

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**207174Orig1s000**

**ADMINISTRATIVE and CORRESPONDENCE  
DOCUMENTS**

## EXCLUSIVITY SUMMARY

NDA # 207174

SUPPL #

HFD #

Trade Name: n/a

Generic Name: paricalcitol injection

Applicant Name: Accord Healthcare, Inc.

Approval Date, If Known February 5, 2015

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

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

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

YES  NO

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

505 (b)(2)

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

YES  NO

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

No clinical, bioavailability, or bioequivalence data was submitted to this original application. The applicant is claiming they are same as the listed drug, NDA 020819, Zemplar (paricalcitol injection). Nonclinical and CMC data were submitted to this application.

FDA granted a waiver of the in vivo bioequivalence study requirement per review dated 12/3/2014.

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

c) Did the applicant request exclusivity?

YES  NO

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

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

YES  NO

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

Pediatric exclusivity has been granted for NDA 020819, Zemplar (paricalcitol injection), the listed drug for this application, NDA 207174.

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# 20819 Zemlar (paricalcitol injection)

NDA#

NDA#

## 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: Meghna M. Jairath, Pharm.D.

Title: Regulatory Project Manager

Date: February 4, 2016

Name of Office/Division Director signing form: Jean-Marc Guettier, M.D.  
Title: Division Director

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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PAMELA LUCARELLI  
02/04/2016

JEAN-MARC P GUETTIER  
02/04/2016

# ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION <sup>1</sup>		
NDA # 207174 BLA #	NDA Supplement # BLA Supplement #	If NDA, Efficacy Supplement Type: <i>(an action package is not required for SE8 or SE9 supplements)</i>
Proprietary Name: : none submitted Established/Proper Name: paricalcitol Dosage Form: Injection [2 mcg/mL (1 mL) and 5 mcg/mL (1 mL and 2 mL)]		Applicant: Accord Healthcare Inc. Agent for Applicant (if applicable):
RPM: Meghna M. Jairath		Division: Metabolism and Endocrinology Products
NDA Application Type: <input type="checkbox"/> 505(b)(1) <input checked="" type="checkbox"/> 505(b)(2) Efficacy Supplement: <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)  BLA Application Type: <input type="checkbox"/> 351(k) <input type="checkbox"/> 351(a) Efficacy Supplement: <input type="checkbox"/> 351(k) <input type="checkbox"/> 351(a)		<p><b><u>For ALL 505(b)(2) applications, two months prior to EVERY action:</u></b></p> <ul style="list-style-type: none"> <li><b>Review the information in the 505(b)(2) Assessment and submit the draft<sup>2</sup> to CDER OND IO for clearance.</b></li> <li><b>Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)</b></li> </ul> <p><input checked="" type="checkbox"/> No changes  <input type="checkbox"/> New patent/exclusivity <i>(notify CDER OND IO)</i>            Date of check: January 27, 2016</p> <p><i>Note: 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.</i></p>
❖ Actions		
<ul style="list-style-type: none"> <li>Proposed action</li> <li>User Fee Goal Date is February 5, 2016 but the approval was taken on February 4, 2016</li> </ul>		<input checked="" type="checkbox"/> AP <input type="checkbox"/> TA <input type="checkbox"/> CR
<ul style="list-style-type: none"> <li>Previous actions <i>(specify type and date for each action taken)</i></li> </ul>		<input type="checkbox"/> None    CR- January 29, 2015
❖ 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 <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf</a> ). If not submitted, explain _____		<input type="checkbox"/> Received
❖ Application Characteristics <sup>3</sup>		

<sup>1</sup> The **Application Information** Section is (only) a checklist. The **Contents of Action Package** Section (beginning on page 2) lists the documents to be included in the Action Package.

<sup>2</sup> For resubmissions, 505(b)(2) applications must be cleared before the action, but it is not necessary to resubmit the draft 505(b)(2) Assessment to CDER OND IO unless the Assessment has been substantively revised (e.g., new listed drug, patent certification revised).

<sup>3</sup> 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.

