CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201195Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

EXCLUSIVITY SUMMARY

NDA # 201195 SUPPL # N/A HFD # 150

Trade Name N/A

Generic Name Docetaxel Injection

Applicant Name Accord Healthcare, Inc.

Approval Date, If Known June 10, 2011

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)

c) 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:

d) Did the applicant request exclusivity?

YES ☐ NO ☒

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

e) 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?

Pediatric exclusivity granted for the RLD, NDA 020449, Taxotere (docetaxel) Injection Concentrate 20 mg and 80 mg.

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#	022534	DOCEFREZ (docetaxel) for Injection, 20 mg/vial and 80 mg/vial.
NDA#	022234	Docetaxel Injection, 20 mg/2 mL single-dose vial, 80 mg/8 mL multi-dose vial, and 160 mg/16 mL multi-dose vial.
NDA#	020449	Taxotere (docetaxel) Injection Concentrate, 20 mg and 80 mg

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 !
!
IND # YES ☐ ! NO ☐
! Explain:

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1 !
!
YES ☐ ! NO ☐

Explain:	! Explain:
Investigation #2	!
	!
YES ☐	! NO ☐
Explain:	! Explain:

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES ☐ NO ☐

If yes, explain:

Name of person completing form: Kim J. Robertson
Title: Regulatory Health Project Manager
Date: June 3, 2011

Name of Office/Division Director signing form: Anthony Murgo, MD, MS, FACP
Title: Acting Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KIM J ROBERTSON
06/06/2011
Exclusivity Summary N201195; Docetaxel Inj. Accord Healthcare

ANTHONY J MURGO
06/08/2011

PEDIATRIC PAGE
(Complete for all filed original applications and efficacy supplements)

.DA/BLA#: 201195 Supplement Number: N/A NDA Supplement Type (e.g. SE5): N/A

Division Name: Drug Oncology Products PDUFA Goal Date: June 10, 2011 Stamp Date: 12/10/2010

Proprietary Name: N/A

Established/Generic Name: Docetaxel

Dosage Form: Injection

Applicant/Sponsor: Accord Healthcare

Indication(s) *previously approved* (please complete this question for supplements and Type 6 NDAs only):
(1)
(2)
(3)
(4)

Pediatric use for each pediatric subpopulation must be addressed for each indication covered by current application under review. A Pediatric Page must be completed for each indication.

Number of indications for this pending application(s): 5
(Attach a completed Pediatric Page for each indication in current application.)

Indication: Locally advanced or metastatic breast cancer; Locally advanced or metastatic non-small cell lung cancer; Hormone refractory prostate cancer; Gastric adenocarcinoma; Squamos cell carcinoma of the head and neck.

1: Is this application in response to a PREA PMR? Yes ☐ Continue

No ☒ Please proceed to Question 2.

If Yes, NDA/BLA#: _____ Supplement #:_____ PMR #:_____

Does the division agree that this is a complete response to the PMR?

☐ Yes. Please proceed to Section D.

☐ No. Please proceed to Question 2 and complete the Pediatric Page, as applicable.

Q2: Does this application provide for (If yes, please check all categories that apply and proceed to the next question):

(a) NEW ☐ active ingredient(s) (includes new combination); ☐ indication(s); ☒ dosage form; ☐ dosing regimen; or ☐ route of administration?*

(b) ☐ No. PREA does not apply. **Skip to signature block.**

**** Note for CDER: SE5, SE6, and SE7 submissions may also trigger PREA.***

Q3: Does this indication have orphan designation?

☐ Yes. PREA does not apply. **Skip to signature block.**

☒ No. Please proceed to the next question.

Q4: Is there a full waiver for all pediatric age groups for this indication (check one)?

☒ Yes: (Complete Section A.)

☐ No: Please check all that apply:

- ☐ Partial Waiver for selected pediatric subpopulations (Complete Sections B)
- ☐ Deferred for some or all pediatric subpopulations (Complete Sections C)
- ☐ Completed for some or all pediatric subpopulations (Complete Sections D)
- ☐ Appropriately Labeled for some or all pediatric subpopulations (Complete Sections E)
- ☐ Extrapolation in One or More Pediatric Age Groups (Complete Section F)

(Please note that Section F may be used alone or in addition to Sections C, D, and/or E.)

Section A: Fully Waived Studies (for all pediatric age groups)

Reason(s) for full waiver: (**check, and attach a brief justification for the reason(s) selected**)

☒ Necessary studies would be impossible or highly impracticable because:

- ☒ Disease/condition does not exist in children
- ☐ Too few children with disease/condition to study
- ☐ Other (e.g., patients geographically dispersed): _____

☐ Product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients AND is not likely to be used in a substantial number of pediatric patients.

☐ Evidence strongly suggests that product would be unsafe in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)

☐ Evidence strongly suggests that product would be ineffective in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)

☐ Evidence strongly suggests that product would be ineffective and unsafe in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)

☐ Justification attached.

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please complete another Pediatric Page for each indication. Otherwise, this Pediatric Page is complete and should be signed.

Section B: Partially Waived Studies (for selected pediatric subpopulations)

Check subpopulation(s) and reason for which studies are being partially waived (fill in applicable criteria below):

Note: If Neonate includes premature infants, list minimum and maximum age in "gestational age" (in weeks).

				Reason (see below for further detail):			
		minimum	maximum	Not feasible[#]	Not meaningful therapeutic benefit*	Ineffective or unsafe[†]	Formulation failed[Δ]
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐

e the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

Reason(s) for partial waiver (**check reason** corresponding to the category checked above, and **attach a brief**

justification):

Not feasible:

☐ Necessary studies would be impossible or highly impracticable because:

☐ Disease/condition does not exist in children

☐ Too few children with disease/condition to study

☐ Other (e.g., patients geographically dispersed): _____

* Not meaningful therapeutic benefit:

☐ Product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this/these pediatric subpopulation(s) AND is not likely to be used in a substantial number of pediatric patients in this/these pediatric subpopulation(s).

† Ineffective or unsafe:

☐ Evidence strongly suggests that product would be unsafe in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)

☐ Evidence strongly suggests that product would be ineffective in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)

☐ Evidence strongly suggests that product would be ineffective and unsafe in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)

Δ Formulation failed:

☐ Applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for this/these pediatric subpopulation(s) have failed. (*Note: A partial waiver on this ground may only cover the pediatric subpopulation(s) requiring that formulation. An applicant seeking a partial waiver on this ground must submit documentation detailing why a pediatric formulation cannot be developed. This submission will be posted on FDA's website if waiver is granted.)*

☐ Justification attached.

For those pediatric subpopulations for which studies have not been waived, there must be (1) corresponding study plans that have been deferred (if so, proceed to Sections C and complete the PeRC Pediatric Plan Template); (2) submitted studies that have been completed (if so, proceed to Section D and complete the PeRC Pediatric Assessment form); (3) additional studies in other age groups that are not needed because the drug is appropriately labeled in one or more pediatric subpopulations (if so, proceed to Section E); and/or (4) additional studies in other age groups that are not needed because efficacy is being extrapolated (if so, proceed to Section F). Note that more than one of these options may apply for this indication to cover all of the pediatric subpopulations.

Section C: Deferred Studies (for selected pediatric subpopulations).

heck pediatric subpopulation(s) for which pediatric studies are being deferred (and fill in applicable reason elow):

Deferrals (for each or all age groups):				**Reason for Deferral**			**Applicant Certification** †
Population		minimum	maximum	Ready for Approval in Adults	Need Additional Adult Safety or Efficacy Data	Other Appropriate Reason (specify below)*	Received
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	All Pediatric Populations	0 yr. 0 mo.	16 yr. 11 mo.	☐	☐	☐	☐
	Date studies are due (mm/dd/yy): _____						

re the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

* Other Reason: _____

† Note: Studies may only be deferred if an applicant submits a certification of grounds for deferring the studies, a description of the planned or ongoing studies, evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time, and a timeline for the completion of the studies. If studies are deferred, on an annual basis applicant must submit information detailing the progress made in conducting the studies or, if no progress has been made, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time. This requirement should be communicated to the applicant in an appropriate manner (e.g., in an approval letter that specifies a required study as a post-marketing commitment.)

If all of the pediatric subpopulations have been covered through partial waivers and deferrals, Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section D: Completed Studies (for some or all pediatric subpopulations).

. ediatric subpopulation(s) in which studies have been completed (check below):

	Population	minimum	maximum	PeRC Pediatric Assessment form attached?.	
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.	Yes ☐	No ☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	Yes ☐	No ☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	Yes ☐	No ☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	Yes ☐	No ☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	Yes ☐	No ☐
☐	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.	Yes ☐	No ☐

Are the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

Note: If there are no further pediatric subpopulations to cover based on partial waivers, deferrals and/or completed studies, Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section E: Drug Appropriately Labeled (for some or all pediatric subpopulations):

ɗditional pediatric studies are not necessary in the following pediatric subpopulation(s) because product is appropriately labeled for the indication being reviewed:

Population		minimum	maximum
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.
☐	Other	__ yr. __ mo.	__ yr. __ mo.
☐	Other	__ yr. __ mo.	__ yr. __ mo.
☐	Other	__ yr. __ mo.	__ yr. __ mo.
☐	Other	__ yr. __ mo.	__ yr. __ mo.
☐	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.

Are the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

If all pediatric subpopulations have been covered based on partial waivers, deferrals, completed studies, and/or existing appropriate labeling, this Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section F: Extrapolation from Other Adult and/or Pediatric Studies (for deferred and/or completed studies)

Note: Pediatric efficacy can be extrapolated from adequate and well-controlled studies in adults and/or other ɘdiatric subpopulations if (and only if) (1) the course of the disease/condition AND (2) the effects of the product are sufficiently similar between the reference population and the pediatric subpopulation for which information will be extrapolated. Extrapolation of efficacy from studies in adults and/or other children usually requires supplementation with other information obtained from the target pediatric subpopulation, such as

pharmacokinetic and safety studies. Under the statute, safety cannot be extrapolated.

ɔdiatric studies are not necessary in the following pediatric subpopulation(s) because efficacy can be extrapolated from adequate and well-controlled studies in adults and/or other pediatric subpopulations:

Population		minimum	maximum	Extrapolated from:	
				Adult Studies?	Other Pediatric Studies?
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐
☐	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.	☐	☐

Are the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

Note: If extrapolating data from either adult or pediatric studies, a description of the scientific data supporting the extrapolation must be included in any pertinent reviews for the application.

If there are additional indications, please complete the attachment for each one of those indications. Otherwise, this Pediatric Page is complete and should be signed and entered into DFS or DARRTS as ppropriate after clearance by PeRC.

This page was completed by:

{See appended electronic signature page}

Kim J. Robertson Kim J. Robertson
Regulatory Project Manager

(Revised: 6/2008)

NOTE: If you have no other indications for this application, you may delete the attachments from this document.

Attachment A

(This attachment is to be completed for those applications with multiple indications only.)

Indication #2: _____

Q1: Does this indication have orphan designation?

- ☐ Yes. PREA does not apply. **Skip to signature block.**
- ☐ No. Please proceed to the next question.

Q2: Is there a full waiver for all pediatric age groups for this indication (check one)?

- ☐ Yes: (Complete Section A.)
- ☐ No: Please check all that apply:
  - ☐ Partial Waiver for selected pediatric subpopulations (Complete Sections B)
  - ☐ Deferred for some or all pediatric subpopulations (Complete Sections C)
  - ☐ Completed for some or all pediatric subpopulations (Complete Sections D)
  - ☐ Appropriately Labeled for some or all pediatric subpopulations (Complete Sections E)
  - ☐ Extrapolation in One or More Pediatric Age Groups (Complete Section F)

  (Please note that Section F may be used alone or in addition to Sections C, D, and/or E.)

Section A: Fully Waived Studies (for all pediatric age groups)

Reason(s) for full waiver: (**check, and attach a brief justification for the reason(s) selected**)

- ☐ Necessary studies would be impossible or highly impracticable because:
  - ☐ Disease/condition does not exist in children
  - ☐ Too few children with disease/condition to study
  - ☐ Other (e.g., patients geographically dispersed): _____
- ☐ Product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients AND is not likely to be used in a substantial number of pediatric patients.
- ☐ Evidence strongly suggests that product would be unsafe in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)
- ☐ Evidence strongly suggests that product would be ineffective in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)
- ☐ Evidence strongly suggests that product would be ineffective and unsafe in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)

☐ Justification attached.

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please complete another Pediatric Page for each indication. Otherwise, this Pediatric Page is complete and should be signed.

Section B: Partially Waived Studies (for selected pediatric subpopulations)

Check subpopulation(s) and reason for which studies are being partially waived (fill in applicable criteria below):

Note: If Neonate includes premature infants, list minimum and maximum age in "gestational age" (in weeks).

