

Food and Drug Administration CDER / Office of Generic Drugs	Document No.: 4000-LPS-066	Version: 02
Document Status: DRAFT		
Title: Approval Routing Summary Form	Author: Heather Strandberg	

Approval Type: FULL APPROVAL TENTATIVE APPROVAL SUPPLEMENTAL APPROVAL (NEW STRENGTH)

RPM: Adil Merchant Team Leader: Taylor

PI PII PIII PIV (eligible for 180 day exclusivity) Yes No MOU RX or OTC

ANDA #: **208363** Applicant: **PuraCap Pharmaceutical LLC**

Established Product Name: **Naproxen Sodium Capsules, 220 mg (OTC)**

Basis of Submission (RLD): **Naproxen Sodium Capsules; N021920; Bionpharma, Inc.**

Basis Of Submission Discontinued? Yes No

If yes, has FR published indicating the Agency determined the product was not withdrawn for reasons of safety or effectiveness?

Yes FR Notice dated _____; Document Citation _____; FR. _____ (Example: 78 FR 67365)

No Consult completed but not yet published in FR

(Is ANDA based on an approved Suitability Petition? Yes No, if yes, use SP language in template)

Does the ANDA contain REMS? Yes No (If YES, initiate approval action 6 weeks prior to target action date)

Regulatory Project Manager Evaluation:

Date: 2/26/2018

Date (Received) Acceptable for Filing -- Date **4/19/2016**

Date last Complete Response (CR) letter was issued -- Date **12/14/2017**

Previously reviewed and tentatively approved (if applicable) -- Date **NA**

YES	NO			
<input type="checkbox"/>	<input type="checkbox"/>	All submissions have been reviewed and relevant disciplines are adequate and finalized in the platform (Date or N/A)		
		<table border="1"> <tr> <td> Date of Acceptable Bioequivalence 11/3/2017 <ul style="list-style-type: none"> Date of BE Guidance (if any) 6/2015 Date of Acceptable Labeling 6/23/2017 <ul style="list-style-type: none"> Date of last RLD labeling update 3/16/2017 Date of Acceptable Quality 3/1/2018 <ul style="list-style-type: none"> DMF No(s). (b) (4) Date(s) Acceptable 2/12/18 No outstanding DMF review amendments <input checked="" type="checkbox"/> Date of Acceptable Overall Manufacturing Inspection 1/16/2018 </td> <td> If applicable: Date of Acceptable Microbiology NA Date of Acceptable Clinical Review NA Date of Acceptable Dissolution 11/30/2017 Date of Acceptable REMS NA </td> </tr> </table>	Date of Acceptable Bioequivalence 11/3/2017 <ul style="list-style-type: none"> Date of BE Guidance (if any) 6/2015 Date of Acceptable Labeling 6/23/2017 <ul style="list-style-type: none"> Date of last RLD labeling update 3/16/2017 Date of Acceptable Quality 3/1/2018 <ul style="list-style-type: none"> DMF No(s). (b) (4) Date(s) Acceptable 2/12/18 No outstanding DMF review amendments <input checked="" type="checkbox"/> Date of Acceptable Overall Manufacturing Inspection 1/16/2018 	If applicable: Date of Acceptable Microbiology NA Date of Acceptable Clinical Review NA Date of Acceptable Dissolution 11/30/2017 Date of Acceptable REMS NA
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<input checked="" type="checkbox"/>	<input type="checkbox"/>	MMA: All amendments submitted to the Agency on or after December 5, 2016 contain (1) a patent certification or section viii statement, (2) a recertification, or (3) a verification statement per 21 CFR 314.96(d).		
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Are consults pending for any discipline?		
<input checked="" type="checkbox"/>	<input type="checkbox"/>	OSIS Clinical Endpoint and Bioequivalence Site Inspections are acceptable		
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Is there a pending legal or regulatory issue (refer to Policy Alert Tracker)? NA – verified tracker dated 2/21/18 If YES → OGD Policy Lead confirmed ANDA may proceed <input type="checkbox"/> ; Memo uploaded (if applicable) <input type="checkbox"/>		
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Has there been an amendment providing for a major change in formulation or new strength since filing? If YES → Verify a second filing review was completed (if applicable) and that all disciplines completed new reviews <input type="checkbox"/>		
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Is ANDA a Priority Approval (First generic, drug shortage, PEPFAR, other OGD Communications priorities)? If YES → Email OGD Communications Staff or Division liaison 30 to 60 days prior to approval, Date emailed 2/28/2018		
Review Discipline/Division and RPM TL Endorsements				
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Applicable review discipline/division endorsements completed		
<input checked="" type="checkbox"/>	<input type="checkbox"/>	RPM Team Leader endorsement completed		
Additional Notes (if applicable)				

Lead Division: Program Management

Effective Date:

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Evidence of review and approval can be located on the corresponding signature sheet on file with QMS.

