adverse events were reported.

After review of the objectionable conditions and the site's response, OSIS recommended that the data from one subject should be excluded from the study but that all remaining data were reliable (Final OSIS Review - January 2023).

Nirmal Hospital Pvt., Ltd.: ORA conducted an inspection for the site in September 2019. The inspection was conducted under the following submission: NON-RESPONSIVE

The following item was discussed with the site:

- A centrifuge used in one study was mislabeled.

After review of the discussion items and the site's response, OSIS concluded that the discussion item did not impact data integrity or subject safety and that the data from the inspected study were reliable.

Therefore, based on the information above, the sites below will not be inspected by OSIS at this time.

Sites

Facility Type	Facility Name	Facility Address
Clinical	Krishna Rajendra (KR) Hospital	Mysore Medical College and Research Institute, Department Surgical Oncology, New Surgical Block, Irwin Road, Mysore, Karnataka, India
Clinical	Nirmal Hospital Pvt., Ltd.	Near Centre Point, Ring Road, Civil Street, Surat, Gujarat, India

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M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 1/19/2024

TO: Division of Oncology I (DO I)
Office of Oncologic Diseases (OOD)

FROM: Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct on-site inspections**

RE: NDA 218711

The Office of Study Integrity and Surveillance (OSIS) determined that inspections are not needed for the sites listed below. The rationale for this decision is noted below.

Rationale

Healthcare Global (HCG) City Cancer Centre: The Office of Regulatory Affairs (ORA) conducted an inspection for the site in March 2023. The inspection was conducted under the following submission: NON-RESPONSIVE

The following item was discussed with the site:

Inaccurate dates were recorded for two lab-based adverse events experienced by two subjects. After review of the inspectional findings, OSIS concluded that data from the reviewed study was reliable.

Kailash Cancer Hospital and Research Center: ORA conducted an inspection for the site in January 2019. The inspection was conducted under the following submission: NON-RESPONSIVE

The following item was discussed with the site:

- The blood sample collection log did not include the collection dates for each blood sample collected over a 24-hour period.

After review of the inspectional findings, OSIS concluded that data from the reviewed study was reliable.

OSIS notes that a clinical inspection is not supportable for this study because only 2 subjects (4% of total subjects) were randomized at the site.

HCG Manavata Cancer Centre: ORA conducted an inspection for the site in September 2019. The inspection was conducted under the following submission: NON-RESPONSIVE

The following objectionable condition were observed:

- Failure to conduct an investigation in accordance with the investigational plan. Specifically, one subject that did not meet inclusion criteria was enrolled in the study.
- Source documents for one subject did not include a film printout of the 2D echocardiogram.

After receiving a written response from the site, OSIS concluded that the inspectional findings did not impact the reliability of the audited data (Final OSIS Review - September 2019).

OSIS notes that a clinical inspection is not supportable for this study because only 3 subjects (7% of total subjects) were randomized at the site.

(b) (4) OSIS conducted a Remote Regulatory Assessment (RRA) for the analytical site in (b) (4) The RRA was conducted under the following submissions: NON-RESPONSIVE

OSIS concluded that data from the reviewed studies were reliable.

Sites

Facility Type	Facility Name	Facility Address
Clinical	Healthcare Global (HCG) City Cancer Centre	33-25-33, Venkata Krishnayya Street, Suryaraopeta, Vijayawada, Andhra Pradesh, India
Clinical	Kailash Cancer Hospital and Research Center	Muni Seva Ashram, Goraj, Waghodia, Vadodara, Gujarat, India
Clinical	HCG Manavata Cancer Centre	Opposite Mahamarg Bus Stand, Mumbai Naka, Renuka Nagar, Nashik, Maharashtra, India
Analytical	(b) (4)	

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/

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