				Reason (see below for further detail):			
		minimum	maximum	Not feasible#	Not meaningful therapeutic benefit*	Ineffective or unsafe†	Formulation failed∆
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐

Are the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

Reason(s) for partial waiver (**check reason** corresponding to the category checked above, and **attach a brief justification**):

Not feasible:

☐ Necessary studies would be impossible or highly impracticable because:

- ☐ Disease/condition does not exist in children
- ☐ Too few children with disease/condition to study
- ☐ Other (e.g., patients geographically dispersed): _____

* Not meaningful therapeutic benefit:

☐ Product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this/these pediatric subpopulation(s) AND is not likely to be used in a substantial number of pediatric patients in this/these pediatric subpopulation(s).

† Ineffective or unsafe:

- ☐ Evidence strongly suggests that product would be unsafe in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)
- ☐ Evidence strongly suggests that product would be ineffective in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)
- ☐ Evidence strongly suggests that product would be ineffective and unsafe in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)

∆ Formulation failed:

☐ Applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for this/these pediatric subpopulation(s) have failed. (*Note: A partial waiver on this ground may only cover the pediatric subpopulation(s) requiring that formulation. An applicant seeking a partial waiver on this ground must submit documentation detailing why a pediatric formulation cannot be developed. This submission will be posted on FDA's website if waiver is granted.)*

☐ Justification attached.

For those pediatric subpopulations for which studies have not been waived, there must be (1) corresponding study plans that have been deferred (if so, proceed to Section C and complete the PeRC Pediatric Plan Template); (2) submitted studies that have been completed (if so, proceed to Section D and complete the PeRC Pediatric Assessment form); (3) additional studies in other age groups that are not needed because the drug is appropriately labeled in one or more pediatric subpopulations (if so, proceed to Section E); and/or (4) additional studies in other age groups that are not needed because efficacy is being extrapolated (if so,

proceed to Section F).. Note that more than one of these options may apply for this indication to cover all of the pediatric subpopulations.

Section C: Deferred Studies (for some or all pediatric subpopulations).

Check pediatric subpopulation(s) for which pediatric studies are being deferred (and fill in applicable reason below):

Deferrals (for each or all age groups):				**Reason for Deferral**			**Applicant Certification †**
Population		minimum	maximum	Ready for Approval in Adults	Need Additional Adult Safety or Efficacy Data	Other Appropriate Reason (specify below)*	Received
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐	☐	☐
☐	All Pediatric Populations	0 yr. 0 mo.	16 yr. 11 mo.	☐	☐	☐	☐
	Date studies are due (mm/dd/yy): _____						

Are the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

* Other Reason: _____

† Note: Studies may only be deferred if an applicant submits a certification of grounds for deferring the studies, a description of the planned or ongoing studies, evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time, and a timeline for the completion of the studies. If studies are deferred, on an annual basis applicant must submit information detailing the progress made in conducting the studies or, if no progress has been made, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time. This requirement should be communicated to the applicant in an appropriate manner (e.g., in an approval letter that specifies a required study as a post-marketing commitment.)

If all of the pediatric subpopulations have been covered through partial waivers and deferrals, Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section D: Completed Studies (for some or all pediatric subpopulations).

Pediatric subpopulation(s) in which studies have been completed (check below):

	Population	minimum	maximum	PeRC Pediatric Assessment form attached?	
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.	Yes ☐	No ☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	Yes ☐	No ☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	Yes ☐	No ☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	Yes ☐	No ☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	Yes ☐	No ☐
☐	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.	Yes ☐	No ☐

Are the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

Note: If there are no further pediatric subpopulations to cover based on partial waivers, deferrals and/or completed studies, Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section E: Drug Appropriately Labeled (for some or all pediatric subpopulations):

Additional pediatric studies are not necessary in the following pediatric subpopulation(s) because product is appropriately labeled for the indication being reviewed:

Population		minimum	maximum
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.
☐	Other	__ yr. __ mo.	__ yr. __ mo.
☐	Other	__ yr. __ mo.	__ yr. __ mo.
☐	Other	__ yr. __ mo.	__ yr. __ mo.
☐	Other	__ yr. __ mo.	__ yr. __ mo.
☐	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.

Are the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

If all pediatric subpopulations have been covered based on partial waivers, deferrals, completed studies, and/or existing appropriate labeling, this Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

ɔction F: Extrapolation from Other Adult and/or Pediatric Studies (for deferred and/or completed studies)

Note: Pediatric efficacy can be extrapolated from adequate and well-controlled studies in adults and/or other pediatric subpopulations if (and only if) (1) the course of the disease/condition AND (2) the effects of the product are sufficiently similar between the reference population and the pediatric subpopulation for which information will be extrapolated. Extrapolation of efficacy from studies in adults and/or other children usually requires supplementation with other information obtained from the target pediatric subpopulation, such as pharmacokinetic and safety studies. Under the statute, safety cannot be extrapolated.

Pediatric studies are not necessary in the following pediatric subpopulation(s) because efficacy can be extrapolated from adequate and well-controlled studies in adults and/or other pediatric subpopulations:

Population		minimum	maximum	Extrapolated from:	
				Adult Studies?	Other Pediatric Studies?
☐	Neonate	__ wk. __ mo.	__ wk. __ mo.	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐
☐	Other	__ yr. __ mo.	__ yr. __ mo.	☐	☐
☐	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.	☐	☐

Are the indicated age ranges (above) based on weight (kg)? ☐ No; ☐ Yes.

Are the indicated age ranges (above) based on Tanner Stage? ☐ No; ☐ Yes.

Note: If extrapolating data from either adult or pediatric studies, a description of the scientific data supporting the extrapolation must be included in any pertinent reviews for the application.

If there are additional indications, please copy the fields above and complete pediatric information as directed. If there are no other indications, this Pediatric Page is complete and should be entered into DFS or DARRTS as appropriate after clearance by PeRC.

This page was completed by:

{See appended electronic signature page}

Regulatory Project Manager

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT THE PEDIATRIC AND MATERNAL HEALTH STAFF at 301-796-0700

(Revised: 6/2008)

accord
healthcare inc.

1009 Slater Road,
Suite 210-B
Durham, NC 27703, USA
Tel. : 1-919-941-7878
Fax : 1-919-941-7881
Website : www.accord-healthcare.com

December 15, 2009

Certification of Compliance with Generic Drug Enforcement Act of 1992

Accord Healthcare 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 505 (b) (2) NDA for Docetaxel Injection 20 mg and 80 mg.

Yours truly,

Samir Mehta, Ph.D.
President

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]

NDA # 201195 BLA #	NDA Supplement # N/A BLA STN #	If NDA, Efficacy Supplement Type: N/A
Proprietary Name: N/A Established/Proper Name: Docetaxel Dosage Form: Injection; 20 mg and 80 mg		Applicant: Accord Healthcare Agent for Applicant (if applicable): N/A
RPM: Kim J. Robertson		Division: Drug Oncology Products

NDAs:
NDA Application Type: ☐ 505(b)(1) ☒ 505(b)(2)
Efficacy Supplement: ☐ 505(b)(1) ☐ 505(b)(2)

(A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). Consult page 1 of the 505(b)(2) Assessment or the Appendix to this Action Package Checklist.)

505(b)(2) Original NDAs and 505(b)(2) NDA supplements:
Listed drug(s) relied upon for approval (include NDA #(s) and drug name(s)):

NDA# 020449; Taxotere (docetaxel) Injection Concentrate, Intravenous Infusion 80 mg/2mL and 20 mg/0.5 mL

Provide a brief explanation of how this product is different from the listed drug.
New information consists of CMC data and impurities. Except for formulation-related sections of the label, other information in the

label is the same as that described for the reference listed drug (RLD).

If no listed drug, explain.
- ☐ This application relies on literature.
- ☐ This application relies on a final OTC monograph.
- ☐ Other (explain)

Two months prior to each action, review the information in the 505(b)(2) Assessment and submit the draft to CDER OND IO for clearance. Finalize the 505(b)(2) Assessment at the time of the approval action.

On the day of approval, check the Orange Book again for any new patents or pediatric exclusivity.

☒ No changes ☐ Updated Date of check: June 08, 2011

If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.

❖ Actions	
• Proposed action • User Fee Goal Date is June 10, 2011	☒ AP ☐ TA ☐ CR
• Previous actions *(specify type and date for each action taken)*	☐ None Complete Response; October 22, 2010

[1] The **Application Information** section is (only) a checklist. The **Contents of Action Package** section (beginning on page 5) lists the documents to be included in the Action Package.

❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received? Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain _____	☐ Received
❖ Application Characteristics [2]	

Review priority: ☒ Standard ☐ Priority
Chemical classification (new NDAs only):

☐ Fast Track
☐ Rolling Review
☐ Orphan drug designation
☐ Rx-to-OTC full switch
☐ Rx-to-OTC partial switch
☐ Direct-to-OTC

NDAs: Subpart H
☐ Accelerated approval (21 CFR 314.510)
☐ Restricted distribution (21 CFR 314.520)
Subpart I
☐ Approval based on animal studies

BLAs: Subpart E
☐ Accelerated approval (21 CFR 601.41)
☐ Restricted distribution (21 CFR 601.42)
Subpart H
☐ Approval based on animal studies

☐ Submitted in response to a PMR
☐ Submitted in response to a PMC
☐ Submitted in response to a Pediatric Written Request

REMS: ☐ MedGuide
☐ Communication Plan
☐ ETASU
☐ REMS not required

Comments:

❖ BLAs only: Ensure *RMS-BLA Product Information Sheet for TBP* and *RMS-BLA Facility Information Sheet for TBP* have been completed and forwarded to OPI/OBI/DRM (Vicky Carter)	☐ Yes, dates
❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 *(approvals only)*	☐ Yes ☐ No
❖ Public communications *(approvals only)*	
• Office of Executive Programs (OEP) liaison has been notified of action	☐ Yes ☒ No
• Press Office notified of action (by OEP)	☐ Yes ☒ No
• Indicate what types (if any) of information dissemination are anticipated	☒ None ☐ HHS Press Release ☐ FDA Talk Paper ☐ CDER Q&As ☐ Other

[2] Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

❖ Exclusivity	
• Is approval of this application blocked by any type of exclusivity?	☐ No ☒ Yes
• NDAs and BLAs: Is there existing orphan drug exclusivity for the "same" drug or biologic for the proposed indication(s)? *Refer to 21 CFR 316.3(b)(13) for the definition of "same drug" for an orphan drug (i.e., active moiety). This definition is NOT the same as that used for NDA chemical classification.*	☒ No ☐ Yes If, yes, NDA/BLA # and date exclusivity expires:
• (b)(2) NDAs only: Is there remaining 5-year exclusivity that would bar effective approval of a 505(b)(2) application)? *(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)*	☒ No ☐ Yes If yes, NDA # and date exclusivity expires:
• (b)(2) NDAs only: Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? *(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)*	☒ No ☐ Yes If yes, NDA # and date exclusivity expires:
• (b)(2) NDAs only: Is there remaining 6-month pediatric exclusivity that would bar effective approval of a 505(b)(2) application? *(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)*	☐ No ☒ Yes If yes, NDA # 020449 and date exclusivity expires: November 13, 2013
• NDAs only: Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? *(Note that, even if the 10-year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)*	☒ No ☐ Yes If yes, NDA # and date 10-year limitation expires:
❖ Patent Information (NDAs only)	
• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. If the drug is an old antibiotic, skip the Patent Certification questions.	☒ Verified ☐ Not applicable because drug is an old antibiotic.
• Patent Certification [505(b)(2) applications]: Verify that a certification was submitted for each patent for the listed drug(s) in the Orange Book and identify the type of certification submitted for each patent.	21 CFR 314.50(i)(1)(*i*)(A) ☒ Verified 21 CFR 314.50(i)(1) ☐ (ii) ☒ (iii)
• [505(b)(2) applications] If the application includes a **paragraph III** certification, it cannot be approved until the date that the patent to which the certification pertains expires (but may be tentatively approved if it is otherwise ready for approval).	☐ No paragraph III certification Date patent will expire 4814470 Expiry date(s): May 14, 2010 4814470*PED Nov. 14, 2010 5698582 July 3, 2012 5698582*PED Jan. 3, 2013 5714512 July 3, 2012 5714512*PED Jan. 3, 2013 5750561 July 3, 2012 5750561*PED Jan. 3, 2013
• [505(b)(2) applications] For **each paragraph IV** certification, verify that the applicant notified the NDA holder and patent owner(s) of its certification that the patent(s) is invalid, unenforceable, or will not be infringed (review documentation of notification by applicant and documentation of receipt of notice by patent owner and NDA holder). *(If the application does not include*	☐ N/A (no paragraph IV certification) ☒ Verified

*any paragraph IV certifications, mark "N/A" and skip to the next section below (*Summary Reviews*)).*

- [505(b)(2) applications] For **each paragraph IV** certification, based on the questions below, determine whether a 30-month stay of approval is in effect due to patent infringement litigation.

  Answer the following questions for **each** paragraph IV certification:

  (1) Have 45 days passed since the patent owner's receipt of the applicant's notice of certification? ☒ Yes ☐ No

  (Note: The date that the patent owner received the applicant's notice of certification can be determined by checking the application. The applicant is required to amend its 505(b)(2) application to include documentation of this date (e.g., copy of return receipt or letter from recipient acknowledging its receipt of the notice) (see 21 CFR 314.52(e))).

