CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203195Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

EXCLUSIVITY SUMMARY

NDA # 203195 SUPPL # HFD #

Trade Name Suprax

Generic Name cefixime

Applicant Name Lupin Limited

Approval Date, If Known 6-1-12

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

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

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

YES ☒ NO ☐

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

505(b)(2)

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

YES ☐ NO ☒

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

This application for cefixime 400 mg capsules includes one bioequivalence study report. The study was conducted under fasting conditions to assess the bioavailability of the capsule relative to the tablet (reference product).

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

d) Did the applicant request exclusivity?

YES ☐ NO ☒

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

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

YES ☐ NO ☒

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

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#

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: Alison Rodgers
Title: Senior Regulatory Project Manager
Date: 5-17-12

Name of Office/Division Director signing form:
Title:

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

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/s/

ALISON K RODGERS
06/05/2012

KATHERINE A LAESSIG
06/05/2012

Rodgers, Alison

From: Leslie Sands [lsands@lupinusa.com]
Sent: Friday, May 11, 2012 3:58 PM
To: Rodgers, Alison
Subject: Re: Suprax Label

Hi Alison,

I will forward the proposed changes to the team.

Regards,

Leslie
Sent via BlackBerry from T-Mobile

From: "Rodgers, Alison" <Alison.Rodgers@fda.hhs.gov>
Date: Fri, 11 May 2012 15:44:32 -0400
To: Leslie Sands<lsands@lupinusa.com>
Subject: Suprax Label

Hi Leslie,

Thank you for submitting your response to our proposed Suprax labeling so promptly.

Three additional revisions to the sections noted below are shown in track changes in the attached label.

Section 2.1 Adults
Section 2.2 Pediatric Patients - See Pediatric Dosing Chart
Section 2.3 Renal Impairment

Please let me know by Tuesday, May 15th, if you accept these changes. If so, please resubmit labeling.

Please let me know if you have any questions.

Please confirm receipt of this email.

Thank you,
Alison

Alison K. Rodgers
Regulatory Health Project Manager
FDA/CDER
Division of Anti-Infective Products
Phone: 301-796-0797
Fax: 301-796-9882
Email: alison.rodgers@fda.hhs.gov

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

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/s/

ALISON K RODGERS
05/15/2012

From:	Leslie Sands
To:	Rodgers, Alison
Subject:	RE: Suprax - Draft Labeling
Date:	Thursday, May 03, 2012 1:27:44 PM

Thanks Alison. I received your email.

Regards,

Leslie

From: Rodgers, Alison [mailto:Alison.Rodgers@fda.hhs.gov]
Sent: Thursday, May 03, 2012 1:26 PM
To: Leslie Sands
Subject: Suprax - Draft Labeling

Hi Leslie,

Attached please find our draft labeling for Suprax. Please review our proposed label and respond by May 10, 2012.

Please let me know if you have any questions.

Please confirm receipt of this email.

Thank you,

Alison

Alison K. Rodgers
Regulatory Health Project Manager
FDA/CDER
Division of Anti-Infective Products
Phone: 301-796-0797
Fax: 301-796-9882
Email: alison.rodgers@fda.hhs.gov

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/s/

ALISON K RODGERS
05/03/2012

From: Leslie Sands
To: Rodgers, Alison
Subject: RE: NDA 203195 Labeling Comments
Date: Wednesday, May 02, 2012 3:44:43 PM

Thanks Alison. We should be able to respond quickly.

Regards,

Leslie

From: Rodgers, Alison [mailto:Alison.Rodgers@fda.hhs.gov]
Sent: Wednesday, May 02, 2012 12:34 PM
To: Leslie Sands
Subject: NDA 203195 Labeling Comments

Hi Leslie,

Attached please find additional comments regarding the carton, container, and blister labeling. As these are relatively minor comments, we would appreciate it if you could respond as quickly as possible.

Please let me know if you have any questions.

Please confirm receipt of this email.

Thank you,

Alison

Alison K. Rodgers
Regulatory Health Project Manager
FDA/CDER
Division of Anti-Infective Products
Phone: 301-796-0797
Fax: 301-796-9882
Email: alison.rodgers@fda.hhs.gov

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/s/

ALISON K RODGERS
05/02/2012

From:	Leslie Sands
To:	Rodgers, Alison
Subject:	RE: NDA 203195 - Patent Certification
Date:	Wednesday, April 25, 2012 10:41:13 AM

Thanks Alison. We will submit the corrected patent cert.

