CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207026Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

PATENT CERTIFICATION

In accordance with the Federal Food, Drug and Cosmetic Act, as amended September 24, 1984, patent certification is hereby provided for our New Drug Application for Phoxilium (Phoxilium BK4/2.5 and Phoxilium B22K4/0), submitted pursuant to section 505(b)(2).

In the opinion and to the best knowledge of Gambro Lundia AB, there is no patent that claims the listed drug referred to in this application or that claims a use of the listed drug.

Marie-Armelle MOURET
Director RA Solutions

Date: 2013-07-19

Fei LAW
QA/RA Manager

Date: 2013-07-19

Anders Onshage
Vice President IP
Legal & Intellectual Property
Gambro Lundia AB

Date: July 4, 2013

Department of Health and Human Services
Food and Drug Administration

Form Approved: OMB No. 0910-0513
Expiration Date: 10/31/2013
See OMB Statement on Page 3.

PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use

NDA NUMBER
21-703

NAME OF APPLICANT/NDA HOLDER
Gambro Lundia AB

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)
Phoxilium BK4/2.5

ACTIVE INGREDIENT(S)	STRENGTH(S)
Calcium chloride, Magnesium chloride, Sodium chloride Potassium chloride, Sodium bicarbonate, Dibasic sodium phosphate.	mEq/L (Except for Phosphate that is in mmol/L) Calcium = 2.5 Magnesium=1.5 Sodium=140 Chloride=114.5 Bicarbonate= 32 Potassium=4.0 Phosphate 1 mmol/L

DOSAGE FORM
Sterile solution, free of endotoxins

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4).
Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the *only* information relied upon by FDA for listing a patent in the Orange Book.

For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you submit an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent	
d. Name of Patent Owner	Address *(of Patent Owner)*		
	City/State		
	ZIP Code	FAX Number *(if available)*	
	Telephone Number	E-Mail Address *(if available)*	
e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States)	Address *(of agent or representative named in 1.e.)*		
	City/State		
	ZIP Code	FAX Number *(if available)*	
	Telephone Number	E-Mail Address *(if available)*	

f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? ☐ Yes ☐ No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? ☐ Yes ☐ No

PSC Graphics (301) 413-1090 EF

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	☐ Yes	☐ No
2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement?	☐ Yes	☐ No
2.3 If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		
2.5 Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.)	☐ Yes	☐ No
2.6 Does the patent claim only an intermediate?	☐ Yes	☐ No
2.7 If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

3. Drug Product (Composition/Formulation)

3.1 Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?	☐ Yes	☐ No
3.2 Does the patent claim only an intermediate?	☐ Yes	☐ No
3.3 If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

4. Method of Use

Sponsors must submit the information in section 4 for each method of using the pending drug product for which approval is being sought that is claimed by the patent. For each pending method of use claimed by the patent, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?		☐ Yes	☐ No
4.2 Patent Claim Number(s) *(as listed in the patent)*	Does (Do) the patent claim(s) referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☐ Yes	☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the proposed labeling.)*		

5. No Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.	☒ Yes

6. Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed
	12/3/2012

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☒ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name Gambro Lundia AB	
Address PO Box 10101	City/State Lund
ZIP Code SE 22010	Telephone Number 0046 46169000
FAX Number *(if available)* 0046 46169690	E-Mail Address *(if available)*

EXCLUSIVITY SUMMARY

NDA # **207026** SUPPL # HFD #

Trade Name **Phoxillum**

Generic Name **N/A**

Applicant Name **Gambro Lundia AB**

Approval Date, If Known **January 13, 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)(1)

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

YES ☐ NO ☒

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

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

d) Did the applicant request exclusivity?

YES ☐ NO ☒

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

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

YES ☐ NO ☒

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

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: Anna Park
Title: Senior Regulatory Project Manager
Date: 06 January 2015

Name of Office/Division Director signing form: Norman Stockbridge, M.D., Ph.D.
Title: Division Director

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

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

/s/

ANNA J PARK
01/11/2015

NORMAN L STOCKBRIDGE
01/12/2015

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

NDA/BLA#: 207026 Supplement Number: _____ NDA Supplement Type (e.g. SE5): _____

Division Name:DCRP PDUFA Goal Date: 01/13/15 Stamp Date: 01/13/14

Proprietary Name: Phoxillum

Established/Generic Name: _____

Dosage Form: Renal Replacement Solution

Applicant/Sponsor: Gambro Renal Products

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

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

Number of indications for this pending application(s):1
(Attach a completed Pediatric Page for each indication in current application.)

Indication: Replacement Solution in patients undergoing Continuous Renal Replacement Therapy (CRRT)

Q1: Is this application in response to a PREA PMR? Yes ☐ Continue

No ☒ Please proceed to Question 2.

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

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

☐ Yes. Please proceed to Section D.

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

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

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

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

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

Q3: Does this indication have orphan designation?

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

☐ No. Please proceed to the next question.

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

☐ Yes: (Complete Section A.)

☐ No: Please check all that apply:

☐ Partial Waiver for selected pediatric subpopulations (Complete Sections B)

☐ Deferred for some or all pediatric subpopulations (Complete Sections C)

☐ Completed for some or all pediatric subpopulations (Complete Sections D)

☐ Appropriately Labeled for some or all pediatric subpopulations (Complete Sections E)

☐ Extrapolation in One or More Pediatric Age Groups (Complete Section F)

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

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

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

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

☐ Justification attached.

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

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

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

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

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

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

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

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

Not feasible:

- ☐ Necessary studies would be impossible or highly impracticable because:
  - ☐ Disease/condition does not exist in children
  - ☐ Too few children with disease/condition to study
  - ☐ Other (e.g., patients geographically dispersed): _____

***** Not meaningful therapeutic benefit:

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

† Ineffective or unsafe:

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

Δ Formulation failed:

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

☐ Justification attached.