  *If "**Yes**," skip to question (4) below. If "**No**," continue with question (2).*

  (2) Has the patent owner (or NDA holder, if it is an exclusive patent licensee) submitted a written waiver of its right to file a legal action for patent infringement after receiving the applicant's notice of certification, as provided for by 21 CFR 314.107(f)(3)? ☐ Yes ☐ No

  *If "**Yes,**" there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip the rest of the patent questions.*

  *If "**No**," continue with question (3).*

  (3) Has the patent owner, its representative, or the exclusive patent licensee filed a lawsuit for patent infringement against the applicant? ☐ Yes ☐ No

  (Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2))).

  *If "**No**," the patent owner (or NDA holder, if it is an exclusive patent licensee) has until the expiration of the 45-day period described in question (1) to waive its right to bring a patent infringement action or to bring such an action. After the 45-day period expires, continue with question (4) below.*

  (4) Did the patent owner (or NDA holder, if it is an exclusive patent licensee) submit a written waiver of its right to file a legal action for patent infringement within the 45-day period described in question (1), as provided for by 21 CFR 314.107(f)(3)? ☐ Yes ☒ No

  *If "**Yes,**" there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other*

*paragraph IV certifications, skip to the next section below (*Summary Reviews*).* *If "**No**," continue with question (5).*	
(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the (b)(2) applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification? (Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)). If no written notice appears in the NDA file, confirm with the applicant whether a lawsuit was commenced within the 45-day period). *If "**No**," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (*Summary Reviews*).* *If "**Yes**," a stay of approval may be in effect. To determine if a 30-month stay is in effect, consult with the OND ADRA and attach a summary of the response.*	☒ Yes ☐ No

CONTENTS OF ACTION PACKAGE	
❖ Copy of this Action Package Checklist[3]	June 2, 2011
Officer/Employee List	
❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list *(approvals only)*	☒ Included
Documentation of consent/non-consent by officers/employees	☒ Included
Action Letters	
❖ Copies of all action letters *(including approval letter with final labeling)*	Action(s) and date(s) October 22, 2010; June 9, 2011
Labeling	
❖ Package Insert *(write submission/communication date at upper right of first page of PI)*	
• Most recent draft labeling. If it is division-proposed labeling, it should be in track-changes format.	
• Original applicant-proposed labeling	December 10, 2009; December 10, 2010
• Example of class labeling, if applicable	

[3] Fill in blanks with dates of reviews, letters, etc.

❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling *(write submission/communication date at upper right of first page of each piece)*	☐ Medication Guide ☐ Patient Package Insert ☐ Instructions for Use ☐ Device Labeling ☒ None
• Most-recent draft labeling. If it is division-proposed labeling, it should be in track-changes format.	
• Original applicant-proposed labeling	
• Example of class labeling, if applicable	
❖ Labels (**full color** carton and immediate-container labels) *(write submission/communication date on upper right of first page of each submission)*	
• Most-recent draft labeling	December 22, 2009; May 31, 2011
❖ Proprietary Name • Acceptability/non-acceptability letter(s) *(indicate date(s))* • Review(s) *(indicate date(s))*	N/A
❖ Labeling reviews *(indicate dates of reviews and meetings)*	☐ RPM ☒ DMEPA September 28, 2010; April 6, 2011; June 3, 2011 ☒ DRISK July 9, 2010 ☒ DDMAC April 22, 2011 ☐ SEALD ☐ CSS ☐ Other reviews
Administrative / Regulatory Documents	
❖ Administrative Reviews *(e.g., RPM Filing Review[4]/Memo of Filing Meeting) (indicate date of each review)* ❖ All NDA (b)(2) Actions: Date each action cleared by (b)(2) Clearance Cmte ❖ NDA (b)(2) Approvals Only: 505(b)(2) Assessment *(indicate date)*	October 18, 2010 ☐ Not a (b)(2) May 9, 2011; June 6, 2011 ☐ Not a (b)(2) June 6, 2011
❖ NDAs only: Exclusivity Summary *(signed by Division Director)*	☒ Included
❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm	
• Applicant is on the AIP	☐ Yes ☒ No
• This application is on the AIP o If yes, Center Director's Exception for Review memo *(indicate date)* o If yes, OC clearance for approval *(indicate date of clearance communication)*	☐ Yes ☒ No ☐ Not an AP action
❖ Pediatrics *(approvals only)* • Date reviewed by PeRC September 8, 2010 If PeRC review not necessary, explain: _____ • Pediatric Page/Record *(approvals only, must be reviewed by PERC before finalized)*	☒ Included
❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent *(include certification)*	☒ Verified, statement is acceptable

[4] Filing reviews for scientific disciplines should be filed behind the respective discipline tab.

❖ Outgoing communications *(letters (except action letters), emails, faxes, telecons)*	Refer to Outgoing Communications tab in Action Package
❖ Internal memoranda, telecons, etc.	April 11, 2011(actual meeting date) Memo signed in DARRTS June 7, 2011
❖ Minutes of Meetings	
• Regulatory Briefing *(indicate date of mtg)*	☐ No mtg
• If not the first review cycle, any end-of-review meeting *(indicate date of mtg)*	☐ N/A or no mtg
• Pre-NDA/BLA meeting *(indicate date of mtg)*	☐ No mtg
• EOP2 meeting *(indicate date of mtg)*	☐ No mtg
• Other milestone meetings (e.g., EOP2a, CMC pilots) *(indicate dates of mtgs)*	Pre IND; June 4, 2008
❖ Advisory Committee Meeting(s)	☒ No AC meeting
• Date(s) of Meeting(s)	
• 48-hour alert or minutes, if available *(do not include transcript)*	
Decisional and Summary Memos	
❖ Office Director Decisional Memo *(indicate date for each review)*	☒ None
Division Director Summary Review *(indicate date for each review)*	☐ None June 08, 2011
Cross-Discipline Team Leader Review *(indicate date for each review)*	☐ None June 07, 2011
PMR/PMC Development Templates *(indicate total number)*	☒ None
Clinical Information[5]	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) *(indicate date for each review)*	N/A
• Clinical review(s) *(indicate date for each review)*	July 2, 2010; May 28, 2011
• Social scientist review(s) (if OTC drug) *(indicate date for each review)*	☒ None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here ☒ and include a review/memo explaining why not *(indicate date of review/memo)*	None No Clinical studies were done
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers *(indicate date of each review)*	☒ None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation *(indicate date of each review)*	☒ Not applicable
❖ Risk Management • REMS Documents and Supporting Statement *(indicate date(s) of submission(s))* • REMS Memo(s) and letter(s) *(indicate date(s))* • Risk management review(s) and recommendations (including those by OSE and CSS) *(indicate date of each review and indicate location/date if incorporated into another review)*	N/A ☐ None
❖ DSI Clinical Inspection Review Summary(ies) *(include copies of DSI letters to investigators)*	☒ None requested

[5] Filing reviews should be filed with the discipline reviews.

Clinical Microbiology ☒ None	
❖ Clinical Microbiology Team Leader Review(s) *(indicate date for each review)*	☐ None
Clinical Microbiology Review(s) *(indicate date for each review)*	☐ None
Biostatistics ☒ None	
❖ Statistical Division Director Review(s) *(indicate date for each review)*	☐ None
Statistical Team Leader Review(s) *(indicate date for each review)*	☐ None
Statistical Review(s) *(indicate date for each review)*	☐ None
Clinical Pharmacology ☐ None	
❖ Clinical Pharmacology Division Director Review(s) *(indicate date for each review)*	☒ None
Clinical Pharmacology Team Leader Review(s) *(indicate date for each review)*	☒ None
Clinical Pharmacology review(s) *(indicate date for each review)*	☐ None September 10, 2010; April 8, 2011
❖ DSI Clinical Pharmacology Inspection Review Summary *(include copies of DSI letters)*	☒ None
Nonclinical ☐ None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) *(indicate date for each review)*	☒ None
• Supervisory Review(s) *(indicate date for each review)*	☒ None
• Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	☐ None September 9, 2010; June 2, 2011
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer *(indicate date for each review)*	☒ None
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	☒ No carc
❖ ECAC/CAC report/memo of meeting	☒ None Included in P/T review, page
❖ DSI Nonclinical Inspection Review Summary *(include copies of DSI letters)*	☒ None requested
Product Quality ☐ None	
❖ Product Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) *(indicate date for each review)*	☒ None
• Branch Chief/Team Leader Review(s) *(indicate date for each review)*	☐ None
• Product quality review(s) including ONDQA biopharmaceutics reviews *(indicate date for each review)*	☐ None October 19, 2010; June 1, 2011
❖ Microbiology Reviews ☒ NDAs: Microbiology reviews (sterility & pyrogenicity) (OPS/NDMS) *(indicate date of each review)* ☐ BLAs: Sterility assurance, microbiology, facilities reviews (DMPQ/MAPCB/BMT) *(indicate date of each review)*	☐ Not needed October 5, 2010
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer *(indicate date of each review)*	☐ None Biopharmaceutics; July 22, 2010

❖ Environmental Assessment (check one) (original and supplemental applications)	
☒ Categorical Exclusion *(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)*	CMC Review; October 19, 2010; June 1, 2011
☐ Review & FONSI *(indicate date of review)*	N/A
☐ Review & Environmental Impact Statement *(indicate date of each review)*	N/A
❖ Facilities Review/Inspection	
☐ NDAs: Facilities inspections (include EER printout) *(date completed must be within **2 years** of action date) (only original NDAs and supplements that include a new facility or a change that affects the manufacturing sites[6])*	Date completed: October 4, 2010; May 16, 2011 ☒ Acceptable ☐ Withhold recommendation ☐ Not applicable
☐ BLAs: TB-EER *(date of most recent TB-EER must be within **30 days** of action date) (original and supplemental BLAs)*	Date completed: ☐ Acceptable ☐ Withhold recommendation
❖ NDAs: Methods Validation *(check box only, do not include documents)*	☐ Completed ☐ Requested ☐ Not yet requested ☒ Not needed (per review)

[6] I.e., a new facility or a change in the facility, or a change in the manufacturing process in a way that impacts the Quality Management Systems of the facility.

Appendix to Action Package Checklist

An NDA or NDA supplemental application is likely to be a 505(b)(2) application if:

(1) It relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application.
(2) **Or** it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval.
(3) **Or** it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations(see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

(1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies).
(2) **And** no additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application.
(3) **And** all other “criteria” are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

(1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2).
(2) **Or** the applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement.
(3) **Or** the applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE’s ADRA.

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/s/

KIM J ROBERTSON
06/08/2011
Action Package Checklist NDA 201195 Docetaxel Injection; Accord Healthcare

MEMORANDUM OF TELECON

DATE: April 11, 2011

APPLICATION NUMBER: NDA 201195

BETWEEN:

Name: Sabita Nair, R.A.C., Director-Regulatory Affairs
Phone: (919) 941-7880
Representing: Intas Pharmaceuticals LTD./Accord Healthcare Inc.

AND

Name: Sarah Pope-Miksinski, Ph.D., CMC Branch Chief
Division of New Drug Quality Assurance I

Haleh Saber, Ph.D., Supervisor; Pharmacology/Toxicology
Division of Hematology Products; for Division of Drug Oncology Products

SUBJECT: Impurity Issues

The FDA requested a teleconference with Accord Healthcare to gain further clarification regarding discrepancies in the acceptance criteria for impurities in the drug product and the proposed release and shelf-life specifications. This included the proposed specification for the impurity at RRT (b) (4)

Accord increased the limit of the (b) (4) impurity from NMT (b) (4) (NDA submission of 2009) to NMT (b) (4) (submission of December 2010), and then to (b) (4) (January 2011). The Agency clarified that the proposed specification of NMT (b) (4) is not acceptable. The Agency stated that the toxicology study submitted to justify the new specification was not designed to show comparable toxicities between Docetaxel Injection (with the proposed level of RRT (b) (4)) and the Reference Listed Drug (RLD), Taxotere. Considering that docetaxel drug products are available with a better impurity profile, the Agency questioned the approval of a docetaxel drug product with a higher level of impurity.

Based on the preceding discussion, the Applicant was asked to reduce the shelf-life specification of this impurity to NMT (b) (4), which is approximately equal to the highest shelf-life specification of the impurity observed in the RLD (b) (4), based on Accord's analytical methods. The Applicant expressed their understanding and stated that they would reduce the acceptance criterion as recommended. The Applicant also agreed to confirm that the proposed release and stability specifications were harmonized.

The Applicant inquired as to how to justify the (b) (4) impurity level post-approval and asked if they could submit questions to the Agency post action. The Agency agreed that questions could be discussed post-approval.