Review priority:  Standard  Priority  
 Chemical classification (new NDAs only):  
*(confirm chemical classification at time of approval)*

- |   |   |
|---|---|
| <input type="checkbox"/> Fast Track                       | <input type="checkbox"/> Rx-to-OTC full switch    |
| <input type="checkbox"/> Rolling Review                   | <input type="checkbox"/> Rx-to-OTC partial switch |
| <input type="checkbox"/> Orphan drug designation          | <input type="checkbox"/> Direct-to-OTC            |
| <input type="checkbox"/> Breakthrough Therapy designation |   |

**(NOTE: Set the submission property in DARRTS and notify the CDER Breakthrough Therapy Program Manager; Refer to the "RPM BT Checklist for Considerations after Designation Granted" for other required actions: [CST SharePoint](#))**

NDAs: Subpart H

- Accelerated approval (21 CFR 314.510)  
 Restricted distribution (21 CFR 314.520)

Subpart I

- 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

BLAs: Subpart E

- Accelerated approval (21 CFR 601.41)  
 Restricted distribution (21 CFR 601.42)

Subpart H

- Approval based on animal studies

- REMS:  MedGuide  
 Communication Plan  
 ETASU  
 MedGuide w/o REMS  
 REMS not required

Comments:

❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 (approvals only)	<input type="checkbox"/> Yes <input type="checkbox"/> No
❖ Public communications (approvals only)	
• Office of Executive Programs (OEP) liaison has been notified of action	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
• Indicate what types (if any) of information were issued	<input checked="" type="checkbox"/> None <input type="checkbox"/> FDA Press Release <input type="checkbox"/> FDA Talk Paper <input type="checkbox"/> CDER Q&As <input type="checkbox"/> Other
❖ Exclusivity	
• Is approval of this application blocked by any type of exclusivity (orphan, 5-year NCE, 3-year, pediatric exclusivity)? • If so, specify the type	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
❖ Patent Information (NDAs only)	
• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought.	<input checked="" type="checkbox"/> Verified <input type="checkbox"/> Not applicable because drug is an old antibiotic.
<b>CONTENTS OF ACTION PACKAGE</b>	
<b>Officer/Employee List</b>	
❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list (approvals only)	<input checked="" type="checkbox"/> Included
Documentation of consent/non-consent by officers/employees	<input type="checkbox"/> Included

### Action Letters

❖ Copies of all action letters ( <i>including approval letter with final labeling</i> )	Action(s) and date(s) AP- draft January 27, 2016 CR-January 29, 2015
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### Labeling

❖ Package Insert ( <i>write submission/communication date at upper right of first page of PI</i> )	
--	--

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• Most recent draft labeling (<i>if it is division-proposed labeling, it should be in track-changes format</i>)</li> </ul> | <input type="checkbox"/> Included<br>See approval letter |
| <ul style="list-style-type: none"> <li>• Original applicant-proposed labeling</li> </ul>  | <input type="checkbox"/> Included                        |

❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling ( <i>write submission/communication date at upper right of first page of each piece</i> )	<input type="checkbox"/> Medication Guide <input type="checkbox"/> Patient Package Insert <input type="checkbox"/> Instructions for Use <input type="checkbox"/> Device Labeling <input checked="" type="checkbox"/> None
--	---

- |   |                                   |
|---|-----------------------------------|
| <ul style="list-style-type: none"> <li>• Most-recent draft labeling (<i>if it is division-proposed labeling, it should be in track-changes format</i>)</li> </ul> | <input type="checkbox"/> Included |
| <ul style="list-style-type: none"> <li>• Original applicant-proposed labeling</li> </ul>  | <input type="checkbox"/> Included |

❖ Labels ( <b>full color</b> carton and immediate-container labels) ( <i>write submission/communication date on upper right of first page of each submission</i> )	
--	--

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Most-recent draft labeling</li> </ul> | <input type="checkbox"/> Included<br>See approval letter |
|--|--|

❖ Proprietary Name <ul style="list-style-type: none"> <li>• Acceptability/non-acceptability letter(s) (<i>indicate date(s)</i>)</li> <li>• Review(s) (<i>indicate date(s)</i>)</li> </ul>	No propriety name was submitted
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❖ Labeling reviews ( <i>indicate dates of reviews</i> )	RPM: <input type="checkbox"/> None 5/15/14 DMEPA: <input type="checkbox"/> None 11/17 and 12/3/14 and 11/24/15 DMPP/PLT (DRISK): <input checked="" type="checkbox"/> None OPDP: <input type="checkbox"/> None 1/28/15 and 1/22/16 SEALD: <input checked="" type="checkbox"/> None CSS: <input checked="" type="checkbox"/> None Product Quality <input type="checkbox"/> None Other: <input checked="" type="checkbox"/> None
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### Administrative / Regulatory Documents