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

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

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

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

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

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

* Other Reason: _____

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

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

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

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

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

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

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

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

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

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

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

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

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

If all pediatric subpopulations have been covered based on partial waivers, deferrals, completed studies, and/or

existing appropriate labeling, this Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

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

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

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

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

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

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

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

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

This page was completed by:

{See appended electronic signature page}

Regulatory Project Manager

(Revised: 6/2008)

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

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

/s/

ANNA J PARK
01/07/2015

DEBARMENT CERTIFICATION

New Drug Application for Phoxilium BK4/2.5 and Phoxilium B22K4/0

Gambro Lundia AB hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Jeremiah J. McIntyre
Senior Vice President and Chief Legal Counsel
Gambro Lundia AB

August 15, 2013

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]

NDA # **207026** BLA #	NDA Supplement # BLA Supplement #	If NDA, Efficacy Supplement Type: *(an action package is not required for SE8 or SE9 supplements)*
Proprietary Name: **Phoxillum** Established/Proper Name: **BK4/2.5 and B22 4/0 solutions** Dosage Form: **Renal Replacement Solution**		Applicant: Gambro Lundia AB Agent for Applicant (if applicable):
RPM: **Anna Park**		Division: **Cardiovascular and Renal Products**

NDA Application Type: ☒ 505(b)(1) ☐ 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 January 13, 2015	☒ AP ☐ TA ☐ CR
• Previous actions *(specify type and date for each action taken)*	☒ 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. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

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

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 ☐ No
• Indicate what types (if any) of information were issued	☒ 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	☒ No ☐ 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.	☒ 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)*	☒ Included
Documentation of consent/non-consent by officers/employees	☒ Included

Action Letters	
❖ Copies of all action letters *(including approval letter with final labeling)*	Action(s) and date(s) Approval 1/13/15
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)*	☒ Included
• Original applicant-proposed labeling	☒ Included
❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling *(write submission/communication date at upper right of first page of each piece)*	☐ Medication Guide ☐ Patient Package Insert ☐ Instructions for Use ☐ Device Labeling ☒ None
• Most-recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☐ 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	☒ Included
❖ Proprietary Name • Acceptability/non-acceptability letter(s) *(indicate date(s))* • Review(s) *(indicate date(s)*	Acceptability – 08/06/14 Review – 08/05/14 Denied – 06/30/14
❖ Labeling reviews *(indicate dates of reviews)*	RPM: ☒ None 04/29/14 DMEPA: ☒ None 10/09/14 DMPP/PLT (DRISK): ☒ None OPDP: ☐ None 1/13/15 SEALD: ☒ None CSS: ☒ None Other: ☒ 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	1/7/15 ☒ Not a (b)(2)
❖ NDAs only: Exclusivity Summary *(signed by Division Director)*	☒ Included
❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm	
• Applicant is on the AIP	☐ Yes ☒ No

[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 ☐ No ☐ Not an AP action
❖ Pediatrics *(approvals only)* • Date reviewed by PeRC _____ If PeRC review not necessary, explain: _____	
❖ 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, etc.) *(do not include previous action letters, as these are located elsewhere in package)*	NDA acknowledgement Letter – 3/20/14 Email – 4/1/14 CMC IR – 4/17/14 Filing communication – 4/29/14 CMC IR – 6/9/14 Proprietary name letter (unacceptable)- 6/30/14 CMC IR – 8/6/14 Proprietary name acceptable – 8/6/14 IR – 9/15, 10/13, 10/20, 12/16/14, 1/2 & 1/8/15 General advice letter – 10/15/14
❖ 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)	T-con minutes DMEPA – 6/26/14
❖ Minutes of Meetings	
• If not the first review cycle, any end-of-review meeting *(indicate date of mtg)*	☒ N/A or no mtg
• Pre-NDA/BLA meeting *(indicate date of mtg)*	☒ No mtg
• EOP2 meeting *(indicate date of mtg)*	☒ No mtg
• Mid-cycle Communication *(indicate date of mtg)*	☒ N/A
• Late-cycle Meeting *(indicate date of mtg)*	☒ N/A
• Other milestone meetings (e.g., EOP2a, CMC pilots) *(indicate dates of mtgs)*	none
❖ Advisory Committee Meeting(s)	☒ No AC meeting
• Date(s) of Meeting(s)	
Decisional and Summary Memos	
❖ Office Director Decisional Memo *(indicate date for each review)*	☒ None
Division Director Summary Review *(indicate date for each review)*	☐ None 1/12/15
Cross-Discipline Team Leader Review *(indicate date for each review)*	☐ None 1/8/15
PMR/PMC Development Templates *(indicate total number)*	☒ None
Clinical	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) *(indicate date for each review)*	☒ No separate review
• Clinical review(s) *(indicate date for each review)*	Clinical memo 12/19/14
• Social scientist review(s) (if OTC drug) *(indicate date for each review)*	☒ None

❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here ☒ and include a review/memo explaining why not *(indicate date of review/memo)*	No clinical studies conducted
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers *(indicate date of each review)*	☒ None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation *(indicate date of each review)*	☒ 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)*	☒ None
❖ OSI Clinical Inspection Review Summary(ies) *(include copies of OSI letters to investigators)*	☒ None requested
Clinical Microbiology ☒ None	
❖ Clinical Microbiology Team Leader Review(s) *(indicate date for each review)*	☐ No separate review
Clinical Microbiology Review(s) *(indicate date for each review)*	☐ None
Biostatistics ☒ None	
❖ Statistical Division Director Review(s) *(indicate date for each review)*	☐ No separate review
Statistical Team Leader Review(s) *(indicate date for each review)*	☐ No separate review
Statistical Review(s) *(indicate date for each review)*	☐ None
Clinical Pharmacology ☒ None	
❖ Clinical Pharmacology Division Director Review(s) *(indicate date for each review)*	☐ No separate review
Clinical Pharmacology Team Leader Review(s) *(indicate date for each review)*	☐ No separate review
Clinical Pharmacology review(s) *(indicate date for each review)*	☐ None
❖ OSI Clinical Pharmacology Inspection Review Summary *(include copies of OSI letters)*	☐ None requested
Nonclinical ☒ None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) *(indicate date for each review)*	☐ No separate review
• Supervisory Review(s) *(indicate date for each review)*	☐ No separate review
• Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	☐ None
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer *(indicate date for each review)*	☐ None
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	☐ No carc
❖ ECAC/CAC report/memo of meeting	☐ None Included in P/T review, page
❖ OSI Nonclinical Inspection Review Summary *(include copies of OSI letters)*	☐ None requested

Product Quality ☐ None	
❖ Product Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) *(indicate date for each review)*	☒ No separate review
• Branch Chief/Team Leader Review(s) *(indicate date for each review)*	☒ No separate review
• Product quality review(s) including ONDQA biopharmaceutics reviews *(indicate date for each review)*	☐ None 11/12/14
❖ Microbiology Reviews ☒ NDAs: Microbiology reviews (sterility & pyrogenicity) (OPS/NDMS) *(indicate date of each review)* ☐ BLAs: Sterility assurance, microbiology, facilities reviews (OMPQ/MAPCB/BMT) *(indicate date of each review)*	☐ Not needed 11/12/14
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer *(indicate date of each review)*	☒ None
❖ Environmental Assessment (check one) (original and supplemental applications)	
☒ Categorical Exclusion *(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)*	11/12/14
☐ Review & FONSI *(indicate date of review)*	
☐ Review & Environmental Impact Statement *(indicate date of each review)*	
❖ Facilities Review/Inspection	
☒ NDAs: Facilities inspections (include EER printout or EER Summary Report only; do NOT include EER Detailed Report; date completed must be within **2 years** of action date) *(only original NDAs and supplements that include a new facility or a change that affects the manufacturing sites[5])*	Date completed: 11/26/14 ☒ Acceptable ☐ Withhold recommendation ☐ Not applicable
☐ BLAs: TB-EER (date of most recent TB-EER must be within **30 days** of action date) *(original and supplemental BLAs)*	Date completed: ☐ Acceptable ☐ Withhold recommendation
❖ NDAs: Methods Validation *(check box only, do not include documents)*	☒ Completed ☐ Requested ☐ Not yet requested ☐ Not needed (per review)

