

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
50-821

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

PEDIATRIC PAGE

(Complete for all filed original applications and efficacy supplements)

NDA/BLA#: 50-821 (505(b)(2)) Supplement Number: N/A NDA Supplement Type (e.g. SE5): N/A

Division Name: DAIOP PDUFA Goal Date: 7/24/09 Stamp Date: 5/25/2008

Proprietary Name: N/A

Established/Generic Name: Cefepime for Injection USP and Dextrose Injection USP in the Duplex Container

Dosage Form: Solution for Injection

Applicant/Sponsor: B. Braun Medical, Inc.

Indication(s) previously approved (please complete this question for supplements and Type 6 NDAs only):

- (1) Pneumonia
 - (2) Febrile neutropenia
 - (3) Uncomplicated and complicated UTI
 - (4) Uncomplicated skin and skin structure infections
 - (5) Complicated intra-abdominal infections
-

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): 6
(Attach a completed Pediatric Page for each indication in current application.)

Indication: N/A (505(b)(2)) application, see below:

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); dosage form; 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 |
| <input type="checkbox"/> Neonate | __ wk. __ mo. | __ wk. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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 † |
|--|---------------|---------------|--------------------------|------------------------------|---|---|---------------------------|
| | | | | Ready for Approval in Adults | Need Additional Adult Safety or Efficacy Data | Other Appropriate Reason (specify below)* | Received |
| Population | minimum | maximum | | | | | |
| <input type="checkbox"/> Neonate | __ wk. __ mo. | __ wk. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> All Pediatric Populations | 0 yr. 0 mo. | 16 yr. 11 mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 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?. | |
| <input type="checkbox"/> | Neonate | __ wk. __ mo. | __ wk. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | All Pediatric Subpopulations | 0 yr. 0 mo. | 16 yr. 11 mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

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 |
|--------------------------|------------------------------|---------------|---------------|
| <input type="checkbox"/> | Neonate | __ wk. __ mo. | __ wk. __ mo. |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. |
| <input type="checkbox"/> | 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? |
| <input type="checkbox"/> | Neonate | __ wk. __ mo. | __ wk. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | All Pediatric Subpopulations | 0 yr. 0 mo. | 16 yr. 11 mo. | <input type="checkbox"/> | <input type="checkbox"/> |

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.

Attachment A

(This attachment is to be completed for those applications with multiple indications only.)

Indication #2: _____

Q1: Does this indication have orphan designation?

- Yes. PREA does not apply. **Skip to signature block.**
 No. Please proceed to the next question.

Q2: 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 |
| <input type="checkbox"/> | Neonate | __ wk. __ mo. | __ wk. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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 Section 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 some or all 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 † |
|--|---------------|---------------|--------------------------|------------------------------|---|---|---------------------------|
| | | | | Ready for Approval in Adults | Need Additional Adult Safety or Efficacy Data | Other Appropriate Reason (specify below)* | Received |
| Population | minimum | maximum | | | | | |
| <input type="checkbox"/> Neonate | __ wk. __ mo. | __ wk. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> All Pediatric Populations | 0 yr. 0 mo. | 16 yr. 11 mo. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 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? | |
| <input type="checkbox"/> | Neonate | __ wk. __ mo. | __ wk. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| <input type="checkbox"/> | All Pediatric Subpopulations | 0 yr. 0 mo. | 16 yr. 11 mo. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

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 |
| <input type="checkbox"/> | Neonate | __ wk. __ mo. | __ wk. __ mo. |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. |
| <input type="checkbox"/> | Other | __ yr. __ mo. | __ yr. __ mo. |
| <input type="checkbox"/> | 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? |
| <input type="checkbox"/> Neonate | __ wk. __ mo. | __ wk. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Other | __ yr. __ mo. | __ yr. __ mo. | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> All Pediatric Subpopulations | 0 yr. 0 mo. | 16 yr. 11 mo. | <input type="checkbox"/> | <input type="checkbox"/> |

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 copy the fields above and complete pediatric information as directed. If there are no other indications, this Pediatric Page is complete and should be entered into DFS or DARRTS as appropriate after clearance by PeRC.