❖ RPM Filing Review <sup>4</sup> /Memo of Filing Meeting ( <i>indicate date of each review</i> ) ❖ All NDA 505(b)(2) Actions: Date each action cleared by 505(b)(2) Clearance Committee	5/15/14  <input type="checkbox"/> Not a (b)(2) AP- 505 (b)(2) Clearance Committee gave clearance email dated 1/6/16. CR- 505 (b)(2) Clearance Committee gave clearance email dated 1/5/15
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❖ NDAs only: Exclusivity Summary ( <i>signed by Division Director</i> )	<input checked="" type="checkbox"/> Included
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❖ Application Integrity Policy (AIP) Status and Related Documents <a href="http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm">http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm</a>	
<ul style="list-style-type: none"> <li>• Applicant is on the AIP</li> </ul>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> <li>• This application is on the AIP                     <ul style="list-style-type: none"> <li>○ If yes, Center Director’s Exception for Review memo (<i>indicate date</i>)</li> <li>○ If yes, OC clearance for approval (<i>indicate date of clearance communication</i>)</li> </ul> </li> </ul>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  <input type="checkbox"/> Not an AP action
❖ Pediatrics ( <i>approvals only</i> ) <ul style="list-style-type: none"> <li>• Date reviewed by PeRC _____ If PeRC review not necessary, explain: _____</li> </ul>	n/a Did not trigger PREA
❖ Breakthrough Therapy Designation	<input checked="" type="checkbox"/> N/A
<ul style="list-style-type: none"> <li>• Breakthrough Therapy Designation Letter(s) (granted, denied, an/or rescinded)</li> </ul>	
<ul style="list-style-type: none"> <li>• CDER Medical Policy Council Breakthrough Therapy Designation Determination Review Template(s) (<i>include only the completed template(s) and not the meeting minutes</i>)</li> </ul>	
<ul style="list-style-type: none"> <li>• CDER Medical Policy Council Brief – Evaluating a Breakthrough Therapy Designation for Rescission Template(s) (<i>include only the completed template(s) and not the meeting minutes</i>)</li> </ul> <p>(<i>completed CDER MPC templates can be found in DARRTS as clinical reviews or on the <a href="#">MPC SharePoint Site</a></i>)</p>	
❖ Outgoing communications: letters, emails, and faxes considered important to include in the action package by the reviewing office/division (e.g., clinical SPA letters, RTF letter, Formal Dispute Resolution Request decisional letters, etc.) ( <i>do not include OPDP letters regarding pre-launch promotional materials as these are non-disclosable; do not include previous action letters, as these are located elsewhere in package</i> )	4/3/14, 6/2/14, 9/8/14, 9/17/14, 11/26/14, 12/8/14, 1/6/15, 1/29/15, 1/30/15, 8/19/15, 11/18/15, 1/27/16 and 2/4/16
❖ Internal documents: memoranda, telecons, emails, and other documents considered important to include in the action package by the reviewing office/division (e.g., Regulatory Briefing minutes, Medical Policy Council meeting minutes)	n/a
❖ Minutes of Meetings	
<ul style="list-style-type: none"> <li>• If not the first review cycle, any end-of-review meeting (<i>indicate date of mtg</i>)</li> </ul>	<input checked="" type="checkbox"/> N/A or no mtg
<ul style="list-style-type: none"> <li>• Pre-NDA/BLA meeting (<i>indicate date of mtg</i>)</li> </ul>	<input checked="" type="checkbox"/> No mtg
<ul style="list-style-type: none"> <li>• EOP2 meeting (<i>indicate date of mtg</i>)</li> </ul>	<input checked="" type="checkbox"/> No mtg
<ul style="list-style-type: none"> <li>• Mid-cycle Communication (<i>indicate date of mtg</i>)</li> </ul>	<input checked="" type="checkbox"/> N/A
<ul style="list-style-type: none"> <li>• Late-cycle Meeting (<i>indicate date of mtg</i>)</li> </ul>	<input checked="" type="checkbox"/> N/A
<ul style="list-style-type: none"> <li>• Other milestone meetings (e.g., EOP2a, CMC focused milestone meetings) (<i>indicate dates of mtgs</i>)</li> </ul>	

<sup>4</sup> Filing reviews for scientific disciplines are NOT required to be included in the action package.