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

Day of Approval Activities	
❖ For all 505(b)(2) applications: • Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)	☐ No changes ☐ New patent/exclusivity *(Notify CDER OND IO)*
• Finalize 505(b)(2) assessment	☐ Done
❖ Send a courtesy copy of approval letter and all attachments to applicant by fax or secure email	☒ 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	☒ Done

---

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/s/

ANNA J PARK
01/14/2015

From: Law, Fei
To: Park, Anna
Subject: European Phoxilium case reports
Date: Monday, October 13, 2014 11:45:33 AM
Attachments: 2014BAX060010_0_CIOMS.PDF
2014BAX020514_CIOMS.PDF
2014BAX030650_CIOMS.PDF

Dear Anna,

Attached please find the case reports as discussed.

In summary:

- We received 3 reports from a hospital in Great Britain related to acidosis (not resolving or worsening) while on CRRT with Phoxilium which is currently on the market in Europe.
- The EU version of Phoxilium has 1.2 mmol/L of phosphate, whereas the US version has 1.0 mmol/L.
- The current Package Insert under review through NDA 207026 already has a statement in the warning and precautions section to monitor acid/base and electrolyte balance and to correct with the appropriate formulation.
- We would like to (b) (4) . Unfortunately, we are not ready with a draft statement and the back-up information to that statement at this point.

We would like your thoughts on two options:

1. Go through the NDA process now and submit a PAS with the new wording shortly after
2. Wait on the new wording before finalizing the labeling for Phoxillum. If option 2, we would also like your thoughts on what the latest date of submitting revised labeling would be in order to meet the January 2015 goal date.

In the meantime, we are preparing to electronically transmit the merged PrismaSol/Phoxillum package inserts to you, and will have that to you this week.
I will send you an email preview copy as soon as it's available.
Best Regards,
Fei

Fei Law
Quality and Regulatory Manager, US Solutions
Gambro Renal Products, Inc.
1845 Mason Avenue, Daytona Beach, FL 32117
Direct: 386-795-4484
fei.law@us.gambro.com

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/s/

ANNA J PARK
01/12/2015

From: Park, Anna
To: "Law, Fei"
Subject: RE: NDA 207026
Date: Tuesday, April 01, 2014 2:11:00 PM

Hi Fei,

Got it. Since NDA 207026 will reference NDA 21703, which belongs to Gambro, this will be processed as a 505(b)(1).

Thanks.
anna

From: Law, Fei [mailto:fei.law@gambro.com]
Sent: Tuesday, April 01, 2014 1:29 PM
To: Park, Anna
Cc: Law, Fei
Subject: Re: NDA 207026

Hello Anna,

Our intent is to reference PrismaSol. Modules 4 and 5 contain simple reference statements to PrismaSol, with the understanding that the original data submitted also applies to Phoxilium. PrismaSol was originally submitted under 505(b)(2) and therefore we carried on the terminology.

Please let me know if we need to adjust the terminology.

Best Regards,
Fei

On Apr 1, 2014, at 12:53 PM, "Park, Anna" <Anna.Park@fda.hhs.gov> wrote:

> Hi Fei,
>
> Quick question.
>
> In your cover letter, you state "this application is submitted under section 505(b)(2)…", however, you are comparing it to your already approved PrismaSol, correct? Or are you relying upon studies not conducted by Gambro for which you do not have a right of reference?
>
> Thanks.
> anna

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/s/

ANNA J PARK
01/11/2015

From: Park, Anna
To: "Law, Fei"
Subject: NDA 207026 CMC request #1
Date: Monday, September 15, 2014 11:55:00 AM

Hi Fei,

The CMC reviewer had the following recommendation:

(b) (4). Our current labeling policy is to either omit this language or replace it with a statement such as, "Not made with natural rubber latex" if that statement is true for all materials used in the manufacture of your medical product and container.

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Thursday, September 11, 2014 1:32 PM
To: Park, Anna
Subject: RE: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

Will do.

From: Park, Anna [mailto:Anna.Park@fda.hhs.gov]
Sent: Thursday, September 11, 2014 1:23 PM
To: Law, Fei
Subject: RE: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

Hi Fei,

I have labeling comment from CMC, so please hold off from sending the label.

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Thursday, September 11, 2014 12:19 PM
To: Park, Anna
Subject: RE: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

OK, thank you. We will submit Phoxillum first since that is electronic and an ongoing project. We will follow with PrismaSol since that is paper-based and will take a bit longer to get the submission ready.

From: Park, Anna [mailto:Anna.Park@fda.hhs.gov]
Sent: Thursday, September 11, 2014 12:15 PM
To: Law, Fei
Subject: RE: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

Hi Fei,

We will defer the decision to you and your team. If you prefer to wait so that the wording is already set, that's fine. Otherwise, we can review both labels concurrently.

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Thursday, September 11, 2014 11:23 AM
To: Park, Anna
Subject: RE: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

Yes, we had planned for a labeling supplement for PrismaSol.
Would you like me to submit it concurrently, or should I wait for approval of the Phoxillum labeling, so that the wording is already set at that point?

From: Park, Anna [mailto:Anna.Park@fda.hhs.gov]
Sent: Thursday, September 11, 2014 10:58 AM
To: Law, Fei
Subject: RE: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

Hi Fei,

(b) (4) Those cannot be included in the PI.

Also, you may want to consider submitting a labeling supplement to PrismaSol (NDA 21703) so that we can harmonize the label.

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Thursday, September 11, 2014 10:40 AM
To: Park, Anna
Subject: RE: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

Hello Anna,

The Highlights and FPI were intended to be on the same page; sorry about the formatting issue.

Could you clarify about the headers? We need to identify the product on the Package Insert, so to clarify:

1- Are you requesting that we (b) (4) with plain text,
2- Or are you requesting that we remove the descriptors (b) (4)

[redacted](b) (4)"? We had added those to try to show that this one Package Insert refers to [redacted](b) (4), but those can be removed if that is what is requested.