This page was completed by:

{See appended electronic signature page}

Regulatory Project Manager

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT THE PEDIATRIC AND MATERNAL HEALTH STAFF at 301-796-0700

(Revised: 6/2008)

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

/s/

Kathrine Laessig
5/11/2009 10:26:47 AM

Davi, Christopher

From: Patti.Smith@bbraun.com
Sent: Wednesday, May 05, 2010 11:18 AM
To: Davi, Christopher
Cc: Susan.Olinger@bbraun.com; kimberly.ernst@bbraun.com; Rebecca.Stolarick@bbraun.com; Kathy.Holdren@bbraun.com
Subject: Re: FW: NDA 50-821 Container Labels

Hi Chris,

B. Braun finds this proposal acceptable. We will address all comments listed below in the first CMC Annual Report. for NDA 050821.

We look forward to hearing from you tomorrow.

Thanks for your help, Patti

Patti Smith, RAC
Senior Specialist, Regulatory Affairs
B. Braun Medical Inc.
PL-RA-US-01
901 Marcon Blvd.
Allentown, PA 18109
Phone: (610)596-2638
Fax: (610)-266-4962
Email: patti.smith@bbraun.com

From: "Davi, Christopher" <Christopher.Davi@fda.hhs.gov>
To: Patti.Smith@bbraun.com
Date: 05/05/2010 10:46 AM
Subject: FW: NDA 50-821 Container Labels

Patti,

I have heard from the Deputy Director regarding these comments and she will permit them being addressed post action. Please respond to this message indicating whether or not this is acceptable to B.Braun. In cases where you are unable to address any of the particular comments below, please also provide a rationale in the annual report.

Thank you,

Chris Davi

5/6/2010

J. Christopher Davi, MS
Senior Regulatory Health Project Manager
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
FDA Center for Drug Evaluation and Research
christopher.davi@fda.hhs.gov
(301) 796-0702

From: Davi, Christopher
Sent: Tuesday, May 04, 2010 4:47 PM
To: 'Patti.Smith@bbraun.com'
Subject: NDA 50-821 Container Labels

Patti,

Here are the comments from DMEPA:

A. Cefepime/Dextrose Duplex Carton (all strengths) (Appendix C)

1. Present the strength "Equivalent to 1 g Cefepime (5% w/v Dextrose)" and "Equivalent to 2 g Cefepime (5% w/v Dextrose)" in the same font size as or greater than the company logo "B|BRAUN"

B. Cefepime/Dextrose Duplex Container Label (all strengths) (Appendix D)

1. Delete the statement "U.S. Patent Nos D388.168... and 6,996.951" and include this information in the insert labeling.

2. Delete the statement "Duplex® Drug Delivery System" and "Duplex is a registered trademark of B. Braun Medical Inc." and include this information in the insert labeling.

3. Delete B. Braun Medical Inc.'s address as this information is included in the insert labeling.

C. Cefepime/Dextrose Duplex Container Label - Drug Chamber Label (all strengths) (Appendix E)

1. Revise the statement [REDACTED] (b) (4)
 [REDACTED] (b) (4) with "Peel foil strip only when ready for use to visually inspect drug prior to reconstitution"

2. Delete the statement [REDACTED] (b) (4)
 [REDACTED] (b) (4) as this information is included in the Container Label.

Please let me know if you can make these changes to the container label and provide PDF mock-ups to me tomorrow. Also, for any corresponding changes to the package insert, track them into the attached label and send that back to me as well.

Let me know if you have questions.

