CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209949Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]

NDA # 209949 BLA # n/a	NDA Supplement # n/a BLA Supplement # n/a	If NDA, Efficacy Supplement Type: n/a *(an action package is not required for SE8 or SE9 supplements)*
Proprietary Name: n/a Established/Proper Name: daptomycin Dosage Form: injection / 350 mg/vial		Applicant: Xellia Pharmaceuticals, ApS Agent for Applicant (if applicable): n/a
RPM: Maureen Dillon-Parker		Division: Anti-Infective Products

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

BLA Application Type: ☐ 351(k) ☐ 351(a)
Efficacy Supplement: ☐ 351(k) ☐ 351(a)

For ALL 505(b)(2) applications, two months prior to EVERY action:

- **Review the information in the 505(b)(2) Assessment and submit the draft[2] to CDER OND IO for clearance.**
- **Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)**

☐ No changes
☐ New patent/exclusivity *(notify CDER OND IO)*
Date of check:

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.

❖ Actions	
• Proposed action • User Fee Goal Date is 10/20/2017	**X AP** ☐ TA ☐ CR
• Previous actions *(specify type and date for each action taken)*	**X None**
❖ 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 [3]	

[1] 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.
[2] 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).
[3] 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.

Reference ID: 4170459

Review priority: **X Standard** ☐ Priority
Chemical classification (new NDAs only): **5/ Glycopeptide/Lipopeptide**
(confirm chemical classification at time of approval)

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

(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

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
☐ 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)*	☐ Yes ☐ No
❖ Public communications *(approvals only)*	
• Office of Executive Programs (OEP) liaison has been notified of action	☐ Yes **X No**
• Indicate what types (if any) of information were issued	**X None** ☐ FDA Press Release ☐ FDA Talk Paper ☐ CDER Q&As ☐ 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	**X No** ☐ Yes n/a
❖ Patent Information (NDAs only)	
• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought.	**X Verified** ☐ Not applicable because drug is an old antibiotic.

CONTENTS OF ACTION PACKAGE

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)* (link)	**X Included**
Documentation of consent/non-consent by officers/employees (link)	**X Included**

Action Letters	
❖ Copies of all action letters *(including approval letter with final labeling)*	Action(s) and date(s): **Approval/ October 20, 2017**
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)*	**X Included**
• Original applicant-proposed labeling	**X Included /Rec'd 12/20/16**
❖ 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 **X None**
• Most-recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☐ Included
• Original applicant-proposed labeling	☐ Included
❖ 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	**X Included**
❖ Proprietary Name • Acceptability/non-acceptability letter(s) *(indicate date(s))* • Review(s) *(indicate date(s)*	**N/A – no name requested**
❖ Labeling reviews *(indicate dates of reviews)*	**RPM: X None** **DMEPA: 07/17/17; 10/10/17** DMPP/PLT (DRISK): **X None** **OPDP: X 08/04/17** SEALD: **X None** CSS: **X None** Product Quality **X 08/24/17** Other: **X None**
Administrative / Regulatory Documents	
❖ RPM Filing Review[4]/Memo of Filing Meeting *(indicate date of each review)* ❖ All NDA 505(b)(2) Actions: Date each action cleared by 505(b)(2) Clearance Committee	**10/03/17** **10/18/17**
❖ NDAs/NDA supplements only: Exclusivity Summary *(signed by Division Director)*	X Completed (Do not include)
❖ Application Integrity Policy (AIP) Status and Related Documents http://www fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm	
• Applicant is on the AIP	☐ Yes **X No**

[4] Filing reviews for scientific disciplines are NOT required to be included in the action package.