Best Regards,
Fei

From: Park, Anna [mailto:Anna.Park@fda.hhs.gov]
Sent: Thursday, September 11, 2014 10:25 AM
To: Law, Fei
Subject: RE: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

Hi Fei,

We will need to conduct a thorough review but please submit the draft label via the Gateway. I do ask that you remove the [redacted](b) (4) from the top of page and try to combine the Highlights and FPI into one page, as required, before submitting.

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Wednesday, September 10, 2014 5:08 PM
To: Park, Anna
Subject: NDA 207-026 - Combination of PrismaSol and Phoxillum Package leaflets

Dear Anna:

As discussed during FDA's and Gambro's conference call on Monday September 8, we understand that it is FDA's preference to combine both PrismaSol and Phoxillum package leaflets into one, and that it is possible to do so while maintaining both Prismasol and Phoxillum as separate tradenames. We understand that this approach is considered to be beneficial for the end user since all formulations will be presented in one document, providing complete visibility with regards to all the therapy options within the PrismaSol and Phoxillum product lines.

After internal discussion, we are in agreement with this approach. I am hereby sending you a draft proposal of the combined PrismaSol and Phoxillum package leaflets for a general review, with the goal to agree on the labeling approach before a formal amendment is submitted. For ease of review, the information that has been combined has been highlighted in yellow.

We would appreciate your feedback on this draft.

Thank you and best regards,
Fei

Fei Law
Quality and Regulatory Manager, US Solutions
Gambro Renal Products, Inc.
1845 Mason Avenue

Daytona Beach, FL 32117
Direct: 386-481-1143
fei.law@us.gambro.com

From: Keelan, Maria
Sent: Wednesday, September 10, 2014 11:23 AM
To: 'Fei Law'
Subject: RE: Phoxillum bag label

Thank you Fei

Attached the final PL with all the changes requested by Jay have been made.

Can you please review and let me know if you agree and I will send it to the whole team
From: Fei Law [mailto:feilaw.fl@gmail.com]
Sent: Wednesday, September 10, 2014 11:09 AM
To: Keelan, Maria
Subject: Re: Phoxillum bag label

Here you go.

I have publisher at home so that's what I used.
I believe Barb also has a full version of Adobe that she and Andy know how to use - conversion to black and white should be possible on that also in case we need for the future.

On Wed, Sep 10, 2014 at 10:46 AM, Keelan, Maria <maria_keelan@baxter.com> wrote:

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/s/

ANNA J PARK
01/11/2015

From: Park, Anna
To: "Law, Fei"
Subject: RE: European Phoxilium case reports
Date: Monday, October 20, 2014 6:24:00 AM

Dear Fei,

The Division has the following request:

Please provide your assessment of these cases. If you feel that further changes to the label are needed because of these cases, you should propose revised text. You should submit your assessment and any proposed changes to the label in the next 30 days. If you are unable to respond within this time window, please indicate why you are unable to meet this deadline. We request a response by November 20, 2014.

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Monday, October 13, 2014 11:45 AM
To: Park, Anna
Subject: European Phoxilium case reports

Dear Anna,

Attached please find the case reports as discussed.

In summary:

- We received 3 reports from a hospital in Great Britain related to acidosis (not resolving or worsening) while on CRRT with Phoxilium which is currently on the market in Europe.
- The EU version of Phoxilium has 1.2 mmol/L of phosphate, whereas the US version has 1.0 mmol/L.
- The current Package Insert under review through NDA 207026 already has a statement in the warning and precautions section to monitor acid/base and electrolyte balance and to correct with the appropriate formulation.
- We would like to [redacted] (b) (4) [redacted]. Unfortunately, we are not ready with a draft statement and the back-up information to that statement at this point.

We would like your thoughts on two options:

1. Go through the NDA process now and submit a PAS with the new wording shortly after
2. Wait on the new wording before finalizing the labeling for Phoxillum. If option 2, we would also like your thoughts on what the latest date of submitting revised labeling would be in order to meet the January 2015 goal date.

In the meantime, we are preparing to electronically transmit the merged PrismaSol/Phoxillum

package inserts to you, and will have that to you this week.
I will send you an email preview copy as soon as it's available.
Best Regards,
Fei

Fei Law
Quality and Regulatory Manager, US Solutions
Gambro Renal Products, Inc.
1845 Mason Avenue, Daytona Beach, FL 32117
Direct: 386-795-4484
fei.law@us.gambro.com

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/s/

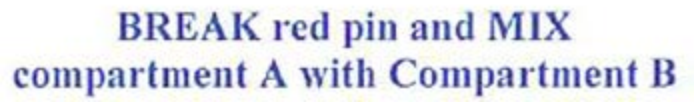
ANNA J PARK
01/11/2015

From: Park, Anna
To: "Law, Fei"
Subject: RE: NDA 207026 draft label
Date: Tuesday, December 16, 2014 11:48:00 AM
Attachments: image001.png

Hi Fei,

Discussions are still ongoing regarding the label. However, there is one editorial change we recommend:

Please consider changing the "c" in compartment so they both match.



Will keep you updated on our progress.

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Tuesday, December 16, 2014 10:15 AM
To: Park, Anna
Subject: FW: NDA 207026 draft label

Dear Anna,

I just wanted to check in with you for planning purposes in case you are expecting any further comments imminently.
Most of our team will be out of the office at various times throughout the weeks of Christmas and New Year's, including myself.
If you are expecting to get more comments, I will make sure to log in to check.

Best Regards,
Fei

Fei Law
Quality and Regulatory Manager, US Solutions
Gambro Renal Products, Inc.
1845 Mason Avenue
Daytona Beach, FL 32117
Direct: 386-481-1143
fei.law@us.gambro.com

From: Law, Fei
Sent: Wednesday, December 10, 2014 9:26 AM
To: 'Park, Anna'
Subject: RE: NDA 207026 draft label

Hello Anna,
Sorry for the inconvenience but last minute I noticed a minor item in the cover letter (just a decimal missing and a typo in Table 1).

Please use this version,
Best Regards,
Fei

From: Law, Fei
Sent: Wednesday, December 10, 2014 9:16 AM
To: 'Park, Anna'
Subject: RE: NDA 207026 draft label

Dear Anna,

Attached please find an updated version of the draft Package Leaflet for PrismaSol and Phoxillum. For ease of review, we have also provided a cover letter with a table that specifies what was changed in each section.