Regards,

Leslie

From: Rodgers, Alison [mailto:Alison.Rodgers@fda.hhs.gov]
Sent: Wednesday, April 25, 2012 9:56 AM
To: Leslie Sands
Subject: NDA 203195 - Patent Certification
Importance: High

Hi Leslie,

We noticed what was probably a typographical error in your Paragraph I patent certification (9/23/11) submission. The correct regulation to cite for Paragraph I certification is 21 CFR 314.50(i)(1)(i)(A)(1). Please continue to provide a patent certification specific to reliance on Lederle's Suprax tablet NDA 50621, just correct the regulation citation.

Please let me know if you have any questions.

Please confirm receipt of this email.

Thank you,

Alison

Alison K. Rodgers
Regulatory Health Project Manager
FDA/CDER
Division of Anti-Infective Products
Phone: 301-796-0797
Fax: 301-796-9882
Email: alison.rodgers@fda.hhs.gov

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/s/

ALISON K RODGERS
04/25/2012

From: Leslie Sands
To: Rodgers, Alison
Subject: RE: NDA 203195 - Request for Information
Date: Monday, April 09, 2012 1:52:45 PM

Thanks Alison. I will get back to you in a day or so with a tentative response date.

Regards,

Leslie

From: Rodgers, Alison [mailto:Alison.Rodgers@fda.hhs.gov]
Sent: Monday, April 09, 2012 1:50 PM
To: Leslie Sands
Subject: NDA 203195 - Request for Information
Importance: High

Hi Leslie,

Please see the following request for information:

The proposed dosing recommendations for cefixime in patients with renal impairment are as follows:

Suprax may be administered in the presence of impaired renal function. Normal dose and schedule may be employed in patients with creatinine clearances of 60 mL/min or greater. ***Patients whose clearance is between 21 and 60 mL/min or patients who are on renal hemodialysis may be given 75 % of the standard dosage at the standard dosing interval (i.e., 300 mg daily).*** *Patients whose clearance is < 20 mL/min, or patients who are on continuous ambulatory peritoneal dialysis may be given half the standard dosage at the standard dosing interval (i.e., 200 mg daily). Neither hemodialysis nor peritoneal dialysis removes significant amounts of drug from the body.*

It is not clear how patients with creatinine clearance values between 21 and 60 mL/min who are on hemodialysis will be dosed 300 mg (i.e. 75% of the standard dose). Please provide recommendations as to how to dose patients with creatinine clearance values between 21 and 60 mL/min who are on hemodialysis (e.g. 300 mg) given the availability of cefixime formulations proposed and currently on the market.

Please submit your response by April 23, 2012, if at all possible.

Please let me know if you have any questions.

Please confirm receipt of this email.

Thank you,

Alison

Alison K. Rodgers
Regulatory Health Project Manager

FDA/CDER
Division of Anti-Infective Products
Phone: 301-796-0797
Fax: 301-796-9882
Email: alison.rodgers@fda.hhs.gov

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/s/

ALISON K RODGERS
04/09/2012

From: Leslie Sands
To: Rodgers, Alison
Subject: RE: NDA 203195 - Request for Information
Date: Tuesday, March 06, 2012 12:49:02 PM

Thanks Alison. I should be able to let you know when we plan to respond tomorrow or Thursday latest.

Regards,

Leslie

From: Rodgers, Alison [mailto:Alison.Rodgers@fda.hhs.gov]
Sent: Tuesday, March 06, 2012 12:37 PM
To: Leslie Sands
Subject: NDA 203195 - Request for Information

Hi Leslie,

Please see the following request for information regarding NDA 203195:

Cefixime capsule is bioequivalent to Suprax® tablet and provides similar exposure as the Suprax® tablet under fasting conditions. However, the capsule formulation is not bioequivalent to the tablet when administered with food; there is approximately a 15% reduction in exposure based on AUC and 25% reduction based on C_{max}. The impact of this reduction in exposure on efficacy when the capsule is given with food is unknown.

Administration of the capsule without regards to food is proposed, however, a justification for this proposal to administer the capsule without regards to food was not provided. Please provide a justification for the proposal to administer the capsule without regard to food.

Please let me know when you plan to submit your response to the NDA.

Please confirm receipt of this email.