• This application is on the AIP ○ If yes, Center Director's Exception for Review memo *(indicate date)* ○ If yes, OC clearance for approval *(indicate date of clearance communication)*	☐ Yes **X No** ☐ Not an AP action
❖ Pediatrics *(approvals only)* • Date reviewed by PeRC _____ If PeRC review not necessary, explain: **Application did not trigger PREA**	
❖ Breakthrough Therapy Designation	**X N/A**
• Breakthrough Therapy Designation Letter(s) (granted, denied, an/or rescinded)	
• CDER Medical Policy Council Breakthrough Therapy Designation Determination Review Template(s) *(include only the completed template(s) and not the meeting minutes)*	
• CDER Medical Policy Council Brief – Evaluating a Breakthrough Therapy Designation for Rescission Template(s) *(include only the completed template(s) and not the meeting minutes)* *(completed CDER MPC templates can be found in DARRTS as clinical reviews or on the MPC SharePoint Site)*	
❖ 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.) *(do not include OPDP letters regarding pre-launch promotional materials as these are non-disclosable; do not include Master File letters; do not include previous action letters, as these are located elsewhere in package)*	**Included**
❖ 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)	**Included**
❖ Minutes of Meetings	
• If not the first review cycle, any end-of-review meeting *(indicate date of mtg)*	**X N/A**
• Pre-NDA/BLA meeting *(indicate date of mtg)*	**X No mtg**
• EOP2 meeting *(indicate date of mtg)*	**X No mtg**
• Mid-cycle Communication *(indicate date of mtg)*	**X N/A**
• Late-cycle Meeting *(indicate date of mtg)*	**X N/A**
• Other milestone meetings (e.g., EOP2a, CMC focused milestone meetings) *(indicate dates of mtgs)*	**X N/A**
❖ Advisory Committee Meeting(s)	**X No AC meeting**
• Date(s) of Meeting(s)	n/a
Decisional and Summary Memos	
❖ Office Director Decisional Memo *(indicate date for each review)*	**X None**
Division Director Summary Review *(indicate date for each review)*	**See CDTL[combined review]**
Cross-Discipline Team Leader Review *(indicate date for each review)*	**October 19, 2017**
PMR/PMC Development Templates *(indicate total number)*	**X None**

Clinical	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) *(indicate date for each review)*	**X No separate review**
• Clinical review(s) *(indicate date for each review)*	**08/24/17**
• Social scientist review(s) (if OTC drug) *(indicate date for each review)*	**X 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)*	
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers *(indicate date of each review)*[5]	**X None**
❖ Controlled Substance Staff review(s) and Scheduling Recommendation *(indicate date of each review)*	**X N/A**
❖ Risk Management • REMS Documents and REMS Supporting Document *(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** **N/A** **X None**
❖ OSI Clinical Inspection Review Summary(ies) *(include copies of OSI letters to investigators)*	**X None requested**
Clinical Microbiology ☐ None	
❖ Clinical Microbiology Team Leader Review(s) *(indicate date for each review)*	**X No separate review**
Clinical Microbiology Review(s) *(indicate date for each review)*	**08/31/17**
Biostatistics ☐ None	
❖ Statistical Division Director Review(s) *(indicate date for each review)*	**X No separate review**
Statistical Team Leader Review(s) *(indicate date for each review)*	**X No separate review**
Statistical Review(s) *(indicate date for each review)*	**No review required**
Clinical Pharmacology ☐ None	
❖ Clinical Pharmacology Division Director Review(s) *(indicate date for each review)*	**X No separate review**
Clinical Pharmacology Team Leader Review(s) *(indicate date for each review)*	**X No separate review**
Clinical Pharmacology review(s) *(indicate date for each review)*	**08/24/17**
❖ OSI Clinical Pharmacology Inspection Review Summary *(include copies of OSI letters)*	**X None requested**

[5] For Part 3 combination products, all reviews from the reviewing Center(s) should be entered into the official archive (for further instructions, see "Section 508 Compliant Documents: Process for Regulatory Project Managers" located in the CST electronic repository).

Nonclinical ☐ None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) *(indicate date for each review)*	**X No separate review**
• Supervisory Review(s) *(indicate date for each review)*	**X No separate review**
• Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	**09/05/17**
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer *(indicate date for each review)*	**X None**
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	**X No carc**
❖ ECAC/CAC report/memo of meeting	**X None** Included in P/T review, page **n/a**
❖ OSI Nonclinical Inspection Review Summary *(include copies of OSI letters)*	**X None requested**
Product Quality ☐ None	
❖ Product Quality Discipline Reviews[6]	
• Tertiary review (*indicate date for each review*)	**X None**
• Secondary review (e.g., Branch Chief) *(indicate date for each review)*	**X None**
• Integrated Quality Assessment (contains the Executive Summary and the primary reviews from each product quality review discipline) *(indicate date for each review)*	**Drug Substance 07/14/17** **Drug Product 08/22/17** **Process 08/17/17** **Facilities 09/26/17** **Biopharmaceutics 08/15/17** **[All reviews combined 10/4/17]**
❖ Reviews by other disciplines/divisions/Centers requested by product quality review team *(indicate date of each review)*	**X None**
❖ Environmental Assessment (check one) (original and supplemental applications)	
X Categorical Exclusion *(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)*	**Pg 33 /Drug Product Quality Assessment Review /8/22/17**
☐ Review & FONSI *(indicate date of review)*	n/a
☐ Review & Environmental Impact Statement *(indicate date of each review)*	n/a
❖ Facilities Review/Inspection	
X Facilities inspections (indicate date of recommendation; within one week of taking an approval action, confirm that there is an acceptable recommendation before issuing approval letter) *(only original applications and efficacy supplements that require a manufacturing facility inspection(e.g., new strength, manufacturing process, or manufacturing site change)*	**X Acceptable 10/19/17** ☐ Withhold recommendation ☐ Not applicable