Please let me know if you have any questions,
Best Regards,
Fei

Fei Law
Quality and Regulatory Manager, US Solutions
Gambro Renal Products, Inc.
1845 Mason Avenue
Daytona Beach, FL 32117
Direct: 386-481-1143
fei.law@us.gambro.com

From: Park, Anna [mailto:Anna.Park@fda.hhs.gov]
Sent: Monday, December 01, 2014 12:06 PM
To: Law, Fei
Subject: NDA 207026 draft label

Hi Fei,

I hope you had a nice Thanksgiving.

Enclosed is our revised draft label for Phoxillum. We are still discussing the label internally but wanted to send you the draft label containing our recommendations/revisions. We have several comments that require feedback.

Thanks.
anna

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/s/

ANNA J PARK
01/11/2015

From: Park, Anna
To: "Law, Fei"
Subject: RE: NDA 207026 Clinical request (1/2/15)
Date: Thursday, January 08, 2015 7:40:00 AM

Hi Fei,

My apologies for the delay. We are writing to clarify we meant the body of the patient.

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Wednesday, January 07, 2015 9:42 AM
To: Park, Anna
Subject: RE: NDA 207026 Clinical request (1/2/15)

Hello Anna,

I am awaiting internal feedback and will get you an ETA as soon as possible. We understand that timing is critical since the goal date is rapidly approaching.

One clarification I would like to ask:

For each of your Prismasol solutions (8 different products) and Phoxillum solutions (2 different products), please provide an estimate of:

- the buffering capacity in the body of the solution

The body of the solution refers to the chemical content of the solution?
It is not requesting its impact on the human body until the second bullet, right?

- the likely net effect on systemic pH in a "typical" patient on CRRT with underlying metabolic acidosis

Fei

From: Park, Anna [mailto:Anna.Park@fda.hhs.gov]
Sent: Wednesday, January 07, 2015 6:15 AM
To: Law, Fei
Subject: RE: NDA 207026 Clinical request (1/2/15)

Hi Fei,

Can you please provide me with an update on when we can expect a response?

Thanks.
anna

From: Law, Fei [mailto:fei_law@baxter.com]
Sent: Monday, January 05, 2015 10:22 AM
To: Park, Anna
Subject: RE: NDA 207026 Clinical request (1/2/15)

Hello Anna,

Happy 2015!
I acknowledge receipt of the request and will get back to you asap with expected timing for the response.

Best Regards,
Fei

From: Park, Anna [mailto:Anna.Park@fda.hhs.gov]
Sent: Friday, January 02, 2015 7:11 AM
To: Law, Fei
Subject: NDA 207026 Clinical request (1/2/15)
Importance: High

Dear Fei,

Happy New Year to you!

We are trying to finalize our review and have the following request for additional information:

We would like to have a better understanding of the ability of Phoxillum to contribute to metabolic acidosis in patients on CRRT.

For each of your Prismasol solutions (8 different products) and Phoxillum solutions (2 different products), please provide an estimate of:

- the buffering capacity in the body of the solution
- the likely net effect on systemic pH in a "typical" patient on CRRT with underlying metabolic acidosis

Your estimates should take into consideration all components of the solution that could contribute to the buffering effect in the body and address the likely effect when the solution is used as:

- a replacement solution for hemofiltration
- a replacement solution for hemodiafiltration
- as both a replacement and dialysate solution during hemodiafiltration

Please submit a description of your planned approach to address this request for Agency review and concurrence.

Thanks.
anna

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/s/

ANNA J PARK
01/11/2015

From:	Park, Anna
To:	Law, Fei (fei_law@baxter.com)
Subject:	NDA 207026 Clinical request (1/2/15)
Date:	Friday, January 02, 2015 7:10:00 AM
Importance:	High

Dear Fei,

Happy New Year to you!

We are trying to finalize our review and have the following request for additional information:

We would like to have a better understanding of the ability of Phoxillum to contribute to metabolic acidosis in patients on CRRT.

For each of your Prismasol solutions (8 different products) and Phoxillum solutions (2 different products), please provide an estimate of:

- the buffering capacity in the body of the solution
- the likely net effect on systemic pH in a "typical" patient on CRRT with underlying metabolic acidosis

Your estimates should take into consideration all components of the solution that could contribute to the buffering effect in the body and address the likely effect when the solution is used as:

- a replacement solution for hemofiltration
- a replacement solution for hemodiafiltration
- as both a replacement and dialysate solution during hemodiafiltration

Please submit a description of your planned approach to address this request for Agency review and concurrence.

Thanks.
anna

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/s/

ANNA J PARK
01/02/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA207026

GENERAL ADVICE

Gambro Renal Products, Inc.
Attention: Ms. Fei Law
Quality and Regulatory Manager, US Solutions
1845 Mason Avenue
Daytona Beach, FL 32117

Dear Ms. Law:

Please refer to your New Drug Application (NDA) dated March 13, 2014, received March 13, 2014, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, for Phoxillum Solutions (BK4/2.5 and B22K4/0).

We also refer to your July 23, 2014 submission, containing your new proprietary name request for the name Phoxillum and updated labeling.

The Office of Medication Error Prevention and Risk Management – Division of Medication Error Prevention and Analysis has reviewed the referenced material and has the following comments and recommendations:

A. Container Labels

1. The proposed container labels for Phoxillum B22K4/0 and Phoxillum BK4/2.5 do not contain (b) (4)
   We recommend adding an extra container label to Phoxillum B22K4/0 and Phoxillum BK4/2.5 bags to provide such identification and adding mixing instructions similar to those used for your PrismaSol products:

   (b) (4)

   Additionally, to clarify the mixing instructions, we recommend revising the mixing instruction statement from (b) (4) to "BREAK red pin and MIX compartment A with compartment B" (or similar language).

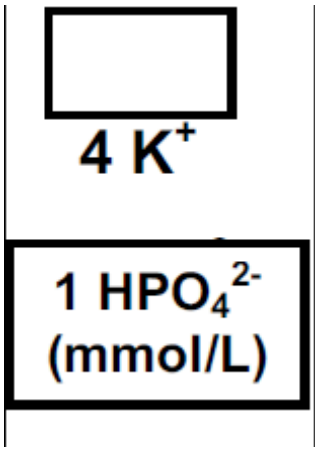
2. The proposed container labels for Phoxillum B22K4/0 and Phoxillum BK4/2.5 do not contain identification of compartment B. We recommend adding a similar graphic "Compartment B" to the compartment B container labels, positioning it near the right

topmost corner of compartment B for identification. This is the example Compartment A graphic from your PrismaSol products:

3. We recommend capitalizing the first letter "P" in the name Phoxillum BK 4/2.5 and Phoxillum B22K4/0 to improve readability of the proprietary names. Consider using the same font, type, size, and typography for the letter "x" to minimize the unintentional interpretation of "pho" and "illum" as separate words.