Thank you,

Alison

Alison K. Rodgers
Regulatory Health Project Manager
FDA/CDER
Division of Anti-Infective Products
Phone: 301-796-0797
Fax: 301-796-9882
Email: alison.rodgers@fda.hhs.gov

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/s/

ALISON K RODGERS
03/06/2012

Cuff, Althea

From: Leslie Sands [lsands@lupinusa.com]
Sent: Tuesday, January 31, 2012 11:01 AM
To: Cuff, Althea
Subject: RE: NDA 203-195 - Information Request

Thanks Althea.

Regards,

Leslie

From: Cuff, Althea [mailto:Althea.Cuff@fda.hhs.gov]
Sent: Tuesday, January 31, 2012 10:58 AM
To: 'lsands@lupinusa.com'
Subject: NDA 203-195 - Information Request

Dear Leslie,

In reviewing the Chemistry, Manufacturing and Control section of the NDA, we have the following Information Request. Please provide a response by February 14, 2012.

Biopharmaceutics Information Request:

Your proposed dissolution method as shown below is acceptable.

US Apparatus: 1 (Basket) with 100 rpm
Medium: pH 7.2 Phosphate buffer, 900 mL at 37ºC

However, your proposed acceptance criterion of Q= (b) (4)% at 45 minutes is not supported by the dissolution data from the biobatch (Clinical and PK) and the stability batches. The dissolution data clearly show that (b) (4)% of the drug is dissolved at 45 minutes. Therefore, (b) (4) the dissolution acceptance criterion to Q= (b) (4)% at 45 minutes for the proposed Suprax (cefixime) 400 mg IR Capsules.

Please update the specification table for your proposed product under section M32P51 and implement the revised acceptance criterion accordingly for the dissolution testing of future stability batches.

CMC Information Request:

1. It appears that the description provided in Section 3.2.P.2.3 is mostly based on the manufacturing process of Cefixime capsules 200 mg (Refer to Table 5, Table 08, and Table 13). Please submit the relevant information on the manufacture of Cefixime Capsules 400 mg, which is the subject of the current NDA. If manufacturing process development was performed for Cefixime Capsules 200 mg only, provide proper justifications to show that the results are applicable to the manufacture of the 400 mg capsules.

Based on the batch analysis data and the available stability data, we recommend that the acceptance criterion (b) (4) of the drug product be (b) (4) to NMT (b) (4)% (Refer to Section 3.2.P.5.1 of the NDA submission).

Based on the batch analysis data and the available stability data, we recommend that the acceptance criterion for total impurities of the drug product (b) (4) NMT (b) (4)% (Refer to Section 3.2.P.5.1 of the NDA submission).

Please provide some samples of the drug product.

nks,

Althea Cuff
Regulatory Health Project Manager
Office of New Drugs Quality Assessment
301-796-4061

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/s/

ALTHEA CUFF
01/31/2012

From: Leslie Sands
To: Rodgers, Alison;
Subject: RE: Suprax capsules labeling- NDa suppl. data required
Date: Friday, October 21, 2011 1:48:59 PM

Thanks Alison.

Enjoy your weekend.

Regards,

Leslie

From: Rodgers, Alison [mailto:Alison.Rodgers@fda.hhs.gov]
Sent: Friday, October 21, 2011 1:41 PM
To: Leslie Sands
Subject: RE: Suprax capsules labeling- NDa suppl. data required

Hi Leslie,

I apologize for the delay in responding to your question regarding geriatric labeling.

Please provide revised labeling that includes a geriatric use section based on whatever limited information you have. Please note the language in the regulations regarding the geriatric use section, 21 CFR 201.57 (f) (10). The regulations include proposed language for renally excreted drugs that would apply to cefixime.

Please let me know if you have any questions.

Please confirm receipt of this email.

Thank you,

Alison

Alison K. Rodgers
Regulatory Health Project Manager
FDA/CDER
Division of Anti-Infective Products
Phone: 301-796-0797
Fax: 301-796-9882
Email: alison.rodgers@fda.hhs.gov

From: Leslie Sands [mailto:lsands@lupinusa.com]
Sent: Thursday, October 13, 2011 11:04 AM

To: Rodgers, Alison
Subject: FW: Suprax capsules labeling- NDa suppl. data required
Importance: High

fyi

From: Leslie Sands [mailto:lsands@lupinusa.com]
Sent: Wednesday, October 12, 2011 4:19 PM
To: 'althea.cuff@fda.hhs.gov'
Cc: 'Debashis Mohanty'
Subject: FW: Suprax capsules labeling- NDa suppl. data required
Importance: High

Dear Althea,

Per the Filing Communication letter dated September 28, 2011, on page 2, the Agency identified a few labeling format issues with regard to Lupin's labeling. It was noted that under "Use in Specific Populations", subsection 8.5 Geriatric Use is required and cannot be omitted. Lupin acquired the trademark rights to the name Suprax from Wyeth/Lederle then discontinued their product (NDA 050622). From the limited documents Lupin has access to, Wyeth submitted a Geriatric Labeling Supplement dated August 27, 1999 which included a Geriatric use section, however we don't have copies of the labeling submitted in the supplement to reference in order to complete our response due by October 15, 2011, per the filing communication date September 28, 2011. A copy of Wyeth's cover letter is attached for your review.