_____
Kim J. Robertson
Regulatory Project Manager,
Division of Drug Oncology Products

_____
Haleh Saber, Ph.D.
Supervisor; Pharmacology/Toxicology
Division of Hematology Products

_____
Sarah Pope-Miksinski, Ph.D.
Branch Chief
Division of New Drug Quality Assurance I

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/s/

KIM J ROBERTSON
06/07/2011
11April11 Memo of Tcon NDA 201195 Docetaxel Inj.; Accord Healthcare

HALEH SABER
06/07/2011

SARAH P MIKSINSKI
06/07/2011

From: Robertson, Kim
Sent: Friday, May 13, 2011 4:47 PM
To: 'Sabita Nair'
Cc: samir mehta
Subject: NDA 201195; Docetaxel Inj.

Importance: High

Attachments: Use for May 13 [Annotated side by side comparison - proposed vs. previous].doc

Hello Sabita/Samir:

Please see the attached Accord label with further FDA comments and recommendations. Please review right away and provide us with a return label with Accord's concurrence, or objections no later than **Friday, May 20, 2011.**

If Accord should have any questions or concerns with regard to any of our comments and/or recommendations, please do not hesitate to let us know right away.

Regards,
Kim

Use for May
Annotated sic

Kim J. Robertson
Regulatory Health Project Manager
Division of Drug Oncology Products
Phone: (301) 796-1441
Fax: (301) 796-9845

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/s/

KIM J ROBERTSON
06/06/2011
03May11--Use for May 13 [Annotated side by side comparison-proposed vs. previous]

From: Robertson, Kim
Sent: Tuesday, May 03, 2011 4:40 PM
To: 'Sabita Nair'
Cc: samir mehta
Subject: RE: NDA 201195-Docetaxel Inj.-Labeling Amendment-Revised container and carton labels

Importance: High

Attachments: Updated 14April11 Annotated side by side (Accord's proposed vs innovator.doc
Hello Sabita:

After quite a bit of team discussion, it was decided that the request of the Docetaxel team will remain with regard to its comments as they pertain to Section 2.9; PREPARATION AND ADMINISTRATION of Accord's Docetaxel Injection label.

Please note that the label included in this e-mail has been given the name "**Updated** 14April11 Annotated side by side (Accord's proposal vs. innovator. doc)" It has been named as such, because we implemented a few more recommendations that the label sent to Accord on April 15, 2011 did not have.

Please review and provide labeling back to the division no later than **Thursday, May 12, 2011**.

Regards,
Kim

From: Sabita Nair [mailto:snair@intaspharma.com]
Sent: Monday, April 25, 2011 6:43 PM
To: Robertson, Kim
Cc: samir mehta
Subject: RE: NDA 201195-Docetaxel Inj.-Labeling Amendment-Revised container and carton labels

Dear Kim,

This is in continuation to the Information Request sent to us on April 15, 2011 for NDA 201195. In response to the revisions requested, we have submitted a Labeling Amendment to the NDA today, April 25, 2011. It should reach the Document Control Room tomorrow.
The amendment contains revisions to the container and carton labels in line with what was requested in the Information Request Document.

I wanted to know if you got the chance to share our clarification question regarding the PI. Once we hear from you, we can accordingly finalize the PI as well. Please do let me know. Thanks.

Regards,
Sabita

Sabita Nair, R.A.C.
Director-Regulatory Affairs

INTAS PHARMACEUTICALS LTD./ACCORD HEALTHCARE INC.
1009 Slater Road, Suite 210-B, Durham NC 27703, USA
Tel : 919-941-7880; Fax: 919-941-7885;
E-Mail: snair@intaspharma.com

From: Sabita Nair
Sent: Tuesday, April 19, 2011 4:27 PM
To: 'Robertson, Kim'
Cc: samir mehta
Subject: FW: NDA 201195-Docetaxel Inj.-Annotated side-by-side labeling
Importance: High

Dear Kim,

This e-mail is in continuation to the Agency communication that you sent us on April 15 regarding the annotated side-by-side comparison of Accord's label with that of Taxotere. I understood that you were out of the office up until tomorrow so I am following up on my phone call with this e-mail.

We are seeking some clarification in regard to the Agency comments on the annotated side-by-side labeling and the Information Request for Labeling. If you could kindly arrange to forward the clarification question given below to the Labeling reviewer/division, it would help us in finalizing the label.

Specifically our request is as follows,

The section *2.9 Preparation and Administration* contains (b) (4) is intended to give better clarity to the user regarding the reconstitution procedure. Therefore we wish to keep the section unchanged, though it differs from the Taxotere® label. We are hoping that the Agency would allow us to do so.

With regards to the Information Request for Labeling in response to the Agency Observations are proposing to keep the following colors for Accord's docetaxel Product (b) (4)

20 mg/0.5 ml – (b) (4)
80 mg/2 ml - (b) (4)

Please advise if this color proposal is considered to be acceptable so that we could provide you with revised labeling.

Thank you.

Regards,
Sabita

Sabita Nair, R.A.C.
Director-Regulatory Affairs

INTAS PHARMACEUTICALS LTD./ACCORD HEALTHCARE INC.
1009 Slater Road, Suite 210-B, Durham NC 27703, USA
Tel : 919-941-7880; Fax: 919-941-7885;
E-Mail: snair@intaspharma.com

From: Robertson, Kim [mailto:Kim.Robertson@fda.hhs.gov]
Sent: Friday, April 15, 2011 2:36 PM
To: Sabita Nair
Cc: samir mehta
Subject: NDA 201195-Docetaxel Inj.
Importance: High

Hello Sabita:

I just left you a voice message with regard to a specific date as to when the Agency can expect a written response from Accord Healthcare as it pertains to the April 11, 2011 t-con. One of the points the Agency stressed to Accord was that **IF** the application is approved in this review cycle, the RRT (b) (4) impurity specs needed to be reduced to (b) (4) When can we expect a written response?

Also, please see your attached Docetaxel PI. It contains Agency comments/ suggestions that we need Accord to address right away. Please review the PI and return it to the Agency by Monday, April 25, 2011.

Lastly, please find the attached .pdf document, as it contains further comments from our DMEPA group with regard to Accord's Carton and Container labels. Please review right away as well.

Regards,
Kim

Kim J. Robertson
Regulatory Health Project Manager
Division of Drug Oncology Products
Phone: (301) 796 1441
Fax: (301) 796 9845

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/s/

KIM J ROBERTSON
06/06/2011
03May11---Updated 14April11 PI for Accord

From: Robertson, Kim
Sent: Thursday, June 02, 2011 9:34 PM
To: 'Sabita Nair'
Cc: samir mehta
Subject: RE: NDA 201195 Docetaxel-Accord's Response to Information Request dated May 27, 2011-dispatched

Importance: High

Attachments: Accord's June 1 revised proposed package insert.doc
Hello Sabita:

Upon reviewing Accord's latest PI, my CMC reviewer saw a type-o that was made on our part. Albeit a minor type-o, we still need Accord to see the change that we made.

If Accord is in agreement with the removal of our type-o, then we need a new PI reflecting that our change has been accepted, and we need it no later than Monday, June 6, 2011. It officially needs to be submitted through our Gateway no later than Monday.

Thank you,
Kim

From: Sabita Nair [mailto:snair@intaspharma.com]
Sent: Tuesday, May 31, 2011 8:38 PM
To: Robertson, Kim
Cc: samir mehta
Subject: RE: NDA 201195 Docetaxel-Accord's Response to Information Request dated May 27, 2011-dispatched

Dear Kim,

Hope you are doing well.

This e-mail is to let you know that we have sent responses to the Information Request dated May 27, along with responses to the revisions requested in the package insert that we received on the 27th.

The package should reach the Agency's Document Control Room by tomorrow. The package also contains a DVD that contains electronic copies of the labels and the package insert.

Please let me know if additionally you need desk copies of the labeling or package insert.

Thanks.

Regards,
Sabita

Sabita Nair, R.A.C.
Director-Regulatory Affairs

INTAS PHARMACEUTICALS LTD./ACCORD HEALTHCARE INC.
1009 Slater Road, Suite 210-B, Durham NC 27703, USA
Tel : 919-941-7880; Fax: 919-941-7885;
E-Mail: snair@intaspharma.com

From: Sabita Nair
Sent: Friday, May 27, 2011 7:29 PM
To: 'Robertson, Kim'
Cc: samir mehta
Subject: RE: NDA 201195 Docetaxel

Dear Kim,

This e-mail is to acknowledge receipt of the labeling comments in your e-mail below. Thank you. We will revert back to you soon with the responses.

Have a nice weekend!

Regards,
Sabita

From: Robertson, Kim [mailto:Kim.Robertson@fda.hhs.gov]
Sent: Friday, May 27, 2011 6:39 PM
To: Sabita Nair; samir mehta
Subject: NDA 201195 Docetaxel
Importance: High

Hello Sabita/Samir:

Please see the attached Word document, as it is Accord's Docetaxel label containing division comments. Please review and provide us with a label by Tuesday, June 1, 2011.

Please also see the attached .pdf document, as it contains comments regarding Accord's revised carton/container. Please review and provide updated C&C information no later than Tuesday, June 1, 2011.

Regards,
Kim

Kim J. Robertson
Regulatory Health Project Manager
Division of Drug Oncology Products
Phone: (301) 796 1441
Fax: (301) 796 9845

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/s/

KIM J ROBERTSON
06/02/2011
To Sabita; June 2nd Accord's Docetaxel Inj. PI with FDA revisions

From: Duvall Miller, Beth A
Sent: Monday, May 09, 2011 3:31 PM
To: Robertson, Kim
Cc: Kim, Tamy; Cross Jr, Frank H
Subject: N201195; Docetaxel Accord Healthcare - (b) (4)

Hi Kim,

We discussed your application at today's 505(b)(2) clearance meeting and (b) (4) .

Please make the following revisions to the more recent version of your assessment that you sent me:

- Q2: please modify the response under "Information provided…" to describe which specific sections of the application rely on TAXOTERE.
- Q14: Please retain the fact that Accord submitted Para III certification to address the 4814470 patent (exp 5/14/2010) and 4814470*PED patent (exp 11/14/2010). Also, since the applicant changed their patent certification between cycles, please indicate under in your listing of the Para IV patents that the applicant had originally submitted Para III certification to address the '582, '512, and '561 patents.
- Q15d: Delete 11/19/10 from your response; that was the shipping date on the FedEx receipt, not the receipt date. The receipt date was 11/22/10.

Let me know if you have any questions.

Beth

Beth Duvall-Miller

Team Leader, Regulatory Affairs Team
CDER/Office of New Drugs
Direct Phone Number: (301) 796-0513
OND IO Phone Number: (301) 796-0700
Fax: (301) 796-9855

From: Duvall Miller, Beth A
Sent: Thursday, May 05, 2011 4:03 PM
To: Robertson, Kim
Cc: Kim, Tamy; Cross Jr, Frank H
Subject: RE: N201195; Docetaxel Accord Healthcare

Hi Kim,

I'm preparing this application for discussion at Monday's 505(b)(2) clearance meeting. Just one point of clarification as to what you wrote below (b) (4)

(b) (4)

I'll be in touch with a final clearance email probably next week.

Beth

Beth Duvall-Miller

Team Leader, Regulatory Affairs Team
CDER/Office of New Drugs
Direct Phone Number: (301) 796-0513
OND IO Phone Number: (301) 796-0700
Fax: (301) 796-9855

From: Robertson, Kim
Sent: Wednesday, April 06, 2011 10:46 AM
To: Duvall Miller, Beth A
Cc: Kim, Tamy; Cross Jr, Frank H
Subject: RE: N201195; Docetaxel Accord Healthcare

Thank you Beth. If you need a copy of the lawsuit notification, please let me know.
Kim

From: Duvall Miller, Beth A
Sent: Wednesday, April 06, 2011 9:28 AM
To: Robertson, Kim
Cc: Kim, Tamy; Cross Jr, Frank H
Subject: RE: N201195; Docetaxel Accord Healthcare

Thanks Kim.

Beth

Beth Duvall-Miller

Team Leader, Regulatory Affairs Team
CDER/Office of New Drugs
Direct Phone Number: (301) 796-0513
OND IO Phone Number: (301) 796-0700
Fax: (301) 796-9855

From: Robertson, Kim
Sent: Tuesday, April 05, 2011 4:48 PM

To: Duvall Miller, Beth A
Cc: Kim, Tamy; Cross Jr, Frank H
Subject: N201195; Docetaxel Accord Healthcare
Importance: High

Hi Beth:

Attached, please find my (b)(2) assessment form for my Class 2 Resubmission NDA for N201195; Docetaxel from Accord Healthcare, Inc. As of this point, this NDA will most likely be approved and the due date is June 7, 2011.

Disregard the text in RED in the form; I highlighted that, so that my pharmtox and CMC reviewers could readily see those sections to confirm for me that what was cut 'n pasted from the previous assessment form is still relevant.

<< File: 2nd Cycle 505(b)(2) Assessment (REV-RPM-07).doc >>

I have also attached for your convenience a few pages from Accord's submissions outlining their Para. IV amendments regarding the patents, along with their Para. IV notifications to the NDA holder.