B. Carton Labeling

1. Relocate the "4 K+" statement inside the box. As currently presented, it is inconsistent with presentation of other information such as "1 HPO4^{2-}"on the carton labeling.



If you have any questions, please call Anna Park, Regulatory Project Manager, at (301) 796-1129.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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NORMAN L STOCKBRIDGE
10/15/2014

From:	Knight, Yvonne
To:	Law, Fei (fei_law@baxter.com)
Cc:	Knight, Yvonne
Subject:	Information Request for NDA 207026 (Prompt Response)
Date:	Wednesday, August 27, 2014 11:52:39 AM
Importance:	High

Good morning Ms. Law,
We have an information request concerning Gambro's New Drug Application for (NDA) NDA 207026. We are reviewing the Quality section of your submission and have the following comments and information requests. We request a prompt written response by **COB Friday September 5, 2014**, in order to continue our evaluation of your NDA.

1) We acknowledge the original (b) (4) validation report DP573-1-PQ-FR dated May 2010 in submission section 3.2.P.3.5, but we cannot locate the most recent re-qualification report. Provide the most recent re-qualification study for the (b) (4) of this product.

Please confirm receipt of this Information Request. Also, please provide me with a courtesy copy via email when you submit your official amendment? If you have any questions or comments feel free to contact me.
Best Regards,

Yvonne Knight, MS
Regulatory Health Project Manager
Division of New Drug Quality Assessment
FDA/CDER/OPS/ONDQA
10903 New Hampshire Avenue
Bldg. 21, Room 2667
Silver Spring, MD 20993-0002
Phone: 301.796.2133
Email: yvonne.knight@fda.hhs.gov

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/s/

YVONNE L KNIGHT
08/27/2014

From:	Knight, Yvonne
To:	Law, Fei (fei.law@gambro.com)
Cc:	Knight, Yvonne
Subject:	Information Request for NDA 207026 (Prompt Response)
Date:	Wednesday, August 06, 2014 9:39:52 AM
Importance:	High

Good morning Fei Law,
We have an information request concerning Gambro's New Drug Application for (NDA) NDA 207026. We are reviewing the Quality section of your submission and have the following comments and information requests. We request a prompt written response by **COB Friday August 29, 2014**, in order to continue our evaluation of your NDA.

1) Provide the method suitability testing for the sterility test.
2) Provide the method suitability testing for the endotoxin test.

Please confirm receipt of this Information Request. Also, please provide me with a courtesy copy via email when you submit your official amendment? If you have any questions or comments feel free to contact me.

Best Regards,
Yvonne Knight, MS
Regulatory Health Project Manager
Division of New Drug Quality Assessment
FDA/CDER/OPS/ONDQA
10903 New Hampshire Avenue
Bldg. 21, Room 2667
Silver Spring, MD 20993-0002
Phone: 301.796.2133
Email: yvonne.knight@fda.hhs.gov

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/s/

YVONNE L KNIGHT
08/06/2014

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 207026

PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE

Gambro Lundia AB
c/o Gambro Renal Products, Inc.
1845 Mason Avenue
Daytona Beach, FL 32117

ATTENTION: Fei Law
Quality and Regulatory Manager, US Solutions

Dear Ms. Law:

Please refer to your New Drug Application (NDA) dated and received March 13, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phoxillum Solutions (BK4/2.5 and B22K4/0).

We also refer to your correspondence, dated and received July 23, 2014, requesting review of your proposed proprietary names, Phoxillum BK4/2.5 and Phoxillum B22K4/0.

We have completed our review of the proposed proprietary names, Phoxillum BK4/2.5 and Phoxillum B22K4/0, and have concluded that they are acceptable.

If any of the proposed product characteristics as stated in your July 23, 2014, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Karen Bengtson, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3338. For any other information regarding this application, contact Anna Park, Regulatory Project Manager in the Office of New Drugs, at (301) 796-1129.

Sincerely,

{See appended electronic signature page}

Kellie A. Taylor, Pharm.D., MPH
Deputy Director
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

KELLIE A TAYLOR
08/06/2014

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 207026

PROPRIETARY NAME REQUEST
UNACCEPTABLE

Gambro Lundia AB
c/o Gambro Renal Products
1845 Mason Avenue
Daytona Beach, FL 32117

ATTENTION: Fei Law
Quality and Regulatory Manager, US Solutions

Dear Ms. Law:

Please refer to your New Drug Application (NDA) dated and received March 13, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phoxilium Solutions (BK4/2.5 and B22K4/0).

We also refer to your correspondence, dated and received April 2, 2014, requesting review of your proposed proprietary names, Phoxilium BK4/2.5 and Phoxilium B22K4/0.

We have completed our review of these proposed proprietary names and have concluded that the names are unacceptable based on the concerns we have with the root name, Phoxilium. We did not identify any concerns with the "BK4/2.5" or "B22K4/0" modifiers at this time that would render the use of these modifiers unacceptable. Our concerns with the root name Phoxilium are as follows:

(b) (4)

[redacted]

[1] PDUFA pilot project proprietary name review concept paper. September 2008.
http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072229.pdf

[2] Guidance for industry: Best practices in developing proprietary names for drugs. Draft Guidance May 2014.
http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM398997.pdf

We note that you have not proposed an alternate proprietary name for review. If you intend to have a proprietary name for this product, we recommend that you submit a new request for a proposed proprietary name review. (See the Guidance for Industry, *Contents of a Complete Submission for the Evaluation of Proprietary Names,* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Karen Bengtson, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-3338. For any other information regarding this application, contact Anna Park, Regulatory Project Manager in the Office of New Drugs, at (301) 796-1129.

Sincerely,

{See appended electronic signature page}

Kellie A. Taylor, Pharm.D., MPH
Deputy Director
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

KELLIE A TAYLOR
06/30/2014

MEMORANDUM of TELECONFERENCE

MEETING DATE:	June 26, 2014
TIME:	2:30 PM - 3:00 PM
APPLICATION:	NDA 207026
APPLICANT:	Gambro Lundia AB
DRUG NAME:	Replacement solutions containing magnesium, sodium, chloride, bicarbonate, potassium, phosphate, with or without calcium
TYPE OF MEETING:	Guidance
MEETING CHAIRS:	Lubna Merchant, Pharm.D.

FDA ATTENDEES:

Lubna Merchant, Pharm.D. - Associate Director, DMEPA
Alice Tu, Pharm.D. - Team Leader, DMEPA
Jean Olumba, Pharm.D. - Safety Evaluator, DMEPA
Karen Bengtson - Safety Regulatory Project Manager, OSE

SPONSOR ATTENDEES:

Maria-Armelle Mouret - Director, RA Solutions
Fei Law - Quality and Regulatory Manager, US Solutions
Maria Keelan - RA Group Leader Manufacturing Operations

BACKGROUND:

On April 2, 2014, Gambro Lundia AB submitted a request for proprietary name review to their pending NDA 207026. Their product, a replacement solution, has two formulations. In order to distinguish the two formulations, two variations of the name were proposed - Phoxilium BK4/2.5 and Phoxilium B22K4/0.