Thanks,

Chris

5/6/2010

<<CefepimePLRFINAL.4May10.doc>>

J. Christopher Davi, MS
Senior Regulatory Health Project Manager
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
FDA Center for Drug Evaluation and Research
christopher.davi@fda.hhs.gov
(301) 796-0702 [attachment "CefepimePLRFINAL.4May10.doc" deleted by Patti Smith/BBMUS/BBRAUN]

The information contained in this communication is confidential, may be attorney-client privileged, may constitute inside information, and is intended only for the use of the addressee. It is the property of the company of the sender of this e-mail. Unauthorized use, disclosure, or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify us immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|-------------------------|------------------------|------------------------|--------------|
| NDA-50821 | ORIG-1 | B BRAUN MEDICAL INC | CEFEPIME |

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/s/

JOSEPH C DAVI
05/06/2010

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|----------------------------|---------------------------|------------------------|--------------|
| NDA-50821 | ORIG-1 | B BRAUN MEDICAL INC | CEFEPIME |

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/s/

JOSEPH C DAVI
02/24/2010

JANICE K POHLMAN
02/24/2010

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|-------------------------|------------------------|------------------------|--------------|
| NDA-50821 | ORIG-1 | B BRAUN MEDICAL INC | CEFEPIME |

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/s/

JOSEPH C DAVI
02/23/2010

JANICE K POHLMAN
02/24/2010



NDA 50-821

ACKNOWLEDGE CLASS 2 RESPONSE

B. Braun Medical, Inc.
Attention: Susan Olinger, JD
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Dr. Olinger:

We acknowledge receipt on November 6, 2009, of your November 6, 2009, resubmission to your new drug application for Cefepime for Injection USP and Dextrose USP in the Duplex[®] container.

We consider this a complete, class 2 response to our July 21, 2009, action letter. Therefore, the user fee goal date is May 6, 2010.

If you have any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Frances V. LeSane
Chief, Project Management Staff
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-50821

ORIG-1

B BRAUN MEDICAL CEFEPIME
INC

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/s/

Frances V LESANE
11/18/2009

Davi, Christopher

From: Davi, Christopher
Sent: Friday, March 27, 2009 3:45 PM
To: 'Patti.Smith@bbraun.com'
Cc: 'Kimberly.Ernst@bbraun.com'
Subject: RE: Cefepime NDA 050821 chemistry questions

Patti,

In response to your questions, please see below (*italics*):

1) In the application we proposed a 12 month expiration date for the finished drug product. Based on our real time data, we believe approval of the drug with this expiry will be granted. Based on our stability protocol, submitted in the NDA, we have proposed optional test intervals beyond the 12 month expiration date. Is it possible to extend the expiration date with real time data on the registration batches that were produced for this NDA application via Annual Report or do we need to perform real time stability testing on commercial lots?

Agency Response: It is acceptable to extend the expiration date with real time data on the batches that were produced pre-approval for the NDA application via Annual Report if three conditions are met: the batches are of commercial scale, the stability was conducted in conformance with the submitted protocol, and there were no out-of-specification data for these lots.

2) In this application we inadvertently listed optional testing intervals at 18 and 24 months instead of listing 15 and 18 months as optional. Since this is a typographical error, can we amend this protocol and submit it without stopping the review clock?

Agency Response: Yes

Let me know if you have questions.

J. Christopher Davi, MS
Senior Regulatory Health Project Manager
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
FDA Center for Drug Evaluation and Research
christopher.davi@fda.hhs.gov
(301) 796-0702

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/s/

Christopher Davi
3/27/2009 03:51:44 PM
CSO



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILING COMMUNICATION

NDA 50-821

B. Braun Medical, Inc.
Attention: Susan Olinger
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Olinger:

Please refer to your new drug application (NDA) dated September 26, 2008, received September 25, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Cefepime for Injection USP and Dextrose Injection USP in the Duplex[®] container.

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 May 25, 2009.

If you have not already done so, you must 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/oc/datacouncil/spl.html>. The content of labeling must be in the Prescribing Information (physician labeling rule) format.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have not fulfilled the requirement. Please submit your pediatric drug development plans within 120 days from the date of this letter unless you believe a waiver is appropriate.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act (the Act) may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" in addition to your plans for pediatric drug development described above. Please note that satisfaction of the requirements in section 505B of the Act alone may not qualify you for pediatric exclusivity.

