

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205934Orig1s000**

**ADMINISTRATIVE and CORRESPONDENCE  
DOCUMENTS**

## EXCLUSIVITY SUMMARY

NDA # 205934

SUPPL #

HFD #

Trade Name Docetaxel Injection (non-alcohol formula) for IV use

Generic Name Docetaxel

Applicant Name Teikoku Pharma USA, Inc.

Approval Date, If Known

### **PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?**

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES  NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3,SE4, SE5, SE6, SE7, SE8

505(b)(2)

b) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES  NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

c) Did the applicant request exclusivity?

YES  NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

d) Has pediatric exclusivity been granted for this Active Moiety?

YES  NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES  NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

## **PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES**

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES  NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#	020449	Taxotere
NDA#	022534	Docetaxel
NDA#	022234	Docetaxel
NDA#	022312	Docetaxel
NDA#	201195	Docetaxel
NDA#	201525	Docetaxel
NDA#	202356	Docetaxel
NDA#	203551	Docetaxel

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES  NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)  
IF "YES," GO TO PART III.

**PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS**

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES  NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES  NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES  NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES  NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES  NO

If yes, explain:

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES  NO

Investigation #2 YES  NO

If you have answered "yes" for one or more investigations, identify each such

investigation and the NDA in which each was relied upon:

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES  NO

Investigation #2 YES  NO

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1 !  
IND # YES  ! NO   
! Explain:

Investigation #2 !



Sakar Wahby, PharmD

Title: Regulatory Project Manager

Date: 12/7/2015

Alice Kacuba, RN, MSN, RAC

Title: Chief, Project Management Staff

Date: 12/8/2015

Name of Office/Division Director signing form: Geoffrey Kim, MD

Title: Division Director, Division of Oncology Products 1

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05; removed hidden data 8/22/12

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/s/  
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SAKAR M WAHBY  
12/22/2015

GEOFFREY S KIM  
12/22/2015

**3. DEBARMENT CERTIFICATION**

Teikoku Pharma USA, Inc. hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.



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Jutaro Shudo, Ph.D.  
Sr. Vice President, R&D and Product Development

2/2/2015

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Date

**From:** Wahby, Sakar  
**To:** ["S. Yolanda "Lonnie" Dickerson"](#)  
**Subject:** FDA Communication, NDA205934/Docetaxel Injection (b)(4), Non-Alcohol formula/IR  
**Date:** Wednesday, November 04, 2015 12:19:00 PM  
**Attachments:** [11-4-15 NDA 205934 FDA revised PPI\(2\).docx](#)  
**Importance:** High

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Dear Ms. Dickerson,

In reference to NDA 205934 for Docetaxel Injection (b)(4), Non-Alcohol formula. Also in reference to the Patient Package Insert (PPI) submitted on October 29, 2015, please see revised PPI attached (format change-text placed in a box format). Please respond with your edits **by COB, Monday, November 9, 2015.**

Feel free to contact me with any questions. Please confirm receipt of this email communication.

Thank you,  
Sakar

Sakar Wahby, PharmD  
Regulatory Project Manager / DOP<sub>1</sub>  
Office of Hematology & Oncology Products (OHOP) / CDER/ FDA  
10903 New Hampshire Avenue / Bldg 22, Room 2133 / Silver Spring, MD 20993  
[sakar.wahby@fda.hhs.gov](mailto:sakar.wahby@fda.hhs.gov)  
(P): 240-402-5364  
(F): 301-796-9845

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/s/  
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SAKAR M WAHBY  
11/04/2015

**From:** Wahby, Sakar  
**To:** ["S. Yolanda "Lonnie" Dickerson"](#)  
**Subject:** FDA Communication, NDA205934/Docetaxel Injection (b)(4), Non-Alcohol formula/IR  
**Date:** Friday, October 30, 2015 1:19:00 PM  
**Importance:** High

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Dear Ms. Dickerson,

In reference to NDA 205934 for Docetaxel Injection (b)(4), Non-Alcohol formula. In addition to the clean PDF copy of the Patient Package Insert (PPI) submitted on October 29, 2015, please also submit a "marked Word version" of the PPI in an email and as a formal submission to the application. Please respond **by COB, Wednesday, November 4, 2015.**

Feel free to contact me with any questions. Please confirm receipt of this email communication.