❖ Advisory Committee Meeting(s) • Date(s) of Meeting(s)	<input checked="" type="checkbox"/> No AC meeting
<b>Decisional and Summary Memos</b>	
❖ Office Director Decisional Memo ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
Division Director Summary Review ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
Cross-Discipline Team Leader Review ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
PMR/PMC Development Templates ( <i>indicate total number</i> )	<input checked="" type="checkbox"/> None
<b>Clinical</b>	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> No separate review 2/4/16 division director review
• Clinical review(s) ( <i>indicate date for each review</i> )	12/17/14
• Social scientist review(s) (if OTC drug) ( <i>indicate date for each review</i> )	<input type="checkbox"/> None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here <input checked="" type="checkbox"/> and include a review/memo explaining why not ( <i>indicate date of review/memo</i> )	No clinical data
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers ( <i>indicate date of each review</i> )	<input checked="" type="checkbox"/> None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation ( <i>indicate date of each review</i> )	<input checked="" type="checkbox"/> N/A
❖ Risk Management • REMS Documents and REMS Supporting Document ( <i>indicate date(s) of submission(s)</i> ) • REMS Memo(s) and letter(s) ( <i>indicate date(s)</i> ) • Risk management review(s) and recommendations (including those by OSE and CSS) ( <i>indicate date of each review and indicate location/date if incorporated into another review</i> )	<input checked="" type="checkbox"/> None
❖ OSI Clinical Inspection Review Summary(ies) ( <i>include copies of OSI letters to investigators</i> )	<input checked="" type="checkbox"/> None requested
<b>Clinical Microbiology</b> <input checked="" type="checkbox"/> None	
❖ Clinical Microbiology Team Leader Review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> No separate review
Clinical Microbiology Review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> None
<b>Biostatistics</b> <input checked="" type="checkbox"/> None	
❖ Statistical Division Director Review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> No separate review
Statistical Team Leader Review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> No separate review
Statistical Review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> None
<b>Clinical Pharmacology</b> <input checked="" type="checkbox"/> None	
❖ Clinical Pharmacology Division Director Review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> No separate review
Clinical Pharmacology Team Leader Review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> No separate review
Clinical Pharmacology review(s) ( <i>indicate date for each review</i> )	<input type="checkbox"/> None
❖ OSI Clinical Pharmacology Inspection Review Summary ( <i>include copies of OSI letters</i> )	<input type="checkbox"/> None requested

<b>Nonclinical</b> <input type="checkbox"/> None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> No separate review
• Supervisory Review(s) ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> No separate review
• Pharm/tox review(s), including referenced IND reviews ( <i>indicate date for each review</i> )	<input type="checkbox"/> None 4/15/14 and 12/16/14
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
❖ Statistical review(s) of carcinogenicity studies ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> No carc
❖ ECAC/CAC report/memo of meeting	<input checked="" type="checkbox"/> None Included in P/T review, page
❖ OSI Nonclinical Inspection Review Summary ( <i>include copies of OSI letters</i> )	<input type="checkbox"/> None requested 5/23/14 and 1/9/15
<b>Product Quality</b> <input type="checkbox"/> None	
❖ Product Quality Discipline Reviews	
• Tertiary review ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
• Secondary review (e.g., Branch Chief) ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
• Integrated Quality Assessment (contains the Executive Summary and the primary reviews from each product quality review discipline) ( <i>indicate date for each review</i> )	<input type="checkbox"/> None 5/16/14 , 1/27/15 (Panorama) and 1/13/16 (Panorama)
❖ Reviews by other disciplines/divisions/Centers requested by product quality review team ( <i>indicate date of each review</i> )	<input type="checkbox"/> None Biopharmaceutics 5/16/14 and 12/2/14 (Panorama) Microbiology 4/23/14 and 1/26/15
❖ Environmental Assessment (check one) (original and supplemental applications)	
<input checked="" type="checkbox"/> Categorical Exclusion ( <i>indicate review date</i> )( <i>all original applications and all efficacy supplements that could increase the patient population</i> )	Page 48 CMC review dated 1/27/15
<input type="checkbox"/> Review & FONSI ( <i>indicate date of review</i> )	
<input type="checkbox"/> Review & Environmental Impact Statement ( <i>indicate date of each review</i> )	
❖ Facilities Review/Inspection	
<input type="checkbox"/> Facilities inspections ( <i>action must be taken prior to the re-evaluation date</i> ) ( <i>only original applications and efficacy supplements that require a manufacturing facility inspection(e.g., new strength, manufacturing process, or manufacturing site change)</i> )	<input checked="" type="checkbox"/> Acceptable Re-evaluation date: 1/12/16 <input type="checkbox"/> Withhold recommendation <input type="checkbox"/> Not applicable

Day of Approval Activities	
❖ For all 505(b)(2) applications: <ul style="list-style-type: none"> <li>• Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)</li> </ul>	<input checked="" type="checkbox"/> No changes <input type="checkbox"/> New patent/exclusivity ( <i>Notify CDER OND IO</i> )
<ul style="list-style-type: none"> <li>• Finalize 505(b)(2) assessment</li> </ul>	<input checked="" type="checkbox"/> Done
❖ For Breakthrough Therapy (BT) Designated drugs: <ul style="list-style-type: none"> <li>• Notify the CDER BT Program Manager</li> </ul>	<input type="checkbox"/> Done n/a ( <i>Send email to CDER OND IO</i> )
❖ For products that need to be added to the flush list (generally opioids): <a href="#">Flush List</a> <ul style="list-style-type: none"> <li>• Notify the Division of Online Communications, Office of Communications</li> </ul>	<input type="checkbox"/> Done n/a
❖ Send a courtesy copy of approval letter and all attachments to applicant by fax or secure email	<input checked="" type="checkbox"/> Done
❖ If an FDA communication will issue, notify Press Office of approval action after confirming that applicant received courtesy copy of approval letter	<input type="checkbox"/> Done n/a
❖ Ensure that proprietary name, if any, and established name are listed in the <i>Application Product Names</i> section of DARRTS, and that the proprietary name is identified as the “preferred” name	<input checked="" type="checkbox"/> Done
❖ Ensure Pediatric Record is accurate	<input type="checkbox"/> Done <b>n/a</b>
❖ Send approval email within one business day to CDER-APPROVALS	<input checked="" type="checkbox"/> Done