Can you provide the labeling submitted in the August 27, 1999, submission?

Regards,

Leslie

From: sagarsutar@lupinpharma.com [mailto:sagarsutar@lupinpharma.com]
Sent: Wednesday, October 12, 2011 10:48 AM
To: Debashis Mohanty
Cc: pramoddahibhate@lupinpharma.com; geetanjalijaguste@lupinpharma.com; lsands@lupinusa.com
Subject: Suprax capsules labeling- NDa suppl. data required
Importance: High

Dear Debashis,
As discussed, pl. get the copies of supplement no. 013 and 014 filed for NDA 050622-Suprax Cefixime for Oral Suspension, 100 mg/5 mL (refer highlighted in the attached file -Suprax fos (b) (4) -nda 050622.pdf) from the agency at the earliest as we have to submit the labeling response before October 15, 2011.
Also attached copy of suppl. 015 filed by Suprax NDA holder (Lederle) for your reference.

Regards

Sagar

| Regulatory Affairs |
| T | +91-22-6640-2305 |
| M | +91 9930104948|

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/s/

ALISON K RODGERS
10/21/2011

From: Leslie Sands
To: Rodgers, Alison;
Subject: RE: NDA 203195 - Request for Information 10-17-11
Date: Monday, October 17, 2011 4:23:23 PM

Thanks Alison.

Regards,

Leslie

From: Rodgers, Alison [mailto:Alison.Rodgers@fda.hhs.gov]
Sent: Monday, October 17, 2011 4:22 PM
To: Leslie Sands
Subject: NDA 203195 - Request for Information 10-17-11

Hi Leslie,

Please note the following request for information regarding NDA 203195:

1. Will you continue to produce the tablets if the capsules were to be approved or would you replace the 400mg tablets with the capsules?

1a. If you plan to replace how long will it take for you to implement it if approved?

2. Will you continue to produce all the other formulations of suprax (e.g. suspension, hard tablets, chewables)?

3. Is the submitted PI meant to include all the available formulations or is it meant to be specific just to the 400mg capsule and separate from the others?

4. Regarding the individual blisters and the labels on the back- will labels be printed on paper (white background) or do you plan to print directly on the foil (aluminum color background)?

Please respond by October 24,2011 if at all possible. Please submit your response to the NDA.

Please let me know if you have any questions.

Please confirm receipt of this email.

Thank you,

Alison

Alison K. Rodgers
Senior Regulatory Health Project Manager
FDA/CDER
Division of Anti-Infective Products
Phone: 301-796-0797
Fax: 301-796-9882
Email: alison.rodgers@fda.hhs.gov

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/s/

ALISON K RODGERS
10/20/2011

Cuff, Althea

From: Leslie Sands [lsands@lupinusa.com]
Sent: Thursday, October 13, 2011 7:29 AM
To: Cuff, Althea
Subject: Re: NDA 203-195 - Information Request

Thanks. I will forward on to our team.

Regards,

Leslie

Sent via BlackBerry from T-Mobile

From: "Cuff, Althea" <Althea.Cuff@fda.hhs.gov>
Date: Wed, 12 Oct 2011 19:04:21 -0400
To: 'lsands@lupinusa.com'<lsands@lupinusa.com>
Subject: NDA 203-195 - Information Request

Ms. Sands,

Please provide response by October 26, 2011.

Confirm receipt of this e-mail.

Thanks,

Althea Cuff
Regulatory Health Project Manager
Office of New Drugs Quality Assessment
301-796-4061

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/s/

ALTHEA CUFF
10/13/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203195

FILING COMMUNICATION

Lupin Limited
c/o Lupin Pharma
Attention: Leslie Sands
Director, Regulatory Affairs
Harborplace Tower, 111 South Calvert Street, 21st Floor
Baltimore, MD 21202

Dear Ms. Sands:

Please refer to your New Drug Application (NDA) dated June 28, 2011, received August 1, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Suprax (cefixime capsules), 400 mg.