Thank you,  
Sakar

Sakar Wahby, PharmD  
Regulatory Project Manager / DOP<sub>1</sub>  
Office of Hematology & Oncology Products (OHOP) / CDER/ FDA  
10903 New Hampshire Avenue / Bldg 22, Room 2133 / Silver Spring, MD 20993  
[sakar.wahby@fda.hhs.gov](mailto:sakar.wahby@fda.hhs.gov)  
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(F): 301-796-9845

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/s/  
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SAKAR M WAHBY  
10/30/2015

**From:** Wahby, Sakar  
**To:** ["S. Yolanda "Lonnie" Dickerson"](#)  
**Subject:** FDA Communication, NDA205934/Docetaxel Injection (b)(4), Non-Alcohol formula/IR  
**Date:** Monday, October 19, 2015 3:08:00 PM  
**Attachments:** [10-17-15 NDA 205934 FDA revised PI.docx](#)  
[10-19-15 NDA 205934 FDA revised PPI.docx](#)  
**Importance:** High

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Dear Ms. Dickerson,

Please find attached the Agency's revisions for the Package Insert (PI) and the Patient Package Insert (PPI) for Docetaxel Injection (b)(4), Non-Alcohol formula under NDA 205934. Please respond with your edits **by COB, Friday, October 30, 2015.**

Feel free to contact me with any questions. Please confirm receipt of this email communication.

Thank you,  
Sakar

Sakar Wahby, PharmD  
Regulatory Project Manager / DOP<sub>1</sub>  
Office of Hematology & Oncology Products (OHOP) / CDER/ FDA  
10903 New Hampshire Avenue / Bldg 22, Room 2133 / Silver Spring, MD 20993  
[sakar.wahby@fda.hhs.gov](mailto:sakar.wahby@fda.hhs.gov)  
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/s/  
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SAKAR M WAHBY  
10/19/2015

**From:** Wahby, Sakar  
**To:** ["S. Yolanda "Lonnie" Dickerson"](#)  
**Subject:** FDA Communication, NDA205934/Docetaxel Injection (b)(4) Non-Alcohol formula/IR  
**Date:** Monday, October 05, 2015 11:10:00 AM  
**Importance:** High

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Dear Ms. Dickerson,

In reference to the Carton and Container Labels for NDA 205934, please amend the primary and secondary container closure labels with the NDC #s and provide color mock ups of the labels **by Thursday October 8, 2015.**

Feel free to contact me with any questions. Please confirm receipt of this email communication.

Thank you,  
Sakar

Sakar Wahby, PharmD  
Regulatory Project Manager / DOP<sub>1</sub>  
Office of Hematology & Oncology Products (OHOP) / CDER/ FDA  
10903 New Hampshire Avenue / Bldg 22, Room 2133 / Silver Spring, MD 20993  
[sakar.wahby@fda.hhs.gov](mailto:sakar.wahby@fda.hhs.gov)  
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/s/  
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SAKAR M WAHBY  
10/05/2015

**From:** Wahby, Sakar  
**To:** [ydickerson@teikokuusa.com](mailto:ydickerson@teikokuusa.com)  
**Subject:** FDA Communication, NDA205934/Docetaxel Injection (b)(4), Non-Alcohol formula/IR  
**Date:** Wednesday, August 05, 2015 2:21:00 PM  
**Attachments:** [8-5-15 nda205934\\_label\\_carton-docetaxel.pdf](#)  
**Importance:** High

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Dear Ms. Dickerson,

Please find attached the Agency's comments on the Carton and Container Labels for NDA 205934. Please respond with your edits to all three bottle and carton labels **by August 31, 2015**.

Feel free to contact me with any questions. Please confirm receipt of this email communication.

Thank you,  
Sakar

Sakar Wahby, PharmD  
Regulatory Project Manager / DOP<sub>1</sub>  
Office of Hematology & Oncology Products (OHOP) / CDER/ FDA  
10903 New Hampshire Avenue / Bldg 22, Room 2133 / Silver Spring, MD 20993  
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/s/  
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SAKAR M WAHBY  
08/05/2015



NDA 205934

## INFORMATION REQUEST

Teikoku Pharma USA, Inc.  
Attention: S. Yolanda (Lonnie) Dickerson, M.S., RAC  
Sr. Manager, Regulatory Affairs  
1718 Ringwood Avenue  
San Jose, CA 95131-1711

Dear Ms. Dickerson:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Docetaxel.

We also refer to your February 26, 2015 submission, containing your new drug application.