<< File: Paragraph IV Certs.pdf >> << File: Notifications to RLD Holder.pdf >>

Thanks,
Kim

Kim J. Robertson
Regulatory Health Project Manager
Division of Drug Oncology Products
Phone: (301) 796-1441
Fax: (301) 796-9845

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/s/

KIM J ROBERTSON
06/02/2011
1st Round b2 Clearance for Docetaxel Inj. b2; N201195

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195 **INFORMATION REQUEST**

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL.

We are reviewing the revised Carton and Container labels of your submission and have the remaining following comments. We request a prompt response to these comments in order to continue our evaluation of your NDA.

COMMENTS AND REQUESTS:

A. General Comment for the 80 mg/2 mL strength labels and labeling

(b) (4) utilized for strength differentiation. As currently presented it is too similar to (b) (4) utilized in Hospira's docetaxel product.

B. Diluent Labels (20 mg/0.5 mL and 80 mg/2 mL)

Use a bold font for the word "Caution".

C. Blister Labels (20 mg/0.5 mL and 80 mg/2 mL)

1. Relocate the statement "FOR INTRAVENOUS INFUSION ONLY AFTER FINAL DILUTION" to the line where the statement "Rx Only" is currently positioned. Relocate the statement "Rx Only" to the position where the statement "FOR INTRAVENOUS INFUSION ONLY AFTER FINAL DILUTION" is positioned.

2. Use a bold font for the statement "FOR INTRAVENOUS INFUSION ONLY AFTER FINAL DILUTION" in bold font.

D. Container Labels (20 mg/0.5 mL and 80 mg/2 mL)

See Comment C.2, above.

E. Carton Labeling (20 mg/0.5 mL and 80 mg/2 mL)

1. Increase the size of the statement “Before Initial Dilution”.

2. Add the statement “Before Initial Dilution*” and “*see side panel for concentration obtained after initial dilution step” to the principal display panel below the statement of strength, like the back panel.

If you have any questions, call Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Kim J. Robertson
Regulatory Project Manager
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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/s/

KIM J ROBERTSON
05/27/2011
27May11 DMEPA Information Request; NDA 201195

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195 **INFORMATION REQUEST**

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL.

We are reviewing the Carton and Container labels of your submission and have the following comments. We request a prompt response to these comments in order to continue our evaluation of your NDA.

COMMENTS AND REQUESTS:

A. General Comments for all Container Labels and Carton Labeling

1. Due to the availability of multiple formulations of docetaxel in varying concentrations that require differing instructions for drug preparation, the potential for confusion among these products is a significant safety concern for DMEPA.
Thus, it is essential to differentiate the labels and labeling of these products such that the potential for confusion is minimized. One important feature of the container labels and carton labeling, that may help to differentiate these products, is color.
Thus, in an effort to help minimize the potential for confusion that can lead to dosing errors due to similarities or overlaps in color between the products, we take into consideration that colors should not overlap between the following:

- One-vial vs. two-vial formulations
- Concentration of 10 mg/mL vs. concentration of 20 mg/mL prior to dilution in infusion bag

The colors you propose for strength differentiation of the 20 mg/0.5 mL and 80 mg/2 mL strengths [redacted] (b) (4) This may lead to confusion due to the differences in formulation (one-vial vs. two-vial) and concentration per

mL. Additionally, [redacted] for Docetaxel Injection 20 mg/0.5 mL is similar to [redacted] and [redacted] for Docetaxel Injection 80 mg/2 mL is similar to [redacted] Therefore, the strengths can also be confused, leading to wrong dose errors. Thus, we request that you choose colors for strength differentiation that do not overlap with the currently marketed one-vial Taxotere or one-vial Docetaxel Injection marketed by Hospira.

2. The "Rx Only" statement is very prominent and detracts from other important information on the principal display panel. Decrease the prominence of the statement by decreasing its size, unbolding it, and relocating it to a less prominent area on the principal display panel.

3. Revise all instances of the abbreviation [redacted] to read "Intravenous" or "Intravenously", as appropriate. The abbreviation [redacted] appears on the ISMP List of Error-Prone Abbreviations, Symbols, and Dose Designations" because it has been confused as [redacted]. As part of a national campaign to reduce medication errors related to error-prone medical abbreviations and dose designations, the FDA agreed not to approve labels and labeling that included the use of error prone abbreviations or dose designations. Thus, we request you revise accordingly.

B. Container Labels, 20 mg/0.5 mL and 80 mg/2 mL

1. There is a typographical error in the Caution statement. In the first sentence, the word "concentration" is misspelled as [redacted]. Revise the word [redacted] to read "concentration".

2. Increase the prominence of the statement "For Intravenous Infusion Only After Final Dilution"

3. [redacted] the storage conditions statements.

4. Box the caution statement to increase its prominence.

C. Carton Labeling

1. Revise the statement [redacted] to read: "see side panel for concentration obtained after initial dilution step."

2. Add the statements "Before Initial Dilution*" and "see side panel for concentration obtained after initial dilution step" on the back panel like it is currently presented on the front panel.

3. See B.4 above

D. Diluent Labels

1. The diluent labels are not well differentiated from the active drug vials which could cause healthcare practitioners to confuse the diluent as the active drug vial and vice versa. The "docetaxel" established name and strength are too prominent on the diluent labels and the trade dress highlights the established name of the active drug, not the ingredients in the diluent. Therefore we request you revise as follows:

a. (b) (4) the statement of strength from the diluent labels.

b. Increase the prominence of the word "Diluent" so that it is the most prominent word on the label.

c. Revise the name to read "Diluent for Docetaxel Injection 20 mg" or 80 mg as appropriate. Additionally, use a bold font for the word "Diluent" or make it much larger than the rest of the statement.

2. In the Caution statement, place the following in bold font: "entire", "1.95 mL" and "7.2 mL".

3. The storage conditions statements are too prominent due to the (b) (4) used. Use a black, unbolded font for the storage conditions statements.

E. Blister Labels

See comments B.2, B.4, and D.3 above.

If you have any questions, call Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Kim J. Robertson
Regulatory Project Manager
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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/s/

KIM J ROBERTSON
04/15/2011
15April11 DMEPA Comments for Docetaxel Inj. C&C; Accord Healthcare N201195;

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

REQUEST FOR DDMAC LABELING REVIEW CONSULTATION

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

TO: HFD-42;Attn: **CDER-DDMAC-RPM**	FROM: (Name/Title, Office/Division/Phone number of requestor) Kim J. Robertson, OND/DDOP/CDER; 6-1441

REQUEST DATE	IND NO.	NDA/BLA NO.	TYPE OF DOCUMENTS (PLEASE CHECK OFF BELOW)
March 17, 2011		**201195**	New 505(b)(2) NDA; Class 2 Resubmission; Dated December 10, 2010

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE (Generally 1 week before the wrap up meeting)
Docetaxel Injection (b) (4); 20 mg and 80 mg	Priority	5	May 10, 2011

NAME OF FIRM: Accord Healthcare, Inc.	PDUFA Date: June 10, 2011

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

EDR link to submission: **\\FDSWA150\NONECTD\N201195\N_000\2011-01-19**

Please Note: There is no need to send labeling at this time. DDMAC reviews substantially complete labeling, which has already been marked up by the CDER Review Team. The DDMAC reviewer will contact you at a later date to obtain the substantially complete labeling for review.

COMMENTS/SPECIAL INSTRUCTIONS: DDOP is requesting that DDMAC review the proposed product labeling and any relevant advertising for this NDA. This is a paper NDA. Draft Carton, Blister, Label, SBS and PI can be found in the EDR: **\\FDSWA150\NONECTD\N201195\N_000\2011-01-19**

Clinical reviewer: Kristen Snyder M.D.; CMC: Joyce Crich, Ph.D..; Proj. Mgr.: Kim Robertson

Mid-Cycle Meeting: [Insert Date] N/A

Labeling Meetings: [Insert Dates] February 9, March 15, March 24, April 14, and May 13, 2011

Wrap-Up Meeting: [Insert Date] N/A

SIGNATURE OF REQUESTER Kim J. Robertson	
SIGNATURE OF RECEIVER	METHOD OF DELIVERY (Check one) ☐ eMAIL ☐ HAND

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/s/

KIM J ROBERTSON
03/17/2011
DDMAC Consult N201195 Docetaxel Inj. Accord Healthcare

From: Robertson, Kim
Sent: Friday, March 04, 2011 11:41 AM
To: Sabita Nair
Cc: samir mehta
Subject: NDA 201195; Docetaxel Inj.--Pharmtox Information Request

Importance: High

Hello Sabita:

Please see the following request for clarification from our Pharmacologists re: Accord's (b)(2) for Docetaxel Inj.:

- In the experimental design, and protocol of your repeat dose toxicology study (pages 19 and 198), you stated that the recovery groups (groups G9 and G10) were administered the high dose (0.2mg/kg) of (b) (4) impurity and Docetaxel Injection, respectively. However, your tabulated data indicate that the impurity recovery group G9 was administered the low dose (0.05mg/kg), and the Docetaxel Injection recovery group G10 was administered the mid dose (0.1mg/kg). Please indicate doses administered to recovery groups G9 and G10.

Please provide a response to this query no later than Monday, March 7, 2011.

Regards,
Kim

Kim J. Robertson
Consumer Safety Officer
Division of Drug Oncology Products
Phone: (301) 796-1441
Fax: (301) 796-9845

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/s/

KIM J ROBERTSON
03/04/2011
04March11 NDA 201195 Docetaxel Inj. Pharmtox Information Request

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

REQUEST FOR CONSULTATION

TO *(Office/Division)*:	FROM (*Name, Office/Division, and Phone Number of Requestor)*:
David Hussong/Jim McVey/Sylvia Gantt NEW DRUG MICROBIOLOGY STAFF OC/OO/CDER/OPS/NDMS - HFD-805	Deborah Mesmer, 301-796-4023

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
March 3, 2011		201195	NDA resubmission, 505(b)(2)	December 10, 2010

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Docetaxel Injection, 20 mg and 80 mg	Class 2 resubmission	Oncology	5/12/11 PDUFA 6/10/11

NAME OF FIRM: Accord Healthcare Inc

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE NDA MEETING
- ☐ END OF PHASE 2a MEETING
- ☐ END OF PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☒ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END OF PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL BIOPHARMACEUTICS
- ☐ IN VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: A microbiology review is requested for this resubmitted 505(b)(2) application. The jackets will be provided to the assigned reviewer for this paper submission.

John Metcalfe was the microbiology reviewer in the last cycle.

Chemistry Reviewer: Joyce Crich
OND Project Manager: Kim Robertson
CMC Lead: Haripada Sarker
ONDQA RPM: Debbie Mesmer

Please notify Debbie Mesmer of reviewer assignment.

SIGNATURE OF REQUESTOR {See appended electronic signature page}	METHOD OF DELIVERY (Check one) ☒ DFS ☒ EMAIL ☐ MAIL ☐ HAND
PRINTED NAME AND SIGNATURE OF RECEIVER	PRINTED NAME AND SIGNATURE OF DELIVERER

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/s/

DEBORAH M MESMER
03/03/2011

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

REQUEST FOR CONSULTATION

TO *(Office/Division)*: CDER OSE CONSULT			FROM (*Name, Office/Division, and Phone Number of Requestor)*: HFD-150/DDOP/Kim Robertson, 6-1441	
DATE February 8, 2011	IND NO.	NDA NO. 201195	TYPE OF DOCUMENT 505(b)(2); PI & Carton and Container Labels	DATE OF DOCUMENT December 07, 2010; received December 10, 2010
NAME OF DRUG Docetaxel Injection (b) (4)	PRIORITY CONSIDERATION Priority		CLASSIFICATION OF DRUG 5	DESIRED COMPLETION DATE May 2, 2011

NAME OF FIRM: Accord Healthcare, Inc.

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE NDA MEETING
- ☐ END OF PHASE 2a MEETING
- ☐ END OF PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☒ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END OF PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL BIOPHARMACEUTICS
- ☐ IN VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: At this time, DDOP is requesting that OSE reviews the sponsor proposed product PI and labeling for this (b)(2) NDA. This is a paper NDA. There appears to be an upload problem in DARRTS/EDR regarding the PI itself; however, to facilitate OSE's review of the PI, I will attach it to this consult. The remaining components necessary for OSE to review (cartons, blisters) can be found in the EDR at the following pathway link: \\FDSWA150\NONECTD\N201195\N_000\2011-01-19.

Clinical reviewer: Kristen Snyder, M.D..; CMC: Sarah Pope-Misinski, Ph.D.; CSO: Kim Robertson

SIGNATURE OF REQUESTOR Kim Robertson, CSO	METHOD OF DELIVERY (Check one) ☒ DFS ☒ EMAIL ☐ MAIL ☐ HAND
PRINTED NAME AND SIGNATURE OF RECEIVER	PRINTED NAME AND SIGNATURE OF DELIVERER

Reference ID: 2902688

64 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page.

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/s/

KIM J ROBERTSON
02/08/2011
08February11 OSE Consult Docetaxel Inj. N201195 Accord Healthcare (b)(2)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195

ACKNOWLEDGE – CLASS 2 RESPONSE

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

We acknowledge receipt on December 10, 2010, of your December 7, 2010 resubmission of your new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL.