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ANDA APPROVAL ROUTING SUMMARY ENDORSEMENTS AND FINAL DECISION

1. Division of Legal and Regulatory Support Endorsement

Date: 3/2/2018

Name: MHS

<p>Patent/Exclusivity Certification: <input checked="" type="checkbox"/> PI <input type="checkbox"/> PII <input type="checkbox"/> PIII <input type="checkbox"/> PIV <input type="checkbox"/> section viii If Paragraph IV Certification- did applicant: Notify patent holder/NDA holder: Yes <input type="checkbox"/> No <input type="checkbox"/> Was applicant sued w/in 45 days: Yes <input type="checkbox"/> No <input type="checkbox"/> Has case been settled: Yes <input type="checkbox"/> No <input type="checkbox"/> Applicant addressed all listed exclusivities Yes <input type="checkbox"/> No <input type="checkbox"/> Do the patent and exclusivity certifications align? Yes <input type="checkbox"/> No <input type="checkbox"/> Have there been any revisions to the use code since the original submission? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p>RLD = <u>Naproxen Sodium</u> NDA# <u>21920</u> <input type="checkbox"/> RX or <input checked="" type="checkbox"/> OTC Date Checked in Orange Book#: _____ Type of Letter: <input type="checkbox"/> APPROVAL <input type="checkbox"/> TENTATIVE APPROVAL <input type="checkbox"/> SUPPLEMENTAL APPROVAL (NEW STRENGTH) LETTER RECOMMENDED FOR DRUGS@FDA Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>Forfeiture Information Is a forfeiture memo needed for the first applicant: Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, the date forfeiture memo was completed Date _____ ANDA # _____</p>	<p>180 Day Exclusivity Information Is applicant eligible for 180 day exclusivity Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> <input type="checkbox"/> Sole <input type="checkbox"/> Shared ANDA Exclusivity for each strength: Yes <input type="checkbox"/> No <input type="checkbox"/> Which strength(s) eligible _____</p>
<p>Comments: ANDA submitted on December 31, 2015, BOS=Naproxen Sodium Capsules 220 mg NDA 21920, PI cert provided. RTR issued on February 25, 2016. ANDA subsequently ACK for filing on April 19, 2016(LO dated 5/23/2016). Sponsor was contacted via e-mail and instructed to address newly listed US Patent Nos. 9693978 and 9693979. Sponsor responded on February 27, 2018 that both of these patents was late-listed per the regulations and therefore Puracap was not required to formally address these patents with a certification. The sponsor of NDA 21920 submitted the '978 and '979 patents for listing under their NDA on November 15, 2017. According to the FDA Form 3542 submitted by Bionpharma the patent owner of the '978 patent is Patheon Softgels Inc and the patent was issued on 7/4/2017. According to the FDA Form 3542 submitted by Bionpharma the patent owner of the '979 patent is Patheon Softgels and the patent was issued on July 4, 2017. The July 4, 2017 patent issue dates for both of these patents comports with information available online via the USPTO. It is also noted that there were no supplements approved under NDA 21920 which would have resulted in the '978 and '979 patents being timely filed had they been listed within 30 days of a new supplement. It is the agency's conclusion that both of these patents are clearly late-listed per 21 CFR 314.53(d)(3) and Puracaps late-listing statement from February 27, 2018 is acceptable as it comports with 314.94((a)(12)(vi) ANDA is eligible for immediate Final AP as they are not required to address the '978 and '979 patents with a formal certification and they can not possibly be blocked by any eligibility for 180-day exclusivity.</p>	
<p>180 Day Exclusivity Status/Landscape: N/A Citizen Petitions Impact: N/A First Legally Approvable Date: N/A If Tentative Approval, anticipated full approval date: N/A</p>	

Lead Division: Program Management

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2. **Final Decision**

Date: **3/15/2018**

Name: **sgk**

ANDA received on **4/19/2016** for the **220 mg** strength

RTR'd? Yes No If yes, RTR'd on **2/25/2016**

Priority Status? Yes No If yes, prioritization factor is **first generic**

Basis of Submission (RLD)

Drug Name **Naproxen sodium capsules**

NDA # **021920**

Applicant Name **Bionpharma, Inc.**

Verified the following:

1. Completion of the following endorsement tasks, if applicable:
 - a. Division of Legal and Regulatory Support Endorsement
 - b. Paragraph IV Evaluation
 - c. REMS Endorsement
 - d. Quality Endorsement
 - e. Bioequivalence Endorsement
 - f. Clinical-Bioequivalence Endorsement
 - g. Labeling Endorsement
 - h. RPM Team Leader Endorsement
2. All applicable endorsement tasks are completed in the platform within 30 days of potential approval.
3. No updates to patents and/or exclusivities in Orange Book since the Division of Legal and Regulatory Support Endorsement
4. No Reference Listed Drug updates at Drugs@FDA since the Labeling Endorsement
5. No issues listed on the current version of the Policy alert list since the RPM Team Leader Endorsement
6. No new alerts in the Submission Facility Status View since the Quality Endorsement
7. Overall Inspection Recommendation of Approve of the current project (see screenshot below)
8. No new DMF amendments since Quality Endorsement
9. No amendments received since the RPM Team Leader Endorsement

This ANDA is ready for **FULL APPROVAL**.

****INCLUDE SNIP OF SUBMISSION FACILITY STATUS VIEW AT THE TIME OF APPROVAL****

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REFERENCES / ASSOCIATED DOCUMENTS

4000-LPS-041 Processing Approval and Tentative Approval of an Original ANDA

REVISION HISTORY

Version	Effective date	Name	Role	Summary of changes
01	10/1/2014	Heather Strandberg	Author	New Form
02		Kevin Denny	Reviser	<ul style="list-style-type: none"> • Update form to reflect revisions to SOP 4000-LPS-041 Processing Approval and Tentative Approval of an Original ANDA, Version 04 • Remove content adequately captured in the platform • Update information captured in the Division of Legal and Regulatory Support Endorsement section • Other minor administrative corrections to format and content

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