We are reviewing the Chemistry, Manufacturing, and Controls sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

1.



2. Please indicate the number of media fills required to requalify a fill line in case of a media fill failure.
3. The preliminary response and the summarized data for the requested studies for comment 9 are acknowledged. It is indicated in the response that the actual studies and the final laboratory report will be submitted in a subsequent amendment. Once submitted, the information will be reviewed by the Agency. It is noted that the actual data and study reports for these studies are required for completion of review.

If you have any questions, please contact me, Rabiya Laiq, Pharm.D., Regulatory Business Process Manager, at (240) 402-6153. Please respond by August 19, 2015.

Sincerely,

*{See appended electronic signature page}*

Olen Stephens, Ph.D.  
Branch Chief, Branch II  
Office of New Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Olen  
Stephens -S

Digitally signed by Olen Stephens -S  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=Olen Stephens -S,  
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Date: 2015.08.04 08:11:42 -04'00'



NDA 205934

## INFORMATION REQUEST

Teikoku Pharma USA, Inc.  
Attention: S. Yolanda (Lonnie) Dickerson, M.S., RAC  
Sr. Manager, Regulatory Affairs  
1718 Ringwood Avenue  
San Jose, CA 95131-1711

Dear Ms. Dickerson:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Docetaxel.

We also refer to your February 26, 2015 submission, containing your new drug application.

We are reviewing the Chemistry, Manufacturing, and Controls sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

1. You state that an additional 6 months of stability will be provided. Please amend your application with a stability update.
2. After first use, multi-use vials are stored up to 2<sup>0</sup> and 8<sup>0</sup>C storage conditions for 28 days. Please provide the stability data, including thermal cycling studies, to support the storage.
3. As communicated via the 74 day letter, note per 21 CFR §314.54(a)(1)(i), the submission should contain the proposed or actual master production record, including a description of the equipment to be used for the manufacture of a commercial lot of the drug product. We note that your submission contains the completed Exhibit batch records for each presentation. Please provide the proposed or actual master production records to facilitate our review. Alternately list the differences in equipment, operations, in-process controls, if any, between registration and future commercial production batches.

4.

(b)(4)

[Redacted] (b)(4)

5. [Redacted] (b)(4)

6. As the drug is a potent anti-cancer agent, explain controls in place to ensure decontamination of [Redacted] (b)(4) [Redacted] (b)(4)

7. [Redacted] (b)(4)

8. Please indicate that the vials used for the container/closure integrity validation study have the same internal neck size specifications as the vials used for production and that the stoppers used for the study are identical to the stoppers used for routine production.

9. Please indicate the [Redacted] (b)(4)

10 [Redacted] (b)(4)

11. With regard to [Redacted] (b)(4)

a. Please indicate the production parameters of temperature and time for components which come in direct contact with the drug product and include the utensils [Redacted] (b)(4) and vessel assembly and ancillary parts [Redacted] (b)(4)

b. The data summaries provided indicate that the acceptance criterion of a temperature of [Redacted] (b)(4) [Redacted] (b)(4) Please explain.

c. Please provide complete BI information (organism, manufacturer, lot, D-value, expiry, population, and indication if the population was confirmed) for the HP/BI studies from 2012 and 2013. Please provide the results for the positive control BIs.

12. Please indicate how the [REDACTED] (b)(4) and provide process validation information, production parameters and validation studies for the [REDACTED] (b)(4). Alternatively please confirm that the [REDACTED] (b)(4) included the validation studies provided for the [REDACTED] (b)(4) are used to hold the [REDACTED] (b)(4)

13 [REDACTED] (b)(4)

verification data. If the dose setting data are several years old, please provide recent dose audit data and bioburden monitoring data as well. Alternatively, if this information is located within a DMF(s) then please provide a Letter of Authorization granting access to the DMF(s) that provides validation results for the [REDACTED] (b)(4).

14. Please provide complete endotoxin indicator (EI) information (supplier, endotoxin species, lot number and expiry) for the [REDACTED] (b)(4) studies performed in 2012-2013 in the [REDACTED] (b)(4)

15. In regard to media fill process simulations performed using the [REDACTED] (b)(4)

- a. Please provide a comparison of media fill filling speeds to the filling speed used for commercial production.
- b. Please provide results for environmental monitoring conducted during media fill runs from 2012-2014.
- c. Please state how decisions are made regarding hold/disposition/release of potentially affected product by a media fill failure and what actions are taken to requalify the filling line after a failure.