MEETING OBJECTIVES:

To inform Gambro Lundia AB of DMEPA's concerns with the proposed root name, Phoxilium, and to provide the applicant with possible modifications to the spelling of the name that could be viable alternatives.

DMEPA CONCERNS WITH THE PROPOSED NAME:

The proposed proprietary names, Phoxilium BK4/2.5, and, Phoxilium B22K4/0, are unacceptable based on the concerns we have with the root name, Phoxilium. We did not identify any concerns with the "BK4/2.5" or "B22K4/0" modifiers at this time that would render the use of that modifier unacceptable. Our concerns with Phoxilium are as follows:

(b) (4)

(b) (4)

DISCUSSION:

DMEPA began the teleconference with an explanation of their safety concerns with the proposed root name, Phoxilium, and an explanation of what (b) (4) is and why they are used. DMEPA informed the applicant that they are going to issue a denial letter for the name Phoxilium based on the (b) (4)

Gambro Lundia AB asked if it was possible to challenge DMEPA's decision. DMEPA informed the applicant that they have the option to resubmit the name for reconsideration per the guidance "Contents of a complete submission for Evaluation of Proprietary Names" and including any additional rationale or data they have to support their argument. DMEPA will review any data Gambro submits in support of (b) (4). However, DMEPA further clarified that the concept paper "PDUFA Pilot Project - Proprietary Name Review" published in 2008 and their draft guidance- Best practices in developing proprietary names for drugs, posted in May 2014, clearly outlines their concerns with (b) (4). It is unlikely that proprietary name (b) (4) (b) (4) will be approved.

DMEPA provided Gambro Lundia AB with viable options for how they could modify the currently proposed (b) (4) (see table below). Further, DMEPA stated that if the applicant was to submit one of the proposed alternative names in Table below, they would commit to completing the review within a two to three week timeframe instead of the standard 90-day PDUFA timeframe.

Applicant Proposed	Phoxilium	(b) (4)
DMEPA Proposed Alternatives		
2 Ls	Phoxillum	(b) (4)
minus second i	Phoxilum	
e replacing second i	Phoxileum	
Transpose u and i	Phoxiluim	

Gambro Lundia AB stated that they clearly understood DMEPA's concern and their options. They will discuss internally before reaching a decision.

[1] PDUFA pilot project proprietary name review concept paper. September 2008. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072229.pdf

[2] Guidance for industry: Best practices in developing proprietary names for drugs. Draft Guidance May 2014. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM398997.pdf

ACTION ITEMS

1. DMEPA will issue a denial letter for the proposed names, Phoxilium BK4/2.5 and Phoxilium B22K4/0.

2. Gambro Lundia AB will discuss internally the best path forward. They have the following options:
   - To resubmit the name "Phoxilium" for reconsideration
   - To submit one of the proposed alternative spellings of the name for an expedited review
   - To submit an alternate name for review under the standard 90-day PDUFA timeframe

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/s/

CHI-MING TU
06/30/2014

LUBNA A MERCHANT
06/30/2014

From:	Knight, Yvonne
To:	Law, Fei (fei.law@gambro.com)
Cc:	Knight, Yvonne
Subject:	Information Request for NDA 207026 (Prompt Response)
Date:	Monday, June 09, 2014 2:28:27 PM
Importance:	High

Good afternoon Ms. Law,

We have an information request concerning Gambro's New Drug Application for NDA 207026. We are reviewing the Quality section of your submission and have the following comments and information request. We request a prompt written response in order to continue our evaluation of your NDA **by COB Thursday June 12, 2014**.

1. Provide DMF references and the corresponding letters of authorization for (b) (4)

Please confirm receipt of this Information Request. Also, please provide me with a courtesy copy via email when you submit your official amendment? If you have any questions or comments feel free to contact me.

Best Regards,

Yvonne Knight, MS
Regulatory Health Project Manager
Division of New Drug Quality Assessment
FDA/CDER/OPS/ONDQA
10903 New Hampshire Avenue
Bldg. 21, Room 2667
Silver Spring, MD 20993-0002
Phone: 301.796.2133
Email: yvonne.knight@fda.hhs.gov

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/s/

YVONNE L KNIGHT
06/09/2014

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

REQUEST FOR CONSULTATION

TO *(Division/Office)*: **Mail: OSE**			FROM: **Anna Park/OND/DCRP/796-1129**	
DATE: April 29, 2014	IND NO.:	NDA NO.: 207026	TYPE OF DOCUMENT: Electronic	DATE OF DOCUMENT: March 13, 2014
NAME OF DRUG: Phoxilium	PRIORITY CONSIDERATION: standard		CLASSIFICATION OF DRUG:	DESIRED COMPLETION DATE: **October 13, 2014**
NAME OF FIRM: Gambro Renal Products				

REASON FOR REQUEST

I. GENERAL

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

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER (SPECIFY BELOW):	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

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

IV. DRUG EXPERIENCE

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

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: Please review the labels for this NDA. This NDA was submitted on March 13, 2014 and the PDUFA goal date is **January 13, 2015.**

EDR Location: \\CDSESUB1\evsprod\NDA207026\207026.enx

SIGNATURE OF REQUESTER: Anna Park	METHOD OF DELIVERY (Check all that apply): ☐ MAIL X DARRTS ☐ HAND
SIGNATURE OF RECEIVER:	SIGNATURE OF DELIVERER:

...18/2013

Reference ID: 3690411

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

/s/

ANNA J PARK
04/29/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207026

FILING COMMUNICATION –
NO FILING REVIEW ISSUES IDENTIFIED

Gambro Renal Products, Inc.
Attention: Ms. Fei Law
Quality and Regulatory Manager, US Solutions
1845 Mason Avenue
Daytona Beach, FL 32117

Dear Ms. Law:

Please refer to your New Drug Application (NDA) dated March 13, 2014, received March 13, 2014, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, for Phoxilium Solutions (BK4/2.5 and B22K4/0).

We also refer to your amendments dated April 2 and 23, 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 **January 13, 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 December 1, 2014.

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.