[6] Do not include Master File (MF) reviews or communications to MF holders. However, these documents should be made available upon signatory request.

Day of Approval Activities	
❖ For all 505(b)(2) applications: • Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)	**X** No changes ☐ New patent/exclusivity *(Notify CDER OND IO)*
• Finalize 505(b)(2) assessment	**X** Done
❖ For Breakthrough Therapy (BT) Designated drugs: • Notify the CDER BT Program Manager	☐ Done *(Send email to CDER OND IO)*
❖ For products that need to be added to the flush list (generally opioids): Flush List • Notify the Division of Online Communications, Office of Communications	☐ Done
❖ Send a courtesy copy of approval letter and all attachments to applicant by fax or secure email	**X** Done
❖ If an FDA communication will issue, notify Press Office of approval action after confirming that applicant received courtesy copy of approval letter	☐ Done
❖ Ensure that proprietary name, if any, and established name are listed in the *Application Product Names* section of DARRTS, and that the proprietary name is identified as the "preferred" name	☐ Done
❖ Ensure Pediatric Record is accurate	☐ Done
❖ Send approval email within one business day to CDER-APPROVALS	Completed 10/20/17
❖ Take Action Package (if in paper) down to Document Room for scanning within **two business days**	Notified Document Room package will be delivered Monday 10/23/17.

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/s/

MAUREEN P DILLON PARKER
10/20/2017

Dillon Parker, Maureen P

From: Edward Eichmann <Edward.Eichmann@xellia.com>
Sent: Friday, October 20, 2017 8:23 AM
To: Dillon Parker, Maureen P
Subject: Re: NDA 209949/Revised Labeling
Attachments: REVISED.draft-package-insert.pediatric carve-out with disclaimers.docx; draft-package-insert-0013.docx

Good morning-

As discussed yesterday, Xellia has reviewed the proposed labeling from the Agency and accepts all the proposed revisions. Xellia commits to incorporating all of these revisions into our package insert. Attached is a word document of the proposed Xellia label with the revisions incorporated.

Please acknowledge receipt of this email. In addition, please feel free to contact me if you have any additional questions or comments.

Ed Eichmann

xellia
Edward Eichmann
Director Regulatory Affairs
Xellia Pharmaceuticals USA, LLC
8900 Capital Blvd
Raleigh NC USA 27616
t +1 919-327-5504 **f** +1 919-871-0309 **m** + (b) (6)
edward.eichmann@xellia.com
www.xellia.com

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Consider the environment before printing this email.

From: "Dillon Parker, Maureen P" <Maureen.DillonParker@fda.hhs.gov>
To: "Edward Eichmann (Edward.Eichmann@xellia.com)" <Edward.Eichmann@xellia.com>
Cc: "Dillon Parker, Maureen P" <Maureen.DillonParker@fda.hhs.gov>
Date: 10/19/2017 03:27 PM
Subject: NDA 209949/Revised Labeling

Hi Ed,

Reference ID: 4169961

As we discussed this afternoon.

With the passage of the FDA Reauthorization Act (FDARA) on August 18, 2017, FDA was given the authority to include a disclaimer statement in product labels for 505(b)(2) applications where protected pediatric information has been removed and statements of appropriate pediatric information necessary to assure safe use (see amended section 505A(o) of the Federal Food, Drug & Cosmetic Act). This is similar to what is currently being implemented in applicable generic product labeling where protected pediatric information has been removed. The attached labeling has been further revised to add the disclaimer statements for your product's proposed labeling.

Please let me know that you receive this email.

I look forward to speaking with you tomorrow.