16. Based on the maximum dose provided in the proposed package insert for [REDACTED] (b)(4) and finished product release endotoxins specification of NMT 1.94 USP EU/mg, the endotoxins exposure [REDACTED] (b)(4) recommended by USP <85>. Please revise the endotoxins specification for release and stability and please provide revised inhibition/enhancement testing, as appropriate. Please also provide method suitability validation data for at least three lots of the drug product.

17. Microbiological studies in support of the storage time for the diluted drug product (as stated in the proposed drug product package insert) have not been provided. Please provide a risk assessment summarizing studies that demonstrate adventitious microbial contamination does not grow under the specified storage conditions (i.e., 24 hours at 2-25°C after dilution in 0.9% Sodium Chloride for Injection or 5% Dextrose). Reference is made to Guidance for Industry: ICH Q8 Pharmaceutical Development, Section II.E and Guidance for Industry: ICH Q1A(R2) Stability Testing of New Drug Substances and Products, Section 2.2.7.

18. Please include a description of the test methods and results of studies that are designed using a minimum countable inoculum ( $\leq 100$  CFU/mL) to simulate potential microbial contamination that may occur during storage of the drug product vials or during product dilution. It is generally accepted that growth is evident when the population increases more than  $0.5 \log_{10}$ , however other evidence of growth may be significant. Please perform the test using the storage conditions (temperature and duration) and diluents specified in product labeling. Please provide justification for the selected test conditions and/or diluents as necessary. Periodic intermediate sample times are recommended, as well as extended sample time points demonstrating that the stored product and the diluted product does not support microbial growth for at least the maximum storage periods under the specified storage conditions. Challenge organisms may include strains described in USP <51> plus typical skin flora or species associated with nosocomial infection, or psychrophilic organisms. Please provide a positive control that demonstrates the viability of the organisms over the duration of the test period.

If you have any questions, please contact me, Rabiya Laiq, Pharm.D., Regulatory Business Process Manager, at (240) 402-6153. Please respond by August 7, 2015.

Sincerely,

*{See appended electronic signature page}*

Xiao-Hong Chen, Ph.D.  
Acting Quality Assessment Lead, Branch II  
Office of New Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Xiaohong  
Chen -A

Digitally signed by Xiaohong Chen -A  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=Xiaohong Chen  
-A,  
0.9.2342.19200300.100.1.1=1300133168  
Date: 2015.07.09 14:45:50 -04'00'



NDA 205934

**FILING COMMUNICATION -  
FILING REVIEW ISSUES IDENTIFIED**

Teikoku Pharma USA, Inc.  
Attention: S. Yolanda Dickerson, M.S., RAC  
1718 Ringwood Avenue  
San Jose, CA 95131-1711

Dear Ms. Dickerson:

Please refer to your New Drug Application dated February 26, 2015, received February 26, 2015, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Docetaxel Injection [REDACTED]<sup>(b)(4)</sup>, Non-Alcohol Formula, 20 mg/mL, 80 mg/4 mL, 160 mg/8 mL.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date we received your application. The review classification for this application is **Standard**. Therefore, the user fee goal date is December 26, 2015.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by October 23, 2015.

We request that you submit the following information:

1. Indicate that the vials used for the container/closure integrity validation study have the same internal neck size specifications as the vials used for production and that the stoppers used for the study are identical to the stoppers used for routine production.

2. [REDACTED]

(b)(4)

3. [REDACTED] (b)(4)
4. With regard to [REDACTED] (b)(4):
- Please indicate the production parameters of temperature and time for components which come in direct contact with the drug product and include the utensils [REDACTED] (b)(4) and vessel assembly and ancillary parts [REDACTED] (b)(4)
  - The data summaries provided indicate that the acceptance criterion of a temperature [REDACTED] (b)(4)
5. Provide complete BI information (organism, manufacturer, lot, D-value, expiry, population, and indication if the population was confirmed) for the HP/BI studies from 2012 and 2013. Please provide the results for the positive control BIs.
6. [REDACTED] (b)(4)
- the dose setting data are several years old, please provide recent dose audit data and bioburden monitoring data as well. Alternatively, if this information is located within a DMF(s) then provide a Letter of Authorization granting access to the DMF(s) that provides validation results for the [REDACTED] (b)(4)
7. Provide complete endotoxin indicator (EI) information (supplier, endotoxin species, lot number and expiry) for the [REDACTED] (b)(4) studies performed in 2012-2013 in the [REDACTED] (b)(4)
8. In regard to media fill process simulations performed using the [REDACTED] (b)(4)
- Provide a comparison of media fill filling speeds to the filling speed used for commercial production.
  - Provide results for environmental monitoring conducted during media fill runs from 2012-2014.
  - State how decisions are made regarding hold/disposition/release of potentially affected product by a media fill failure and what actions are taken to requalify the filling line after a failure.
9. Based on the maximum dose provided in the proposed package insert for [REDACTED] (b)(4) and finished product release endotoxins specification of NMT 1.94 USP EU/mg, the endotoxins exposure [REDACTED] (b)(4)