We consider this a complete, Class 2 response to our October 22, 2010 action letter. Therefore, the user fee goal date is June 10, 2011.

If you have any questions, call Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Kim J. Robertson
Consumer Safety Officer
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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/s/

KIM J ROBERTSON

02/02/2011

Acknowledgement of Class 2 Resubmission-Accord Healthcare Docetaxel Inj. 20 mg/0.5 mL and 80 mg/2.0 mL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195 **INFORMATION REQUEST**

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL.

We also refer you to your December 7, 2010 submission, received December 10, 2010. We are reviewing your submission and have ascertained the following information request from the pharmacology/toxicology discipline. We request a prompt written response in order to continue our evaluation of your NDA no later than Friday, January 21, 2011.

INFORMATION REQUEST:

1. Please provide the amount of (b) (4) impurity contained in the Docetaxel Injection Concentrate (batch ASDCTP1124) used in the repeat-dose rat study (Study #10108). Also provide information necessary to calculate the dose of impurity that animals received in Study 10108; this includes dilutions made prior to dose administration.

2. Please provide the Certificate of Analysis for the Docetaxel Injection Concentrate (batch ASDCTP1124).

3. You indicate in your submission that the impurity "has been observed to appear in both Accord's product as well as the innovator product at the same RRT (b) (4). However, you do not provide the level of the impurity in the reference listed drug (RLD) in your current submission. Please provide the side-by-side comparison of impurities that was performed with Docetaxel Injection and the RLD to include the level of RRT (b) (4) in the RLD.

If you have any questions, call Kim J. Robertson, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Kim J. Robertson
Consumer Safety Officer
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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/s/

KIM J ROBERTSON
01/18/2011
18January11 Pharmtox IR Docetaxel Inj. Accord Healthcare

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]

NDA # 201195 BLA #	NDA Supplement # N/A BLA STN #	If NDA, Efficacy Supplement Type: N/A
Proprietary Name: N/A Established/Proper Name: Docetaxel Dosage Form: Injection; 20 mg and 80 mg		Applicant: Accord Healthcare Agent for Applicant (if applicable): N/A
RPM: Kim J. Robertson		Division: Drug Oncology Products

NDAs:
NDA Application Type: ☐ 505(b)(1) ☒ 505(b)(2)
Efficacy Supplement: ☐ 505(b)(1) ☐ 505(b)(2)

(A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). Consult page 1 of the 505(b)(2) Assessment or the Appendix to this Action Package Checklist.)

505(b)(2) Original NDAs and 505(b)(2) NDA supplements:
Listed drug(s) relied upon for approval (include NDA #(s) and drug name(s)):

NDA# 020449; Taxotere (docetaxel) Injection Concentrate, Intravenous Infusion 80 mg/2mL and 20 mg/0.5 mL

Provide a brief explanation of how this product is different from the listed drug.

New information consists of CMC data and impurities. Except for formulation-related sections of the label, other information in the label is the same as that described for the reference listed drug (RLD).

If no listed drug, explain.
- ☐ This application relies on literature.
- ☐ This application relies on a final OTC monograph.
- ☐ Other (explain)

Two months prior to each action, review the information in the 505(b)(2) Assessment and submit the draft to CDER OND IO for clearance. Finalize the 505(b)(2) Assessment at the time of the approval action.

On the day of approval, check the Orange Book again for any new patents or pediatric exclusivity.

☐ No changes ☐ Updated Date of check: N/A

If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.

❖ Actions	
• Proposed action • User Fee Goal Date is October 22, 2010	☐ AP ☐ TA ☒ CR
• Previous actions *(specify type and date for each action taken)*	☒ None

[1] The **Application Information** section is (only) a checklist. The **Contents of Action Package** section (beginning on page 5) lists the documents to be included in the Action Package.

❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received? Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain N/A	☐ Received
❖ Application Characteristics [2]	

Review priority: ☒ Standard ☐ Priority
Chemical classification (new NDAs only):

☐ Fast Track
☐ Rolling Review
☐ Orphan drug designation
☐ Rx-to-OTC full switch
☐ Rx-to-OTC partial switch
☐ Direct-to-OTC

NDAs: Subpart H
☐ Accelerated approval (21 CFR 314.510)
☐ Restricted distribution (21 CFR 314.520)
Subpart I
☐ Approval based on animal studies

BLAs: Subpart E
☐ Accelerated approval (21 CFR 601.41)
☐ Restricted distribution (21 CFR 601.42)
Subpart H
☐ Approval based on animal studies

☐ Submitted in response to a PMR
☐ Submitted in response to a PMC
☐ Submitted in response to a Pediatric Written Request

REMS: ☐ MedGuide
☐ Communication Plan
☐ ETASU
☐ REMS not required

Comments:

❖ BLAs only: Ensure *RMS BLA Product Information Sheet for TBP* and *RMS BLA Facility Information Sheet for TBP* have been completed and forwarded to OPI/OBI/DRM (Vicky Carter)	☐ Yes, dates
❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 *(approvals only)*	☐ Yes ☐ No
❖ Public communications *(approvals only)*	
• Office of Executive Programs (OEP) liaison has been notified of action	☐ Yes ☒ No
• Press Office notified of action (by OEP)	☐ Yes ☒ No
• Indicate what types (if any) of information dissemination are anticipated	☒ None ☐ HHS Press Release ☐ FDA Talk Paper ☐ CDER Q&As ☐ Other

[2] Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS BLA Product Information Sheet for TBP* must be completed.

❖ Exclusivity	
• Is approval of this application blocked by any type of exclusivity?	☐ No ☒ Yes
• NDAs and BLAs: Is there existing orphan drug exclusivity for the "same" drug or biologic for the proposed indication(s)? *Refer to 21 CFR 316.3(b)(13) for the definition of "same drug" for an orphan drug (i.e., active moiety). This definition is NOT the same as that used for NDA chemical classification.*	☒ No ☐ Yes If, yes, NDA/BLA # and date exclusivity expires:
• (b)(2) NDAs only: Is there remaining 5-year exclusivity that would bar effective approval of a 505(b)(2) application)? *(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)*	☒ No ☐ Yes If yes, NDA # and date exclusivity expires:
• (b)(2) NDAs only: Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? *(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)*	☐ No ☒ Yes If yes, NDA # 020449 and date exclusivity expires: PED Nov. 13, 2013
• (b)(2) NDAs only: Is there remaining 6-month pediatric exclusivity that would bar effective approval of a 505(b)(2) application? *(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)*	☐ No ☒ Yes If yes, NDA # 020449 and date exclusivity expires: PED Nov. 13, 2013
• NDAs only: Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? *(Note that, even if the 10 year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)*	☒ No ☐ Yes If yes, NDA # and date 10-year limitation expires:
❖ Patent Information (NDAs only)	
• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. If the drug is an old antibiotic, skip the Patent Certification questions.	☒ Verified ☐ Not applicable because drug is an old antibiotic.
• Patent Certification [505(b)(2) applications]: Verify that a certification was submitted for each patent for the listed drug(s) in the Orange Book and identify the type of certification submitted for each patent.	21 CFR 314.50(i)(1)(*i*)(A) ☒ Verified 21 CFR 314.50(i)(1) ☐ (ii) ☒ (iii)
• [505(b)(2) applications] If the application includes a **paragraph III** certification, it cannot be approved until the date that the patent to which the certification pertains expires (but may be tentatively approved if it is otherwise ready for approval).	☐ No paragraph III certification Date patent will expire 4814470 Expiry date(s): May 14, 2010 4814470*PED Nov. 14, 2010 5698582 July 3, 2012 5698582*PED Jan. 3, 2013 5714512 July 3, 2012 5714512*PED Jan. 3, 2013 5750561 July 3, 2012 5750561*PED Jan. 3, 2013
• [505(b)(2) applications] For **each paragraph IV** certification, verify that the applicant notified the NDA holder and patent owner(s) of its certification that the patent(s) is invalid, unenforceable, or will not be infringed (review documentation of notification by applicant and documentation of receipt of notice by patent owner and NDA holder). *(If the application does not include*	☐ N/A (no paragraph IV certification) ☒ Verified

*any paragraph IV certifications, mark "N/A" and skip to the next section below (*Summary Reviews*)).*

- [505(b)(2) applications] For **each paragraph IV** certification, based on the questions below, determine whether a 30-month stay of approval is in effect due to patent infringement litigation.

  Answer the following questions for **each** paragraph IV certification:

  (1) Have 45 days passed since the patent owner's receipt of the applicant's notice of certification? ☒ Yes ☐ No

  (Note: The date that the patent owner received the applicant's notice of certification can be determined by checking the application. The applicant is required to amend its 505(b)(2) application to include documentation of this date (e.g., copy of return receipt or letter from recipient acknowledging its receipt of the notice) (see 21 CFR 314.52(e))).

  *If "**Yes**," skip to question (4) below. If "**No**," continue with question (2).*

  (2) Has the patent owner (or NDA holder, if it is an exclusive patent licensee) submitted a written waiver of its right to file a legal action for patent infringement after receiving the applicant's notice of certification, as provided for by 21 CFR 314.107(f)(3)? ☐ Yes ☐ No

  *If "**Yes,**" there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip the rest of the patent questions.*

  *If "**No**," continue with question (3).*

  (3) Has the patent owner, its representative, or the exclusive patent licensee filed a lawsuit for patent infringement against the applicant? ☐ Yes ☐ No

  (Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2))).

  *If "**No**," the patent owner (or NDA holder, if it is an exclusive patent licensee) has until the expiration of the 45 day period described in question (1) to waive its right to bring a patent infringement action or to bring such an action. After the 45 day period expires, continue with question (4) below.*

  (4) Did the patent owner (or NDA holder, if it is an exclusive patent licensee) submit a written waiver of its right to file a legal action for patent infringement within the 45-day period described in question (1), as provided for by 21 CFR 314.107(f)(3)? ☐ Yes ☒ No

  *If "**Yes,**" there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other*

*paragraph IV certifications, skip to the next section below (*Summary Reviews*).* *If "**No**," continue with question (5).*	
(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the (b)(2) applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification? (Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)). If no written notice appears in the NDA file, confirm with the applicant whether a lawsuit was commenced within the 45-day period). *If "**No**," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (*Summary Reviews*).* *If "**Yes**," a stay of approval may be in effect. To determine if a 30 month stay is in effect, consult with the OND ADRA and attach a summary of the response.*	☐ Yes ☒ No

CONTENTS OF ACTION PACKAGE	
❖ Copy of this Action Package Checklist[3]	October 22, 2010
Officer/Employee List	
❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list *(approvals only)*	☐ Included
Documentation of consent/non-consent by officers/employees	☐ Included
Action Letters	
❖ Copies of all action letters *(including approval letter with final labeling)*	Action(s) and date(s) October 22, 2010
Labeling	
❖ Package Insert *(write submission/communication date at upper right of first page of PI)*	
• Most recent draft labeling. If it is division-proposed labeling, it should be in track-changes format.	December 22, 2009
• Original applicant-proposed labeling	December 22, 2009
• Example of class labeling, if applicable	None

[3] Fill in blanks with dates of reviews, letters, etc.

❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling *(write submission/communication date at upper right of first page of each piece)*	☐ Medication Guide ☐ Patient Package Insert ☐ Instructions for Use ☐ Device Labeling ☒ None
• Most-recent draft labeling. If it is division-proposed labeling, it should be in track-changes format.	
• Original applicant-proposed labeling	
• Example of class labeling, if applicable	
❖ Labels (**full color** carton and immediate-container labels) *(write submission/communication date on upper right of first page of each submission)*	
• Most-recent draft labeling	December 22, 2009
❖ Proprietary Name • Acceptability/non-acceptability letter(s) *(indicate date(s))* • Review(s) *(indicate date(s))*	 N/A N/A
❖ Labeling reviews *(indicate dates of reviews and meetings)*	☐ RPM ☐ DMEPA September 28, 2010 ☒ DRISK July 9, 2010 ☐ DDMAC ☐ CSS ☒ Other reviews OSE; September 27, 2010
Administrative / Regulatory Documents	
❖ Administrative Reviews *(e.g., RPM Filing Review[4]/Memo of Filing Meeting) (indicate date of each review)* ❖ All NDA (b)(2) Actions: Date each action cleared by (b)(2) Clearance Cmte ❖ NDA (b)(2) Approvals Only: 505(b)(2) Assessment *(indicate date)*	October 18, 2010 ☐ Not a (b)(2) October 12, 2010 ☐ Not a (b)(2)
❖ NDAs only: Exclusivity Summary *(signed by Division Director)*	☐ Included
❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm	
• Applicant is on the AIP	☐ Yes ☒ No
• This application is on the AIP o If yes, Center Director's Exception for Review memo *(indicate date)* o If yes, OC clearance for approval *(indicate date of clearance communication)*	☐ Yes ☒ No ☐ Not an AP action
❖ Pediatrics *(approvals only)* • Date reviewed by PeRC September 8, 2010 If PeRC review not necessary, explain: N/A • Pediatric Page/Record *(approvals only, must be reviewed by PERC before finalized)*	 ☐ Included
❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent *(include certification)*	☒ Verified, statement is acceptable

[4] Filing reviews for scientific disciplines should be filed behind the respective discipline tab.