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MEGHNA M JAIRATH  
02/08/2016

**From:** [Sabita Nair](#)  
**To:** [Lucarelli, Pamela K](#)  
**Subject:** RE: NDA 207174 Final PI  
**Date:** Thursday, February 04, 2016 10:03:35 AM  
**Attachments:** [NDA 207174 final PI.DOC](#)

---

Hello Pam,

This e-mail is to confirm that the attached label is acceptable to us.  
Thank you.

Regards,  
Sabita

---

**From:** Sabita Nair  
**Sent:** Thursday, February 04, 2016 8:31 AM  
**To:** 'Lucarelli, Pamela K' <Pamela.Lucarelli@fda.hhs.gov>  
**Subject:** RE: NDA 207174 Final PI

Hi Pam,

I am acknowledging receipt of the e-mail with the label. I will respond back soonest. Thanks.

Regards,  
Sabita

---

**From:** Lucarelli, Pamela K [<mailto:Pamela.Lucarelli@fda.hhs.gov>]  
**Sent:** Thursday, February 04, 2016 8:29 AM  
**To:** Sabita Nair <[snair@intaspharma.com](mailto:snair@intaspharma.com)>  
**Subject:** NDA 207174 Final PI

Hi Sabita,

Per our phone conversation, please see the attached label. I made one additional change to update the revised date. Please confirm that this attached label is acceptable.

Thanks,  
Pam

Pamela Lucarelli  
Chief, Project Management Staff  
FDA/Center for Drug Evaluation and Research  
Division of Metabolism and Endocrinology Products  
WO22 - Room 3364  
10903 New Hampshire Avenue  
Silver Spring, MD 20903  
Phone 301.796.3961

15 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

Fax 301.796.9712

[pamela.lucarelli@fda.hhs.gov](mailto:pamela.lucarelli@fda.hhs.gov)

This Incoming email has been scanned by the Symantec Email Security.cloud service.  
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**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.

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PAMELA LUCARELLI  
02/04/2016

From: [Jairath, Meghna](#)  
To: [snair@intaspharma.com](mailto:snair@intaspharma.com)  
Subject: final labeling NDA 207174  
Date: Wednesday, January 27, 2016 12:09:47 PM  
Attachments: [NDA 207174 final PI 1\\_26\\_16.doc](#)  
Importance: High

---

Hello,

I received your voice mail. As I said before we are not able to take an action prior to the PDFUA date of February 5, 2016.

I am sending the package insert with track changes for your review. Please place comments with the changes you do not agree when sending the label back.

Please do not submit anything to the NDA until we have agreed on a final label. If you have no changes then please state that.

Please respond by today January 28, 2016.

Please acknowledge the receipt of this email.

Thx  
Meghna

Thx  
Meghna

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/s/  
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MEGHNA M JAIRATH  
01/27/2016

From: [Jairath, Meghna](#)  
To: [snair@intaspharma.com](mailto:snair@intaspharma.com)  
Subject: IR NDA 207174  
Date: Friday, November 13, 2015 12:48:15 PM  
Importance: High

---

**Information Request**  
**NDA 207174**

Hello,  
Please respond to our comment below.

*Please clarify if you would like to use the container and carton labels and labeling submitted on January 28, 2015 for this resubmission.*

Please acknowledge the receipt of this email.

Thx  
Meghna  
Meghna M. Jairath, Pharm.D.  
Regulatory Project Manager  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II (ODEII)/ Office of New Drugs (OND)/ Center of Drug Evaluation  
and Research (CDER)  
[Meghna.jairath@fda.hhs.gov](mailto:Meghna.jairath@fda.hhs.gov)  
301-796-4267

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/s/  
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MEGHNA M JAIRATH  
11/18/2015



NDA 207174

**ACKNOWLEDGE –  
CLASS 2 RESUBMISSION**

Accord Healthcare Inc.  
Attention: Sabita Nair  
Director, Regulatory Affairs  
1009 Slater Road, Suite 210-B  
Durham, NC 27703

Dear Ms. Nair:

We acknowledge your resubmission dated and received on August 5, 2015, to your supplemental new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for paricalcitol injection.