(b)  
(4) recommended by USP <85>. Revise the endotoxins specification for release and stability and please provide revised inhibition/enhancement testing, as appropriate. Also provide method suitability validation data for at least three lots of the drug product.

10. Microbiological studies in support of the storage time for the diluted drug product (as stated in the proposed drug product package insert) have not been provided. Provide a risk assessment summarizing studies that demonstrate adventitious microbial contamination does not grow under the specified storage conditions (i.e., 24 hours at 2- 25<sup>0</sup>C after dilution in 0.9% Sodium Chloride for Injection or 5% Dextrose). Reference is made to Guidance for Industry: ICH Q8 Pharmaceutical Development, Section II.E and Guidance for Industry: ICH Q1A(R2) Stability Testing of New Drug Substances and Products, Section 2.2.7. Include a description of the test methods and results of studies that are designed using a minimum countable inoculum ( $\leq 100$  CFU/mL) to simulate potential microbial contamination that may occur during storage of the drug product vials or during product dilution. It is generally accepted that growth is evident when the population increases more than 0.5 log<sub>10</sub>, however other evidence of growth may be significant. Perform the test using the storage conditions (temperature and duration) and diluents specified in product labeling. Provide justification for the selected test conditions and/or diluents as necessary. Periodic intermediate sample times are recommended, as well as extended sample time points demonstrating that the stored product and the diluted product does not support microbial growth for at least the maximum storage periods under the specified storage conditions. Challenge organisms may include strains described in USP <51> plus typical skin flora or species associated with nosocomial infection, or psychrophilic organisms. Provide a positive control that demonstrates the viability of the organisms over the duration of the test period.
11. Per 21 CFR §314.54(a)(1)(i), the submission should contain the proposed or actual master production record, including a description of the equipment to be used for the manufacture of a commercial lot of the drug product. We note that your submission contains the completed Exhibit batch records for each presentation. Also provide the proposed or actual master production records to facilitate our review.

### **PRESCRIBING INFORMATION**

Your proposed prescribing information (PI) must conform to the content and format regulations found at 21 [CFR 201.56\(a\) and \(d\)](#) and [201.57](#). As you develop your proposed PI, we encourage you to review the labeling review resources on the [PLR Requirements for Prescribing Information](#) website including:

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products
- Regulations and related guidance documents
- A sample tool illustrating the format for Highlights and Contents
- The Selected Requirements for Prescribing Information (SRPI) – a checklist of 42 important format items from labeling regulations and guidances, and
- FDA’s established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading.

During our preliminary review of your submitted labeling, we have identified the following labeling issues and have the following labeling comments or questions:

Under HIGHLIGHTS section:

1. Highlights (HL) and Table of Content (TOC) are on two different pages. Insert a horizontal line on the second page before the TOC.
2. Please move " Initial U.S. Approval: 1996" to a new line.
3. Under HL limitaion statement, change the drug product name to UPPER CASE letters.
4. Under Adverse reactions, add the manufacturer's phone number before final printing.
5. Under revision date, add the word "Revised" before the date.

Under Contents: Table of Contents (TOC) section:

1. Please bold all section headings in the TOC.

Under Full Prescribing information (FPI) section:

1. Under adverse reactions, the following verbatim statement should precede the presentation of Adverse reactions, please add:  
“Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.”

We request that you resubmit labeling (in Microsoft Word format) that addresses these issues by June 1, 2015. The resubmitted labeling will be used for further labeling discussions. Use the SRPI checklist to correct any formatting errors to ensure conformance with the format items in regulations and guidances.

At the end of labeling discussions, use the SRPI checklist to ensure that the PI conforms with format items in regulations and guidances.

Please respond only to the above requests for information. While we anticipate that any response submitted in a timely manner will be reviewed during this review cycle, such review decisions will be made on a case-by-case basis at the time of receipt of the submission.