❖ Outgoing communications *(letters (except action letters), emails, faxes, telecons)*	Refer to Outgoing Comm. tab in Action Pkg.
❖ Internal memoranda, telecons, etc.	None
❖ Minutes of Meetings	
• Regulatory Briefing *(indicate date of mtg)*	☐ No mtg
• If not the first review cycle, any end-of-review meeting *(indicate date of mtg)*	☐ N/A or no mtg
• Pre-NDA/BLA meeting *(indicate date of mtg)*	☐ No mtg
• EOP2 meeting *(indicate date of mtg)*	☐ No mtg
• Other milestone meetings (e.g., EOP2a, CMC pilots) *(indicate dates of mtgs)*	Pre IND; June 4, 2008
❖ Advisory Committee Meeting(s)	☒ No AC meeting
• Date(s) of Meeting(s)	
• 48-hour alert or minutes, if available *(do not include transcript)*	
Decisional and Summary Memos	
❖ Office Director Decisional Memo *(indicate date for each review)*	☒ None
Division Director Summary Review *(indicate date for each review)*	☐ None October 22, 2010
Cross-Discipline Team Leader Review *(indicate date for each review)*	☐ None October 22, 2010
PMR/PMC Development Templates *(indicate total number)*	☒ None
Clinical Information[5]	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) *(indicate date for each review)*	N/A
• Clinical review(s) *(indicate date for each review)*	July 2, 2010
• Social scientist review(s) (if OTC drug) *(indicate date for each review)*	☒ None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here ☒ and include a review/memo explaining why not *(indicate date of review/memo)*	None No Clinical Studies were done
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers *(indicate date of each review)*	☒ None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation *(indicate date of each review)*	☒ Not applicable
❖ Risk Management • REMS Documents and Supporting Statement *(indicate date(s) of submission(s))* • REMS Memo(s) and letter(s) *(indicate date(s))* • Risk management review(s) and recommendations (including those by OSE and CSS) *(indicate date of each review and indicate location/date if incorporated into another review)*	☒ None
❖ DSI Clinical Inspection Review Summary(ies) *(include copies of DSI letters to investigators)*	☐ None requested

[5] Filing reviews should be filed with the discipline reviews.

Clinical Microbiology ☒ None	
❖ Clinical Microbiology Team Leader Review(s) *(indicate date for each review)*	☐ None
Clinical Microbiology Review(s) *(indicate date for each review)*	☐ None
Biostatistics ☒ None	
❖ Statistical Division Director Review(s) *(indicate date for each review)*	☐ None
Statistical Team Leader Review(s) *(indicate date for each review)*	☐ None
Statistical Review(s) *(indicate date for each review)*	☐ None
Clinical Pharmacology ☐ None	
❖ Clinical Pharmacology Division Director Review(s) *(indicate date for each review)*	☒ None
Clinical Pharmacology Team Leader Review(s) *(indicate date for each review)*	☒ None
Clinical Pharmacology review(s) *(indicate date for each review)*	☐ None September 10, 2010
❖ DSI Clinical Pharmacology Inspection Review Summary *(include copies of DSI letters)*	☒ None
Nonclinical ☐ None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) *(indicate date for each review)*	☒ None
• Supervisory Review(s) *(indicate date for each review)*	☒ None
• Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	☐ None September 9, 2010
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer *(indicate date for each review)*	☒ None
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	☒ No carc
❖ ECAC/CAC report/memo of meeting	☒ None Included in P/T review, page
❖ DSI Nonclinical Inspection Review Summary *(include copies of DSI letters)*	☒ None requested
Product Quality ☐ None	
❖ Product Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) *(indicate date for each review)*	☒ None
• Branch Chief/Team Leader Review(s) *(indicate date for each review)*	☐ None October 19, 2010
• Product quality review(s) including ONDQA biopharmaceutics reviews *(indicate date for each review)*	☐ None October 19, 2010
❖ Microbiology Reviews ☒ NDAs: Microbiology reviews (sterility & pyrogenicity) (OPS/NDMS) *(indicate date of each review)* ☐ BLAs: Sterility assurance, microbiology, facilities reviews (DMPQ/MAPCB/BMT) *(indicate date of each review)*	☐ Not needed October 5, 2010
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer *(indicate date of each review)*	☐ None Biopharmaceutics; July 22, 2010

❖ Environmental Assessment (check one) (original and supplemental applications)	
☒ Categorical Exclusion *(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)*	CMC Review; October 19, 2010
☐ Review & FONSI *(indicate date of review)*	
☐ Review & Environmental Impact Statement *(indicate date of each review)*	
❖ Facilities Review/Inspection	
☐ NDAs: Facilities inspections (include EER printout) *(date completed must be within **2 years** of action date) (only original NDAs and supplements that include a new facility or a change that affects the manufacturing sites[6])*	Date completed: October 4, 2010 ☒ Acceptable ☐ Withhold recommendation ☐ Not applicable
☐ BLAs: TB-EER *(date of most recent TB EER must be within **30 days** of action date) (original and supplemental BLAs)*	Date completed: ☐ Acceptable ☐ Withhold recommendation
❖ NDAs: Methods Validation *(check box only, do not include documents)*	☐ Completed ☐ Requested ☐ Not yet requested ☒ Not needed (per review)

[6] I.e., a new facility or a change in the facility, or a change in the manufacturing process in a way that impacts the Quality Management Systems of the facility.

Appendix to Action Package Checklist

An NDA or NDA supplemental application is likely to be a 505(b)(2) application if:

(1) It relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application.
(2) **Or** it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval.
(3) **Or** it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations(see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

(1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies).
(2) **And** no additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application.
(3) **And** all other "criteria" are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

(1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2).
(2) **Or** the applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement.
(3) **Or** the applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE's ADRA.

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/s/

KIM J ROBERTSON
10/22/2010
Action Package Checklist NDA 201195; Docetaxel Inj. Accord Healthcare 505(b)(2)

From: Robertson, Kim
Sent: Sunday, September 19, 2010 9:45 PM
To: Sabita Nair
Cc: samir mehta
Subject: NDA 201195; Docetaxel Inj.

Importance: High

Hello Sabita:

Please see the following comment, as it pertains to your Docetaxel for Injection application:

The drug product release specification provides a limit for bacterial endotoxins of NMT [redacted] (b) (4) while the diluent release specification includes a limit for this attribute of NMT [redacted] (b) (4) Preparation of a dose of 100 mg/m^2 for a patient with a BSA of 1.8m^2 would necessitate the use of 9 product vials and 9 diluent vials. If both the product and diluent contain the maximum allowable limit for bacterial endotoxins, a total load of [redacted] (b) (4) will be delivered to the patient. An endotoxin load of [redacted] (b) (4) exceeds the USP<85> allowable limit of 350 EU per hour.

- Lower the diluent limit for bacterial endotoxins to provide an individual with a BSA of 1.8m^2 a margin of safety regarding bacterial endotoxins. Reference is made to USP<85> which states the following regarding the establishment of endotoxin limits:
  "For formulations (usually anticancer products) administered on a per square meter body surface, the formula is K/M, where K 5 EU/kg and M is the (maximum dose/m^2/hour x 1.80 m^2)/70 Kg."

Thank you,
Kim

Kim J. Robertson
Consumer Safety Officer
Division of Drug Oncology Products
Phone: (301) 796-1441
Fax: (301) 796-9845

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/s/

KIM J ROBERTSON
09/19/2010
NDA 201195 CMC Micro Info. Request; Docetaxel Inj.; Accord Healthcare

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195

INFORMATION REQUEST

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

Please refer to your December 21, 2009 New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL.

We are reviewing the Chemistry and Non-clinical 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. Using the analytical method in your NDA, there are two new impurity peaks identified as RRT (b) (4) and RRT (b) (4) The acceptance criteria for these two compounds are set at NMT (b) (4) This acceptance criteria is above the threshold of 0.2% set by ICH Q3B (R2) based on the maximum daily dose of 180 mg/person. Please identify these two impurity peaks.

   If the impurity peaks at RRT (b) (4) and RRT (b) (4) cannot be identified, their levels should be adequately justified (e.g. based on nonclinical studies), or reduced to meet the ICH Q3B(R2) threshold. If the impurity peaks at RRT (b) (4) and RRT (b) (4) are identified to be an impurity in the RLD, their levels should be reduced not to exceed the levels in the RLD; levels above the RLD should be adequately justified based on nonclinical or clinical studies.

We also refer to our June 29, 2010, letter in which we notified you that you have failed to meet the commitment in the pre-NDA agreement dated May 6, 2008 in which you were to file updated stability data prior to the mid-cycle date (May 22, 2010). Therefore, any submission of additional stability date will be considered a major amendment that extends the review clock, should we elect to review the data in this cycle.

As indicated above, we require a prompt written response to these issues in order to continue our evaluation of your NDA.

If you have any questions, call Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Sarah Pope-Miksinski, Ph.D.
Branch Chief
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

WILLIAM M ADAMS
08/02/2010
William Adams, acting for Sarah Pope Miksinski

From: Robertson, Kim
Sent: Tuesday, June 29, 2010 6:05 PM
To: Sabita Nair
Cc: samir mehta
Subject: NDA 201195; Docetaxel Injection--CMC Deficiencies

Importance: High

Attachments: 29June10 Deficiencies Preclude Discussions for NDA 201195 Docetaxel Inj (COR-NDAIR-22) (3).pdf

Hello Sabita:

I hope you are well.

Please see the attached .pdf document, as it pertains to your 505(b)(2) NDA for Docetaxel Injection. It is imperative that you review this correspondence right away.

Please let us know if you have any concerns regarding this correspondence as soon as possible.

Regards,
Kim

29June10
iencies Preclu

Kim J. Robertson
Consumer Safety Officer
Division of Drug Oncology Products
Phone: (301) 796-1441
Fax: (301) 796-9845

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195

DEFICIENCIES PRECLUDE DISCUSSION

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

Please refer to your December 21, 2009 New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL.

We also refer to our March 5, 2010, letter in which we notified you of our target date of September 24, 2010 for communicating labeling changes and/or postmarketing requirements/commitments in accordance with the "PDUFA Reauthorization Performance Goals And Procedures Fiscal Years 2008 Through 2012."

As part of our ongoing review of your application, we have identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time:

1. Revise the drug product release specification to include single criteria for purity and related substances to be used at release and on stability. Include a justification for the proposed criteria.

2. In section 3.2.P.2 Table 18, Comparator Comparison Stability Study, the levels of impurity (b) (4) at 3 and 6 months are lower at 40±2°C/75±5% RH than at 25±2°C/60±5% RH. However, other impurity levels are generally higher at the higher temperature than at the lower temperature. Explain this apparent discrepancy.

3. Either provide additional stability data and information to support the proposed storage condition (b) (4) in the absence of light) or revise the proposed label storage statement to indicate a condition supported by the submitted long-term stability studies. The current stability information is not sufficient to support storage (b) (4)

4. Provide additional long term stability data to support the proposed initial drug product expiry period. The submitted 6 month data is not sufficient to support approval (b) (4)

   You have failed to meet the commitment in the pre-NDA agreement dated May 6, 2008 in which you were to file updated stability data prior to the mid-cycle date (May 22, 2010). Therefore, any submission of additional stability date will be considered a major amendment that extends the review clock, should we elect to review the data in this cycle.

This notification does not reflect a final decision on the information under review.

If you have any questions, call Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Sarah Pope-Miksinski, Ph.D.
Branch Chief
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

WILLIAM M ADAMS
06/29/2010
William Adams, acting for Sarah Pope Miksinski

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

KIM J ROBERTSON
06/29/2010
NDA 201195; Docetaxel Inj. CMC Deficiencies conveyed to the applicant-Accord Healthcare

From: Robertson, Kim
Sent: Thursday, May 27, 2010 6:46 PM
To: Sabita Nair
Cc: samir mehta
Subject: RE: Docetaxel Question

Importance: High

Hello Sabita:

After reviewing Accord Healthcare's pediatric waiver, the clinicians discerned the following:

- Your pediatric waiver is inadequate because the waiver did not include all the indications listed in your proposed label. Besides the waivers for BCA, NSCLC, and HRPC, you should also ask for pediatric waivers for the gastric CA and HNSCC indications. Please note that the Taxotere pediatric head and neck study was for non-squamous cell cancers and that there isn't a pediatrics indication.

Please submit a revised pediatric waiver. We will accept a courtesy copy to review right away; however, you will still need to submit it officially to your NDA.

Regards,
Kim

From: Sabita Nair [mailto:snair@intaspharma.com]
Sent: Monday, May 24, 2010 4:07 PM
To: Robertson, Kim
Cc: samir mehta
Subject: RE: Docetaxel Question

Hello Kim,

Enclosed is the pdf version of the waiver letter.
I will arrange to re-send all of the documents to the address given below by FedEx.