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 and have the following labeling comments or questions:

1. **Highlights (HL) must be in a minimum of 8-point font and should be in two-column format, with ½ inch margins on all sides and between columns.**

2. **White space should be present before each major heading in HL. There must be no white space between the HL Heading and HL Limitation Statement. There must be no white space between the product title and Initial U.S. Approval.**

3. **Each summarized statement or topic in HL must reference the section(s) or subsection(s) of the Full Prescribing Information (FPI) that contain more detailed information. The preferred format is the numerical identifier in parenthesis [e.g., (1.1)] at the end of each summarized statement or topic.**

4. **Under Highlights, the Patient Counseling Information Statement is omitted.**

5. **Initial U.S. Approval in HL must be bolded, and include the verbatim statement "Initial U.S. Approval:" followed by the 4-digit year.**

6. **The revision date must be at the end of HL must be updated.**

7. **The TOC should be in a two-column format.**

8. **In the TOC, all subsection headings must be indented and not bolded. The headings should be in title case [first letter of all words are capitalized except first letter of prepositions (through), articles (a, an, and the), or conjunctions (for, and)].**

9. **Under FPI, the Patient Counseling Information is omitted.**

10. **The preferred presentation for cross-references in the FPI is the section (not subsection) heading followed by the numerical identifier. The entire cross-reference should be in italics and enclosed within brackets. For example, "[see Warnings and Precautions (5.2)]" or "[see Warnings and Precautions (5.2)]".**

11. **Under FPI, if no Contraindications are known, this section must state "None."**

12. **Under FPI, you must reference any FDA-approved patient labeling in Section 17 (PATIENT COUNSELING INFORMATION section). The reference should appear at the beginning of Section 17 and include the type(s) of FDA-approved patient labeling (e.g., Patient Information, Medication Guide, Instructions for Use).**

We request that you resubmit labeling (in Microsoft Word format) that addresses these issues by May 30, 3014. 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 the drug product for this indication has orphan drug designation, you are exempt from this requirement.

If you have any questions, please call Anna Park, Regulatory Project Manager, at (301) 796-1129.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

NORMAN L STOCKBRIDGE
04/29/2014

From:	Knight, Yvonne
To:	fei.law@us.gambro.com
Cc:	Knight, Yvonne
Subject:	Information Request for NDA
Date:	Thursday, April 17, 2014 3:17:30 PM
Importance:	High

Good Afternoon Fei Law,
We have an information request concerning Gambro's New Drug Application for (NDA) NDA 207026. We are reviewing the Quality section of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

1. Please submit a revised 356h form that includes all *Manufacturers* for both Drug Substance and Drug Product facilities. The list should also include any and all contract testing sites for both as well.

    a. The information should include: site name, address, FEI#, contact person, contact #, contact fax, email and a list of all steps and or testing being performed.

Please confirm receipt of this Information Request. Also, please provide me with a courtesy copy via email when you submit your official amendment? If you have any questions or comments feel free to contact me.
Best Regards,

Yvonne Knight, MS
Regulatory Health Project Manager
Division of New Drug Quality Assessment
FDA/CDER/OPS/ONDQA
10903 New Hampshire Avenue
Bldg. 21, Room 2667
Silver Spring, MD 20993-0002
Phone: 301.796.2133
Email: yvonne.knight@fda.hhs.gov

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/s/

YVONNE L KNIGHT
04/17/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207026

NDA ACKNOWLEDGMENT

Gambro Lundia AB
c/o Gambro Renal Products
Attention: Ms. Fei Law, US Agent
Quality & Regulatory Manager, US Solutions
1845 Mason Avenue
Daytona Beach, FL 32117

Dear Ms. Law:

We have received your New Drug Application (NDA) submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Phoxilium Solutions (BK4/2.5 and B22K4/0)

Date of Application: March 13, 2014

Date of Receipt: March 13, 2014

Our Reference Number: NDA 207026

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 12, 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).

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 Cardiovascular and Renal 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. Please note that secure email may not be used for formal regulatory submissions to applications.

If you have any questions, please contact:

Anna Park, R.Ph., RAC
Regulatory Health Project Manager
(301) 796-1129

Sincerely,

{See appended electronic signature page}

Edward Fromm, R.Ph., RAC
Chief, Project Management Staff
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
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/

EDWARD J FROMM
03/20/2014

Form Approved: OMB No. 0910 - 0297 Expiration Date: December 31, 2015. See instructions for OMB Statement, below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	PRESCRIPTION DRUG USER FEE COVERSHEET

A completed form must be signed and accompany each new drug or biologic product application and each new supplement. See exceptions on the reverse side. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment instructions and fee rates can be found on FDA's website:
http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm

1. APPLICANT'S NAME AND ADDRESS	4. BLA SUBMISSION TRACKING NUMBER (STN) / NDA NUMBER
GAMBRO RENAL PRODUCTS INC Fei Law 1845 Mason Avenue Daytona Beach Volusia FL 32117 US	207-026

2. NAME AND TELEPHONE NUMBER OF REPRESENTATIVE	5. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL?
386-481-1143	[ ] YES [X] NO
	IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM. IF RESPONSE IS "YES", CHECK THE APPROPRIATE RESPONSE BELOW:
	[ ] THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION
	[ ] THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO:

3. PRODUCT NAME	6. USER FEE I.D. NUMBER
Phoxilium Solutions (Phoxilium BK4/2.5 and B22K4/0)	PD3014076

7. ARE YOU REDEEMING A PRIORITY REVIEW VOUCHER FOR THE TREATMENT OF TROPICAL DISEASES? [ ] YES [X] NO

PRIORITY REVIEW VOUCHER NUMBER:

8. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.
[ ] A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BEFORE 9/1/92 (Self Explanatory)
[X] THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(F) of the Federal Food,Drug, and Cosmetic Act
[ ] THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY

9. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION? [X] YES [ ] NO
If a waiver has been granted, include a copy of the official FDA notification with your submission.

Privacy Act Notice:
This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. 371, 379, 379e, 379h, 379h-1, 379j, 379j-12, 379j-21, 387s, and 393(d)(2); 42 U.S.C. 263b(r)(1); 5 U.S.C. 301 and 552; and 42 U.S.C. 3101. FDA will use the information to assess, collect and process user fee payments, and, facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional detail regarding FDA's use of information is available online:
http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/default.htm.

OMB Statement:
Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Information Management (HFA-710)
1350 Piccard Drive, 4th Floor
Rockville, MD 20850

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Information Management (HFA-710)
1350 Piccard Drive, 4th Floor
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PRINTED NAME AND SIGNATURE OF AUTHORIZED REPRESENTATIVE	TITLE	DATE
FEI LAW	GARA MANAGER, US SOLUTIONS	03/13/2014

9. USER FEE PAYMENT AMOUNT FOR THIS APPLICATION
$0.00

Form FDA 3397 (03/12)