## **PROMOTIONAL MATERIAL**

You may request advisory comments on proposed introductory advertising and promotional labeling. Please submit, in triplicate, a detailed cover letter requesting advisory comments (list each proposed promotional piece in the cover letter along with the material type and material identification code, if applicable), the proposed promotional materials in draft or mock-up form with annotated references, and the proposed package insert (PI), and patient PI Submit consumer-directed, professional-directed, and television advertisement materials separately and send each submission to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion (OPDP)  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Do not submit launch materials until you have received our proposed revisions to the package insert (PI), and patient PI, and you believe the labeling is close to the final version.

For more information regarding OPDP submissions, please see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>. If you have any questions, call OPDP at 301-796-1200.

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

If you have any questions, call Sakar Wahby, Regulatory Project Manager, at (240) 402-5364 or email me at [sakar.wahby@fda.hhs.gov](mailto:sakar.wahby@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Amna Ibrahim, MD  
Deputy Division Director  
Division of Oncology Products 1  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

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/s/  
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AMNA IBRAHIM  
05/11/2015

**REQUEST FOR OPDP (previously DDMAC) LABELING REVIEW  
CONSULTATION**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

**\*\*Please send immediately following the Filing/Planning meeting\*\***

TO:  
**CDER-OPDP-RPM**

FROM: (Name/Title, Office/Division/Phone number of requestor)  
Sakar Wahby, PharmD  
Regulatory Project Manager  
OND/OHOP/DOP1  
Phone: 240-402-5364

REQUEST DATE:  
March 19, 2015

IND NO.

NDA/BLA NO.  
NDA 205934

TYPE OF DOCUMENTS  
(PLEASE CHECK OFF BELOW)  
NEW NDA Application

NAME OF DRUG:  
Docetaxel Injection (b)(4), Non-  
Alcohol Formula

PRIORITY CONSIDERATION:  
Standard review

CLASSIFICATION OF DRUG  
Oncology

DESIRED COMPLETION DATE  
(Generally 1 week before the wrap-up meeting)  
TBD

NAME OF FIRM:  
Teikoku Pharma USA, Inc.

PDUFA Date: December 26, 2015

**TYPE OF LABEL TO REVIEW**

**TYPE OF LABELING:**

(Check all that apply)

- PACKAGE INSERT (PI)
- PATIENT PACKAGE INSERT (PPI)
- CARTON/CONTAINER LABELING
- MEDICATION GUIDE
- INSTRUCTIONS FOR USE(IFU)

**TYPE OF APPLICATION/SUBMISSION**

- ORIGINAL NDA/BLA
- IND
- EFFICACY SUPPLEMENT
- SAFETY SUPPLEMENT
- LABELING SUPPLEMENT
- PLR CONVERSION

**REASON FOR LABELING CONSULT**

- INITIAL PROPOSED LABELING
- LABELING REVISION

**For OSE USE ONLY**

- REMS

**EDR link to submission:**

EDR Location: <\\CDSESUB1\evsprod\NDA205934\205934.enx>

**Please Note: There is no need to send labeling at this time. OPDP reviews substantially complete labeling, which has already been marked up by the CDER Review Team. After the disciplines have completed their sections of the labeling, a full review team labeling meeting can be held to go over all of the revisions. Within a week after this meeting, "substantially complete" labeling should be sent to OPDP. Once the substantially complete labeling is received, OPDP will complete its review within 14 calendar days.**

**OSE/DRISK ONLY: For REMS consults to OPDP, send a word copy of all REMS materials and the most recent labeling to CDER DDMAC RPM. List out all materials included in the consult, broken down by audience (consumer vs provider), in the comments section below.**

**COMMENTS/SPECIAL INSTRUCTIONS: The purpose of this consult is to request review of labeling for this alcohol-free 505b2 NDA.**

Filing Meeting: April 22, 2015  
Mid-Cycle Meeting: TBS  
Labeling Meetings: TBS  
Wrap-Up Meeting: PDUFA Date: December, 26, 2015; Target Action Date: December, 14, 2015