Regards,
Sabita

Sabita Nair, RAC
Asst. Director-Regulatory Affairs

INTAS PHARMACEUTICALS LTD./ACCORD HEALTHCARE INC.
1009 Slater Road, Suite 210-B, Durham NC 27703, USA
Tel : 919-941-7880; Fax: 919-941-7885;
E-Mail: snair@intaspharma.com

From: Robertson, Kim [mailto:Kim.Robertson@fda.hhs.gov]
Sent: Monday, May 24, 2010 2:13 PM
To: Sabita Nair
Cc: samir mehta
Subject: RE: Docetaxel Question

The address you provided is correct Sabita. Do you happen to have a .pdf version of the waiver that you can send to us via e-mail, so that we may review it now?

Kim

From: Sabita Nair [mailto:snair@intaspharma.com]
Sent: Monday, May 24, 2010 12:41 PM
To: Robertson, Kim
Cc: samir mehta
Subject: RE: Docetaxel Question

Hello Kim,

The submission that was sent on February 17 (and which was delivered through FedEx priority overnight on Feb. 18) was titled **Clinical Amendment to the NDA # 201195**.

In order for me to send this information again, I wanted to re-confirm the address of the dispatch:

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

Please let me know if the above address is correct, and I will arrange to dispatch these documents soonest.

Thanks.

Regards,
Sabita

Sabita Nair, RAC
Asst. Director-Regulatory Affairs

INTAS PHARMACEUTICALS LTD./ACCORD HEALTHCARE INC.
1009 Slater Road, Suite 210-B, Durham NC 27703, USA
Tel : 919-941-7880; Fax: 919-941-7885;
E-Mail: snair@intaspharma.com

From: Robertson, Kim [mailto:Kim.Robertson@fda.hhs.gov]
Sent: Monday, May 24, 2010 12:00 PM
To: Sabita Nair
Cc: samir mehta
Subject: RE: Docetaxel Question

Thank you Sabita. Upon looking in our database, I do not see a February 17, 2010 submission of this and the other information you mentioned. All of these items need to be submitted right away *officially* to the NDA.

Thank you,
Kim

From: Sabita Nair [mailto:snair@intaspharma.com]
Sent: Monday, May 24, 2010 11:36 AM
To: Robertson, Kim
Cc: samir mehta
Subject: RE: Docetaxel Question

Dear Kim,

Accord did submit a Pediatric Waiver request for the Docetaxel NDA. The waiver request was included in a communication dated February 17, 2010. This communication also included two other pieces of information, namely, the request for Categorical exclusion from Environmental Assessment and Form 3542a.

Please do let me know if you need any further information in this context.

Thank you.

Regards,
Sabita

Sabita Nair, RAC
Asst. Director-Regulatory Affairs

INTAS PHARMACEUTICALS LTD./ACCORD HEALTHCARE INC.
1009 Slater Road, Suite 210-B, Durham NC 27703, USA
Tel : 919-941-7880; Fax: 919-941-7885;
E-Mail: snair@intaspharma.com

From: Robertson, Kim [mailto:Kim.Robertson@fda.hhs.gov]
Sent: Monday, May 24, 2010 10:59 AM
To: Sabita Nair
Subject: Docetaxel Question
Importance: High

Hello Sabita:

A question for you.....by chance, did Accord Healthcare submit a Pediatric Waiver for their NDA for Docetaxel?

Please advise.

Thanks,

Kim

Kim J. Robertson

Consumer Safety Officer

Division of Drug Oncology Products

Phone: (301) 796-1441

Fax: (301) 796-9845

Docetaxel Question

DISCLAIMER:
Please note that this e-mail and its attachments are intended for the named addressee only and may contain information that is confidential and privileged. If you have by coincidence or mistake or without specific authorization received this e-mail and its attachments we request that you notify us immediately that you have received them in error, uphold strict confidentiality and neither read, copy, nor otherwise make use of their content in any way. Please note that the sender of this e-mail and its attachments is solely responsible for its content if it does not concern the operations of Intas group or its subsidiaries.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

KIM J ROBERTSON
05/27/2010
Inadequate Pediatric Waiver re: NDA 201195; Docetaxel Injection; Accord Healthcare

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195 **INFORMATION REQUEST**

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL.

We are reviewing the pharmacology/toxicology and chemistry 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.

INFORMATION REQUEST:

1. The NDA submission for Docetaxel Injection indicates that citric acid will be added as an excipient (q.s.to pH) to the formulation of your drug product. Please provide the actual amount of citric acid in each docetaxel (i.e. 20 mg/0.5mL and 80 mg/2.0 mL) vial.

2. The NDA also indicates that polysorbate (PS) 80 will be added (b) (4) to the formulation of your drug product. Please provide the actual amount of PS 80 in each docetaxel vial and the ratio of PS80 to docetaxel, in the docetaxel vials and in the initial diluted solutions.

3. Please indicate if the Product Shelf-life Specification submitted on page 11 of Section 3.2.P.5.1a of your submission is the most updated specification of individual impurities for your drug product.

If you have any questions, call Kim J. Robertson, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Kim J. Robertson
Consumer Safety Officer
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

KIM J ROBERTSON
05/06/2010
Pharmtox CMC Information Request re: NDA 201195; Docetaxel; Accord Healthcare

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

REQUEST FOR CONSULTATION

TO *(Office/Division)*: CDER OSE CONSULT			FROM (*Name, Office/Division, and Phone Number of Requestor)*: HFD-150/DDOP/Kim Robertson, 6-1441	
DATE March 7, 2010	IND NO.	NDA NO. 201195	TYPE OF DOCUMENT 505(b)(2); PI & Carton and Container Labels	DATE OF DOCUMENT December 21, 2009
NAME OF DRUG Docetaxel Injection (b) (4)	PRIORITY CONSIDERATION Priority		CLASSIFICATION OF DRUG 5	DESIRED COMPLETION DATE August 31, 2010

NAME OF FIRM: Accord Healthcare, Inc.

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END-OF-PHASE 2a MEETING
- ☐ END-OF-PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☒ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END-OF-PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL - BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: At this time, DDOP is requesting that OSE reviews the sponsor proposed product PI and labeling for this (b)(2) NDA. This is a paper NDA; however, the components that OSE requires to intiate their review can be found in the EDR at the following pathway link: \\FDSWA150\NONECTD\N201195\N_000\2009-12-21. To facilitate your review, I will send via email the labels and PI once the PI for the Listed Drug (Taxotere) has been finalized.

Clinical reviewer: Qin Ryan, M.D, Ph.D.; CMC: Sarah Pope-Misinski, Ph.D.; CSO: Kim Robertson

SIGNATURE OF REQUESTOR Kim Robertson, CSO	METHOD OF DELIVERY (Check one) ☒ DFS ☒ EMAIL ☐ MAIL ☐ HAND
PRINTED NAME AND SIGNATURE OF RECEIVER	PRINTED NAME AND SIGNATURE OF DELIVERER

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

KIM J ROBERTSON
03/07/2010
07March10 OSE Consult for NDA 201195; Docetaxel Inj. (b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195

FILING COMMUNICATION

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

Please refer to your new drug application (NDA) dated December 21, 2009, received December 22, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 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 October 22, 2010.

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, midcycle, 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 September 24, 2010.

During our filing review of your application, we identified the following potential review issues:

1. Stability data for the prepared infusion solution are not provided.

2. In-use stability and compatibility data are not provided.

We request that you submit the following information:

1. Provide stability data for the prepared infusion solution (drug product) that covers the period of intended short-term storage time.

2. Provide in-use stability and compatibility data for the drug product infusion solution.

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review. Issues may be added, deleted, expanded upon, or modified as we review the application.

If you have not already done so, you must 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. The content of labeling must be in the Prescribing Information (physician labeling rule) format.

Please respond only to the above requests for additional 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.

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We acknowledge receipt of your request for a full waiver of pediatric studies for this application. Once we have reviewed your request, we will notify you if the full waiver request is denied and a pediatric drug development plan is required.

If you have any questions, call Kim J. Robertson, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

ANTHONY J MURGO

03/05/2010

Anthony J. Murgo, M.D., M.S., signing for:
Robert L. Justice, M.D., M.S.

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

REQUEST FOR CONSULTATION

TO *(Office/Division)*:	FROM (*Name, Office/Division, and Phone Number of Requestor)*:
David Hussong/Jim McVey/Sylvia Gantt NEW DRUG MICROBIOLOGY STAFF OC/OO/CDER/OPS/NDMS - HFD-805	Haripada Sarker, ONDQA, through Deborah Mesmer, 301-796-4023

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
February 03, 2010		201195	NDA original submission, 505(b)(2)	December 21, 2009 Received December 22, 2009

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Docetaxel Injection, 20 mg and 80 mg	Not yet determined	Oncology	May 21, 2010

NAME OF FIRM: Accord Healthcare Inc

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END-OF-PHASE 2a MEETING
- ☐ END-OF-PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☒ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END-OF-PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL - BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: A microbiology review is requested for this 505(b)(2) application. The jackets will be provided to the assigned reviewer.

Chemistry Reviewer: Ted Chang
OND Project Manager: Kim Robertson
ONDQA PAL: Haripada Sarker
ONDQA RPM: Debbie Mesmer

Please notify Debbie Mesmer of reviewer assignment.

SIGNATURE OF REQUESTOR {See appended electronic signature page}	METHOD OF DELIVERY (Check one) ☒ DFS ☒ EMAIL ☐ MAIL ☐ HAND
PRINTED NAME AND SIGNATURE OF RECEIVER	PRINTED NAME AND SIGNATURE OF DELIVERER

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

DEBORAH M MESMER
02/04/2010

HARIPADA SARKER
02/04/2010

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

REQUEST FOR CONSULTATION

TO *(Office/Division)*:	FROM (*Name, Office/Division, and Phone Number of Requestor)*:
Patrick Marroum CDER/OPS/ONDQA, Angelica Dorantes CDER/OPS/ONDQA	Haripada Sarker, ONDQA, through Deborah Mesmer, 301-796-4023

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
February 03, 2010		201195	NDA original submission, 505(b)(2)	December 21, 2009 Received December 22, 2009

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Docetaxel Injection, 20 mg and 80 mg	Not yet determined	Oncology	May 21, 2010

NAME OF FIRM: Accord Healthcare Inc

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE NDA MEETING
- ☐ END OF PHASE 2a MEETING
- ☐ END OF PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☒ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END OF PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL BIOPHARMACEUTICS
- ☐ IN VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: A biopharmaceutics review is requested for this 505(b)(2) application. The jackets will be provided to the assigned reviewer.

Chemistry Reviewer: Ted Chang
OND Project Manager: Kim Robertson
ONDQA PAL: Haripada Sarker
ONDQA RPM: Debbie Mesmer

Please notify Debbie Mesmer of reviewer assignment.

SIGNATURE OF REQUESTOR

METHOD OF DELIVERY (Check one)

{See appended electronic signature page}	☒ DFS ☒ EMAIL ☐ MAIL ☐ HAND
PRINTED NAME AND SIGNATURE OF RECEIVER	PRINTED NAME AND SIGNATURE OF DELIVERER

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

DEBORAH M MESMER
02/04/2010

HARIPADA SARKER
02/04/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195

INFORMATION REQUEST

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

Please refer to your New Drug Application (NDA) submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL.

Upon the initial review of your submission, we have determined that we are in need of an additional four (4) copies of the following modules of your paper NDA: Module 1, and Module 3. We also request that Accord Healthcare, Inc. makes a .pdf copy of the aforementioned modules and burn them to a CD. You may mail the CD directly to me at the following address:

Food and Drug Administration
Center for Drugs and Evaluation Research
White Oak Building #22
10903 New Hampshire Avenue
Silver Spring, MD 20903
Attention: Kim J. Robertson
Room #: 2123

If you have any questions, call Kim J. Robertson, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Kim J. Robertson
Consumer Safety Officer
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

KIM J ROBERTSON
02/01/2010
NDA 201195 Request for Additional Copies of Mods. 1 and 3 of NDA.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201195

NDA ACKNOWLEDGMENT

Accord Healthcare, Inc. USA
1009 Slater Road
Suite 210-B
Durham, NC 27703

Attention: Samir Mehta, Ph.D.
President

Dear Dr. Mehta:

We have received your new drug application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Docetaxel Injection; 20 mg/0.5 mL and 80 mg/2.0 mL

Date of Application: December 21, 2009

Date of Receipt: December 22, 2009

Our Reference Number: NDA # 201195

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 February 21, 2010 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.

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 Drug Oncology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm

If you have any questions, call Kim J. Robertson, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Kim J. Robertson
Consumer Safety Officer
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201195	ORIG-1	ACCORD HEALTHCARE INC	DOCETAXEL INJECTION 20 MG and 80 MG

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/s/

KIM J ROBERTSON
02/01/2010
Acknowledgement Letter for NDA 201195; Docetaxel Injection; Accord Healthcare, Inc. USA