We consider this a complete, class 2 response to our January 29, 2015 action letter. Therefore, the user fee goal date is February 5, 2016.

If you have any questions, call me, at (301) 796-4267.

Sincerely,

*{See appended electronic signature page}*

Meghna M. Jairath, Pharm.D.  
Regulatory Project Manager  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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MEGHNA M JAIRATH  
08/19/2015

From: [Jairath, Meghna](#)  
To: [Sabita Nair](#)  
Subject: Second round of labeling of PI\_NDA 207174 paricalcitol  
Date: Wednesday, January 28, 2015 12:39:00 PM  
Attachments: [NDA\\_207174\\_final\\_PI\\_1\\_28.15.doc](#)  
Importance: High

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**NDA 207174**

**Product: Paricalcitol injection**

**Indication: For the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5.**

**Sponsor: Accord Healthcare, Inc.**

Hello,

I am sending the package insert with track changes for your review. Please place comments with the changes you do not agree when sending the label back.

Please do not submit anything to the NDA until we have agreed on a final label.

If you have no changes then please state submit the final version of the PI to the NDA.

Please respond by today January 28, 2015.

Please acknowledge the receipt of this email.

Thanks,

Meghna M. Jairath, Pharm.D.  
Regulatory Project Manager  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II (ODEII)/ Office of New Drugs (OND)/ Center of Drug Evaluation and Research (CDER)  
[Meghna.jairath@fda.hhs.gov](mailto:Meghna.jairath@fda.hhs.gov)  
301-796-4267

---

**From:** Sabita Nair [<mailto:snair@intaspharma.com>]  
**Sent:** Friday, January 16, 2015 12:04 PM  
**To:** Jairath, Meghna  
**Subject:** RE: First round of labeling of PI\_NDA 207174 paricalcitol

Dear Meghna,

In continuation to the discussion, this is to let you know that we agree to all the changes described in the label template that the Agency provided.

Please let us know if any additional information is required from our side.

Thanks.

Regards,  
Sabita

---

**From:** Jairath, Meghna [<mailto:Meghna.Jairath@fda.hhs.gov>]

**Sent:** Wednesday, December 31, 2014 10:38 AM  
**To:** Sabita Nair  
**Subject:** First round of labeling of PI\_NDA 207174 paricalcitol  
**Importance:** High

**NDA 207174**

**Product: Paricalcitol injection**

**Indication: For the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5.**

**Sponsor: Accord Healthcare, Inc.**

Hello,

I am sending the package insert with track changes for your review. Please place comments with the changes you do not agree when sending the label back.  
Please do not submit anything to the NDA until we have agreed on a final label.

If you have no changes then please state that.

Please respond by today January 9, 2015.

Please acknowledge the receipt of this email.

Thanks,

Meghna M. Jairath, Pharm.D.  
Regulatory Project Manager  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II (ODEII)/ Office of New Drugs (OND)/ Center of Drug Evaluation and Research (CDER)  
[Meghna.jairath@fda.hhs.gov](mailto:Meghna.jairath@fda.hhs.gov)  
301-796-4267

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/s/  
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MEGHNA M JAIRATH  
01/30/2015

From: [Jairath, Meghna](#)  
To: [Sabita Nair](#)  
Subject: First round of labeling of PI\_NDA 207174 paricalcitol  
Date: Wednesday, December 31, 2014 10:37:32 AM  
Attachments: [NDA 12 31 14 updated PI.doc](#)  
Importance: High

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**NDA 207174**

**Product: Paricalcitol injection**

**Indication: For the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5.**

**Sponsor: Accord Healthcare, Inc.**

Hello,

I am sending the package insert with track changes for your review. Please place comments with the changes you do not agree when sending the label back.

Please do not submit anything to the NDA until we have agreed on a final label.

If you have no changes then please state that.

Please respond by today January 9, 2015.

Please acknowledge the receipt of this email.

Thanks,

Meghna M. Jairath, Pharm.D.  
Regulatory Project Manager  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II (ODEII)/ Office of New Drugs (OND)/ Center of Drug Evaluation and Research (CDER)  
[Meghna.jairath@fda.hhs.gov](mailto:Meghna.jairath@fda.hhs.gov)  
301-796-4267

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MEGHNA M JAIRATH  
01/06/2015

From: [Jairath, Meghna](#)  
To: [snair@intaspharma.com](mailto:snair@intaspharma.com)  
Subject: IR NDA 207174 paricalcitol\_label  
Date: Tuesday, December 02, 2014 12:59:41 PM

---

## Information Request

NDA 207174  
Drug: Paricalcitol Injection  
Applicant: Accord Healthcare Inc.