SIGNATURE OF REQUESTER  
Sakar Wahby

SIGNATURE OF RECEIVER

METHOD OF DELIVERY (Check one)

eMAIL

HAND

APPEARS THIS WAY ON ORIGINAL

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/s/  
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SAKAR M WAHBY  
03/25/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		<b>REQUEST FOR PATIENT LABELING REVIEW CONSULTATION</b>	
TO: <b>CDER-DMPP-PatientLabelingTeam</b>		FROM: (Name/Title, Office/Division/Phone number of requestor) Sakar Wahby, PharmD Regulatory Project Manager OND/OHOP/DOP1 Phone: 240-402-5364	
REQUEST DATE: March 19, 2015	NDA/BLA NO.: NDA 205934	TYPE OF DOCUMENTS: NEW NDA Application	
NAME OF DRUG: Docetaxel Injection (b)(4), Non-Alcohol Formula	PRIORITY CONSIDERATION: Standard review	CLASSIFICATION OF DRUG: Oncology	DESIRED COMPLETION DATE (Generally 2 Weeks after receiving substantially complete labeling) TBD
SPONSOR: Teikoku Pharma USA, Inc.		PDUFA Date: December 26, 2015	
<b>TYPE OF LABEL TO REVIEW</b>			
<b>TYPE OF LABELING:</b> (Check all that apply) <input checked="" type="checkbox"/> PATIENT PACKAGE INSERT (PPI) <input type="checkbox"/> MEDICATION GUIDE <input type="checkbox"/> INSTRUCTIONS FOR USE(IFU)		<b>TYPE OF APPLICATION/SUBMISSION</b> <input checked="" type="checkbox"/> ORIGINAL NDA/BLA <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> SAFETY SUPPLEMENT <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> MANUFACTURING (CMC) SUPPLEMENT <input type="checkbox"/> PLR CONVERSION	
		<b>REASON FOR LABELING CONSULT</b> <input checked="" type="checkbox"/> INITIAL PROPOSED LABELING <input type="checkbox"/> LABELING REVISION	
<b>EDR link to submission:</b>			
EDR Location: <a href="\\CDSESUB1\evsprod\NDA205934\205934.enx">\\CDSESUB1\evsprod\NDA205934\205934.enx</a>			
<b>Please Note: DMPP uses substantially complete labeling, which has already been marked up by the CDER Review Team, when reviewing MedGuides, IFUs, and PPIs. Once the substantially complete labeling is received, DMPP will complete its review within 14 calendar days. Please provide a copy of the sponsor's proposed patient labeling in Word format.</b>			
<b>COMMENTS/SPECIAL INSTRUCTIONS: The purpose of this consult is to request review of the PPI for this new pending 505b2 NDA.</b>  Filing/Planning Meeting: April 22, 2015  Mid-Cycle Meeting: TBS  Labeling Meetings: TBS  Wrap-Up Meeting:			
SIGNATURE OF REQUESTER Sakar Wahby			
SIGNATURE OF RECEIVER		METHOD OF DELIVERY (Check one) <input type="checkbox"/> eMAIL (BLAs Only) <input checked="" type="checkbox"/> DARRTS	

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SAKAR M WAHBY  
03/25/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		<b>REQUEST FOR CONSULTATION</b>			
TO (Office/Division): OSE/DMEPA			FROM (Name, Office/Division, and Phone Number of Requestor): Sakar Wahby, PharmD Regulatory Project Manager OND/OHOP/DOP1 Phone: 240-402-5364		
DATE March 19, 2015	IND NO.	NDA NO. NDA 205934	TYPE OF DOCUMENT NEW NDA Application	DATE OF DOCUMENT February, 26, 2015	
NAME OF DRUG Docetaxel Injection (b)(4), Non-Alcohol Formula		PRIORITY CONSIDERATION Standard review	CLASSIFICATION OF DRUG Oncology	DESIRED COMPLETION DATE TBD	
NAME OF FIRM: Teikoku Pharma USA, Inc.					
<b>REASON FOR REQUEST</b>					
<b>I. GENERAL</b>					
<input type="checkbox"/> NEW PROTOCO <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> NEW CORRESPONDENCE <input type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> ADVERSE REACTION REPORT <input type="checkbox"/> MANUFACTURING CHANGE / ADDITION <input type="checkbox"/> MEETING PLANNED BY <input type="checkbox"/> PRE-NDA MEETING <input type="checkbox"/> END-OF-PHASE 2a MEETING <input type="checkbox"/> END-OF-PHASE 2 MEETING <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SAFETY / EFFICACY <input type="checkbox"/> CONTROL SUPPLEMENT <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> LABELING REVISION <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> FORMULATIVE REVIEW <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): New NDA					
<b>II. BIOMETRICS</b>					
<input type="checkbox"/> PRIORITY P NDA REVIEW <input type="checkbox"/> END-OF-PHASE 2 MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER (SPECIFY BELOW):			<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):		
<b>III. BIOPHARMACEUTICS</b>					
<input type="checkbox"/> DISSOLUTION <input type="checkbox"/> BIOAVAILABILTY STUDIES <input type="checkbox"/> PHASE 4 STUDIES			<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL - BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST		
<b>IV. DRUG SAFETY</b>					
<input type="checkbox"/> PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL <input type="checkbox"/> DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP			<input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE <input type="checkbox"/> POISON RISK ANALYSIS		
<b>V. SCIENTIFIC INVESTIGATIONS</b>					
<input type="checkbox"/> CLINICAL			<input type="checkbox"/> NONCLINICAL		
<b>COMMENTS / SPECIAL INSTRUCTIONS:</b> The purpose of this consult is to request review of the proposed labeling for this new alcohol-free 505b2 NDA. Mid-Cycle meeting: TBS Labeling meeting: TBS PDUFA Date: December, 26, 2015 Target Action Date: December, 14, 2015					
SIGNATURE OF REQUESTOR Sakar Wahby			METHOD OF DELIVERY (Check all that apply) <input checked="" type="checkbox"/> DARRTS <input type="checkbox"/> EMAIL <input type="checkbox"/> MAIL <input type="checkbox"/> HAND		
PRINTED NAME AND SIGNATURE OF RECEIVER			PRINTED NAME AND SIGNATURE OF DELIVERER		