Regards,
Maureen

Maureen P. Dillon-Parker | Chief, Project Management Staff |
Division of Anti-Infective Products | Office of Antimicrobial Products |
Center for Drug Evaluation and Research |
ph: 301.796.0706 | fax: 301.796.9881 |
Email: maureen.dillonparker@fda.hhs.gov

Please consider the environment before printing this e-mail

This e-mail and attached documents, if any, are intended only for the party to whom it is addressed and may contain information that is PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver this document(s) to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone, fax, e-mail or mail. Thank you.

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

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/s/

MAUREEN P DILLON PARKER
10/20/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209949

INFORMATION REQUEST
PATENT CERTIFICATION OR VERIFICATION

Xellia Pharmaceuticals ApS
c/o Xellia Pharmaceuticals USA, LLC
Attention: Edward Eichmann
U.S. Agent
8900 Capital Boulevard
Raleigh, NC 27616

Dear Mr. Eichmann:

Please refer to your New Drug Application (NDA) dated December 20, 2016, received December 20, 2016, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Daptomycin for Injection, 350 mg/vial.

We also refer to your amendment dated June 23, 2017. This amendment does not comply with 21 CFR 314.60(f), which was added by the final rule on Abbreviated New Drug Applications and 505(b)(2) Applications; Final Rule, 81 FR 69580 (October 6, 2016). The final rule became effective on December 5, 2016.

Section 314.60(f) requires that an amendment to an unapproved 505(b)(2) application contain an appropriate patent certification or statement described in 21 CFR 314.50(i), or a "recertification" for a previously submitted paragraph IV certification, if approval is sought for changes described in any of the following types of amendments:

- To add a new indication or other condition of use;
- To add a new strength;
- To make other than minor changes in product formulation; or
- To change the physical form or crystalline structure of the active ingredient.

If an amendment to the 505(b)(2) application does not contain a patent certification (or recertification) or statement, the applicant must verify that the proposed change described in the amendment is not one of the types of amendments described above.

We recommend that the cover letter for your response to this information request and for future amendments to your unapproved 505(b)(2) application either:

1) states that the amendment contains a patent certification (or recertification) or statement required by 21 CFR 314.60(f)(1); or
2) verifies that the proposed change described in the amendment is not one of the types of amendments described in 21 CFR 314.60(f)(1), as appropriate.

Your response to this information request must clearly reference your amendment dated June 23, 2017.

If you have any questions, contact me at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Maureen Dillon-Parker
Chief, Regulatory Health Project Management Staff
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

MAUREEN P DILLON PARKER
07/07/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209949

FILING COMMUNICATION –
NO FILING REVIEW ISSUES IDENTIFIED

Xellia Pharmaceuticals ApS
c/o Xellia Pharmaceuticals USA LLC
Attention: Edward Eichmann
U.S. Agent
8900 Capital Boulevard
Raleigh, NC 27616

Dear Mr. Eichmann:

Please refer to your New Drug Application (NDA) dated December 20, 2016, received December 20, 2016, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Daptomycin for Injection, 350 mg.

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 20, 2017. This application is also subject to the provisions of "the Program" under the Prescription Drug User Fee Act (PDUFA) V (refer to http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm.

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 September 15, 2017.

We are not currently planning to hold an advisory committee meeting to discuss this application.

If your 505(b)(2) application relies on FDA's finding of safety and/or effectiveness for a listed drug and contains a paragraph IV certification, this filing communication is the "paragraph IV acknowledgment letter" described in 21 CFR 314.52(b) and the "postmark" is 4 calendar days after the date on which this letter is signed. Notice of the paragraph IV certification must be sent

to the persons described in 21 CFR 314.52(a) no later than 20 days after the date of the postmark on this paragraph IV acknowledgment letter and must contain the information described in 21 CFR 314.52(c).

If your 505(b)(2) application relies on FDA's finding of safety and/or effectiveness for a listed drug, we recommend that the cover letter for amendments to your unapproved 505(b)(2) application either: 1) state that the amendment contains a patent certification (or recertification) or statement required by 21 CFR 314.60(f)(1); or 2) verify that the proposed change described in the amendment is not one of the types of amendments described in 21 CFR 314.60(f)(1), as appropriate.

PRESCRIBING INFORMATION

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

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

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

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:

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

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

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 Maureen Dillon-Parker, Chief, Project Management Staff, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

SUMATHI NAMBIAR
03/02/2017