Hello,

We recently approved two 505(b)(2) NDA 201657 and NDA 205917 for paricalcitol injection. Please submit another package insert mirroring the recently approved paricalcitol to your application for review.

Please submit this by December 9, 2014.  
Thanks,  
Meghna

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MEGHNA M JAIRATH  
12/08/2014

From: [Jairath, Meghna](mailto:Jairath.Meghna)  
To: [snair@intaspharma.com](mailto:snair@intaspharma.com)  
Subject: IR NDA 207174 paricalcitol\_label  
Date: Tuesday, November 25, 2014 12:20:55 PM

---

## Information Request

NDA 207174  
Drug: Paricalcitol Injection  
Applicant: Accord Healthcare Inc.,

Hello,

We have the following comments below to the label. This is to mitigate any potential risks due to the high alcohol content in your proposed paricalcitol formulation. Please respond to these changes by December 5, 2014.

### A. Vial label

1. Per FDA's Guidance for Industry: Container Labels and Carton Labeling (April 2013) <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf>, relocate the "Rx Only" statement to the bottom of the vial label so that the statement does not compete with other important information on the label.
2. Per FDA's Guidance for Industry: Container Labels and Carton Labeling (April 2013) <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf>, decrease the prominence of the net quantity statement to mitigate the risk of dosing errors where the net quantity is mistaken for the product strength.
3. Given the drug product's high alcohol content (35% v/v), revise the statement (b) (4) in order to highlight the unique route of administration and the importance of not injecting the drug product directly into a vein. Suggested language may include: "*For intravenous use through hemodialysis vascular access port only*"
4. **2 mcg/mL, 5 mcg/mL vial label:**
  - To ensure safe handling and appropriate use of the drug product, increase the prominence (size) of the following statement: "*Single-Dose Vial. Discard unused portion*"

### B. Carton labeling

1. Per FDA's Guidance for Industry: Container Labels and Carton Labeling (April 2013), relocate the "Rx Only" statement to the bottom of the Principal Display Panel (PDP) so that the statement does not compete with other important information on the label.
2. Given the drug product's high alcohol content (35% v/v), revise the statement (b) (4) on the PDP and back panel in order to highlight the unique route of administration and the importance of not injecting the drug product directly into a vein. Suggested language may include: "*For intravenous use through hemodialysis vascular access port only*". Additionally, increase the prominence (size) of this statement on the PDP.
3. Consider removing route of administration statement from back panel as this information is repetitive.
4. **2 mcg/mL, 5 mcg/mL carton labeling:**
  - To ensure safe handling and appropriate use of the drug product, revise the statement "Single-Dose Vial" to the following and increase its prominence (size): "*Single-Dose Vial. Discard*"

*unused portion.”*

- Consider revising the net quantity statement [REDACTED] (b) (4) to “1 mL vial” to decrease clutter and extraneous text.

**5. 10 mcg/2 mcg carton labeling:**

- The expiration date differs from that of typical multiple-dose vials where the product should be discarded within [REDACTED] (b) (4) days after initial use. To prevent errors associated with using expired drug products, revise the storage information statement on the back panel to include the following information: “*After initial use, discard within 7 days when stored at controlled room temperature.*”
- Consider revising the net quantity statement [REDACTED] (b) (4) to “2 mL vial” to decrease clutter and extraneous text.

You can submit the communication via email and to the NDA.

Thanks,  
Meghna

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/s/  
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MEGHNA M JAIRATH  
11/26/2014

## Kumar, Priyanka

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**From:** Kumar, Priyanka  
**Sent:** Wednesday, September 17, 2014 2:52 PM  
**To:** 'snair@intaspharma.com'  
**Subject:** Information Request regarding NDA 207174

Good Afternoon

We have the following information request in regards to NDA 207174 for Paricalcitol Injection. Please respond by e-mail followed by an official submission via the gateway by October 1, 2014.