We also refer to your amendment dated September 15, 2011.

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 June 1, 2012.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, midcycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by May 4, 2012.

At this time, we are notifying you that, we have not identified any potential review issues. Please note that our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review.

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

1. Highlights Limitation Statement – Must be placed at the beginning of highlights, bolded, and read as follows: "**These highlights do not include all the information needed to use (insert name of drug product in UPPER CASE) safely and effectively. See full prescribing information for (insert name of drug product in UPPER CASE).**"

2. Use in Specific Populations – Subsections 8.4 Pediatric Use and 8.5 Geriatric Use are required and cannot be omitted.

We request that you resubmit labeling that addresses these issues by October 15, 2011. The resubmitted labeling will be used for further labeling discussions.

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.

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.

We note that you have not addressed how you plan to fulfill this requirement. Within 30 days of the date of this letter, please submit (1) a full waiver request, (2) a partial waiver request and a pediatric development plan for the pediatric age groups not covered by the partial waiver request, or (3) a pediatric drug development plan covering the full pediatric age range. All waiver requests must include supporting information and documentation. A pediatric drug development plan must address the indications proposed in this application.

If you request a full waiver, we will notify you if the full waiver is denied and a pediatric drug development plan is required.

Pediatric studies conducted under the terms of section 505B of the Federal Food, Drug, and Cosmetic Act (the Act) may also qualify for pediatric exclusivity under the terms of section 505A of the Act. If you wish to qualify for pediatric exclusivity please consult the **Division of Anti-Infective Products**. Please note that satisfaction of the requirements in section 505B of the Act alone may not qualify you for pediatric exclusivity under 505A of the Act.

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

John Farley, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

JOHN J FARLEY
09/28/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203195

NDA ACKNOWLEDGEMENT
USER FEES RECEIVED

Lupin Limited
c/o Lupin Pharma
Attention: Leslie Sands
Director, Regulatory Affairs
Harborplace Tower, 111 South Calvert Street, 21st Floor
Baltimore, MD 21202

Dear Ms. Sands:

Please refer to your new drug application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for SUPRAX (cefiximine capsules), 400 mg.

You were notified in our letter dated July 13, 2011, that your application was not accepted for filing due to non-payment of fees. This is to inform you that the Agency has received all required fees and your application has been accepted as of August 1, 2011.

Unless we notify you within 60 days of the above date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on September 30, 2011 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 cited above should be included 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 Anti-Infective Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, contact Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

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

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/s/

MAUREEN P DILLON PARKER
08/29/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203195 **UNACCEPTABLE FOR FILING**

Lupin Limited c/o Lupin Pharmaceuticals, Inc.
Attention: Leslie Sands
Director, Regulatory Affairs
Harborplace Tower
111 South Calvert Street, 21st Floor
Baltimore, MD 21202

Dear Ms. Sands:

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

Name of Drug Product: Suprax (cefixime) Capsules, 400 mg

Date of Application: June 28, 2011

Date of Receipt: June 28, 2011

Our Reference Number: NDA 203195

We have not received the appropriate user fee for this application. An application is considered incomplete and cannot be accepted for filing until all fees owed have been paid. Therefore, this application is not accepted for filing. We will not begin a review of this application's adequacy for filing until FDA has been notified that the appropriate fee has been paid. Payment should be submitted to the following address:

Food and Drug Administration
P.O. Box 979107
St. Louis, MO 63197-9000

Checks sent by courier should be addressed to:

U.S. Bank
Attention: Government Lockbox 979107
1005 Convention Plaza
St. Louis, MO 63101

When submitting payment for an application fee, include the User Fee I.D. Number, the Application number, and a copy of the user fee coversheet (Form 3397) with your application fee payment. When submitting payment for previously unpaid product and establishment fees, please include the Invoice Number(s) for the unpaid fees and the summary portion of the invoice(s) with your payment. The FDA P.O. Box number (P.O. Box 979107) should be included on any check you submit.

The receipt date for this submission (which begins the review for filability) will be the date the review division is notified that payment has been received by the bank.

Please cite the NDA number listed above 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 Anti-Infective Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you wish to send payment by wire transfer, or if you have any other user fee questions, please call Bev Friedman or Mike Jones at 301-796-3602.

If you have any questions, please contact Alison Rodgers, Regulatory Health Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

John Farley, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

JOHN J FARLEY
07/13/2011