06/18/2013

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/s/  
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SAKAR M WAHBY  
03/25/2015



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research

Memorandum

Date: March 17, 2015

From: Frances Fahnbulleh, OSE Project Manager, FDA

Subject: NDA 205934 Docetaxel Injection (b)(4),  
Non-Alcohol Formula

Dear Ms. Dickerson,

Reference is made to your NDA 205934 submitted on February 26, 2015. Reference is also made to your submission stating your proposed proprietary name as Docetaxel Injection (b)(4) Non-Alcoholic Formula.

Please note that your submission does not constitute a complete request for a Proprietary Name Review. You should submit a Request for PNR following the instructions in the *Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names* (link below).

Include the statement "**REQUEST FOR PROPRIETARY NAME REVIEW**" in bold capital letters, at the top of your cover letter and on the first page of the main submission document (please refer to the complete submission guidance link below). The review of this name will be initiated when the new submission is received.

If you require additional information on developing proprietary names for drugs or proposing alternative proprietary names for consideration, we refer you to the following:

- Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names  
(<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf>)
- Draft Guidance for Industry Best Practices in Developing Proprietary Names for Drugs,  
(<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM398997.pdf>)
- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017,  
(<http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>)

Thanks,  
Frances Fahnbulleh  
Regulatory Health Project Manager  
Office of Surveillance and Epidemiology,  
CDER, FDA

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/s/  
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FRANCES G FAHNBULLEH  
03/17/2015



NDA 205934

**NDA ACKNOWLEDGMENT**

Teikoku Pharma USA, Inc.  
Attention: S. Yolanda Dickerson, M.S., RAC  
1718 Ringwood Avenue  
San Jose, CA 95131-1711

Dear Ms. Dickerson:

We have received your New Drug Application (NDA) submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Docetaxel Injection (b)(4), Non-Alcohol formula, 20 mg/mL, 80 mg/4 mL, 160 mg/8 mL

Date of Application: February 26, 2015

Date of Receipt: February 26, 2015

Our Reference Number: NDA 205934

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on April 27, 2015, in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

You are also responsible for complying with the applicable provisions of sections 402(i) and 402(j) of the Public Health Service Act (PHS Act) [42 USC §§ 282 (i) and (j)], which was amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No. 110-85, 121 Stat. 904).

The NDA number provided above should be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Oncology Products 1  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Secure email between CDER and applicants is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with the FDA and would like to set it up, send an email request to [SecureEmail@fda.hhs.gov](mailto:SecureEmail@fda.hhs.gov). Please note that secure email may not be used for formal regulatory submissions to applications.

If you have any questions, call me at (240) 402-5364 or email me at [sakar.wahby@fda.hhs.gov](mailto:sakar.wahby@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Sakar Wahby, PharmD  
Regulatory Project Manager  
Division of Oncology Products 1  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

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SAKAR M WAHBY  
03/13/2015