1. **Additional information is needed for the antimicrobial effectiveness testing (AET) conducted to support the multiple dose vial. Provide the following:**
  - a. Justify the conduct of AET at (b) (4)
  - b. Justify the conduct of AET on a single batch of the 5 mg/mL formulation. Traditionally, three batches are evaluated.
  - c. Summarize the (b) (4) report. We refer to page 208/210 of Module 3.2.P.2.
2. **Provide a description of the (b) (4) utilized in routine and validation runs (b) (4)**
3. **We refer to the (b) (4) validation studies for P-035 and P-036. Provide the following information (b) (4)**
  - a. Confirm that the biological (b) (4)
  - b. Provide the (b) (4)

For more information please refer to the following Guidance document(s):

Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072171.pdf>

Thank you

*Priyanka Kumar, Pharm.D.  
Regulatory Project Manager  
Division of New Drug Quality Assessment III  
Office of New Drug Quality Assessment  
CDER, FDA  
Phone: (240)-402-3722  
Fax: (301)-796-9749*

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PRIYANKA KUMAR  
09/17/2014

## **Kumar, Priyanka**

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**From:** Kumar, Priyanka  
**Sent:** Monday, September 08, 2014 9:26 AM  
**To:** 'snair@intaspharma.com'  
**Subject:** Information Request regarding NDA 207174

Good Morning,

We have the following information request in regards to NDA 207174 for Paricalcitol Injection. Please respond by e-mail followed by an official submission via the gateway by September 30, 2014.

1. Provide your proposed drug product's osmolality and pH values and the analytical procedure/s used to measure them. Also provide the same information of your reference product.

If you have any questions, please contact me.

Thank you

*Priyanka Kumar, Pharm.D.  
Regulatory Project Manager  
Division of New Drug Quality Assessment III  
Office of New Drug Quality Assessment  
CDER, FDA  
Phone: (240)-402-3722  
Fax: (301)-796-9749*

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PRIYANKA KUMAR  
09/08/2014



NDA 207174

**FILING COMMUNICATION –  
NO FILING REVIEW ISSUES IDENTIFIED**

Accord Healthcare Inc.  
Attention: Sabita Nair  
Director, Regulatory Affairs  
1009 Slater Road, Suite 210-B  
Durham, NC 27703

Dear Ms. Nair:

Please refer to your New Drug Application (NDA) dated April 1, 2014, received April 1, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for paricalcitol injection.

We also refer to your amendment dated May 2, 2014.

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 **February 1, 2015**.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by January 1, 2015.

## **PRESCRIBING INFORMATION**

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

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products
- Regulations and related guidance documents
- A sample tool illustrating the format for Highlights and Contents, and
- The Selected Requirements for Prescribing Information (SRPI) – a checklist of 42 important format items from labeling regulations and guidances.

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

1. The length of HL must be one-half page or less.
2. There must be no white space between the product title and Initial U.S. Approval.
3. In the bolded Highlights Limitation Statement, “These highlights do not include all the information needed to use (insert name of drug product) safely and effectively. See full prescribing information for (insert name of drug product),” the name of drug product should appear in UPPER CASE letters.
4. If a product belongs to an established pharmacologic class, the following statement is required under the Indications and Usage heading in HL: “(Product) is a (name of established pharmacologic class) indicated for (indication)”. The established pharmacologic class is vitamin D3 analog.
5. When clinical trials adverse reactions data are included in the “Clinical Trials Experience” subsection of ADVERSE REACTIONS, the following verbatim statement or appropriate modification should precede the presentation of adverse reactions:

“Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.”

6. When postmarketing adverse reaction data are included in the “Postmarketing Experience” subsection of ADVERSE REACTIONS, the following verbatim statement or appropriate modification should precede the presentation of adverse reactions:

“The following adverse reactions have been identified during post-approval use of (insert drug name). Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.”

We request that you resubmit labeling (in Microsoft Word format) that addresses these issues by **July 7, 2014**. The resubmitted labeling will be used for further labeling discussions. Use the SRPI checklist to correct any formatting errors to ensure conformance with the format items in regulations and guidances.

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

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

### **PROMOTIONAL MATERIAL**

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

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

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

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

### **REQUIRED PEDIATRIC ASSESSMENTS**

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

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

If you have any questions, call Julie Van der Waag, Chief, Project Management Staff, at (301) 796-1280.

Sincerely,

*{See appended electronic signature page}*

Jean-Marc Guettier, M.D.  
Director  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/  
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JULIE C VAN DER WAAG

06/02/2014

J. Van der Waag signing for J.M. Guettier



NDA 207174

**NDA ACKNOWLEDGMENT**

Accord Healthcare Inc.  
Attention: Sabita Nair  
Director, Regulatory Affairs  
1009 Slater Road, Suite 210-B  
Durham, NC 27703

Dear Ms. Nair:

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: paricalcitol injection

Date of Application: April 1, 2014 (letter dated March 31, 2014)

Date of Receipt: April 1, 2014

Our Reference Number: NDA 207174

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 May 31, 2014, in accordance with 21 CFR 314.101(a).

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

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

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

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Metabolism and Endocrinology 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>.

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

If you have any questions, call me at (301) 796-1280.

Sincerely,

*{See appended electronic signature page}*

Julie Van der Waag  
Chief, Project Management Staff  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JULIE C VAN DER WAAG  
04/03/2014