If you have any questions, call J. Christopher Davi, MS, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Acting Division Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

Wiley Chambers
1/23/2009 03:00:18 PM

REQUEST FOR CONSULTATION

TO (Office/Division): **Sylvia Gantt, Tech. Information Specialist
WO51 Room 4195 (HFD-003)**

FROM (Name, Office/Division, and Phone Number of Requestor):
J. Christopher Davi, MS, RPM, DAIOP

DATE
December 10, 2008

IND NO.
N/A

NDA NO.
50-821

TYPE OF DOCUMENT
NDA 505(b)(2)

DATE OF DOCUMENT
September 25, 2008

NAME OF DRUG
Cefepime for Injection

PRIORITY CONSIDERATION
Standard

CLASSIFICATION OF DRUG
Parenteral Antibiotic

DESIRED COMPLETION DATE
March 31, 2009

NAME OF FIRM: **B. Braun Medical, Inc.**

REASON FOR REQUEST

I. GENERAL

- | | | |
|--|--|--|
| <input type="checkbox"/> NEW PROTOCOL | <input type="checkbox"/> PRE-NDA MEETING | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER |
| <input type="checkbox"/> PROGRESS REPORT | <input type="checkbox"/> END-OF-PHASE 2a MEETING | <input type="checkbox"/> FINAL PRINTED LABELING |
| <input type="checkbox"/> NEW CORRESPONDENCE | <input type="checkbox"/> END-OF-PHASE 2 MEETING | <input type="checkbox"/> LABELING REVISION |
| <input type="checkbox"/> DRUG ADVERTISING | <input type="checkbox"/> RESUBMISSION | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE |
| <input type="checkbox"/> ADVERSE REACTION REPORT | <input type="checkbox"/> SAFETY / EFFICACY | <input type="checkbox"/> FORMULATIVE REVIEW |
| <input type="checkbox"/> MANUFACTURING CHANGE / ADDITION | <input type="checkbox"/> PAPER NDA | <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): |
| <input type="checkbox"/> MEETING PLANNED BY | <input type="checkbox"/> CONTROL SUPPLEMENT | |

II. BIOMETRICS

- | | |
|---|---|
| <input type="checkbox"/> PRIORITY P NDA REVIEW | <input type="checkbox"/> CHEMISTRY REVIEW |
| <input type="checkbox"/> END-OF-PHASE 2 MEETING | <input type="checkbox"/> PHARMACOLOGY |
| <input type="checkbox"/> CONTROLLED STUDIES | <input type="checkbox"/> BIOPHARMACEUTICS |
| <input type="checkbox"/> PROTOCOL REVIEW | <input type="checkbox"/> OTHER (SPECIFY BELOW): |
| <input type="checkbox"/> OTHER (SPECIFY BELOW): | |

III. BIOPHARMACEUTICS

- | | |
|--|--|
| <input type="checkbox"/> DISSOLUTION | <input type="checkbox"/> DEFICIENCY LETTER RESPONSE |
| <input type="checkbox"/> BIOAVAILABILITY STUDIES | <input type="checkbox"/> PROTOCOL - BIOPHARMACEUTICS |
| <input type="checkbox"/> PHASE 4 STUDIES | <input type="checkbox"/> IN-VIVO WAIVER REQUEST |

IV. DRUG SAFETY

- | | |
|--|--|
| <input type="checkbox"/> PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL | <input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY |
| <input type="checkbox"/> DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES | <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE |
| <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) | <input type="checkbox"/> POISON RISK ANALYSIS |
| <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP | |

V. SCIENTIFIC INVESTIGATIONS

- | | |
|-----------------------------------|--------------------------------------|
| <input type="checkbox"/> CLINICAL | <input type="checkbox"/> NONCLINICAL |
|-----------------------------------|--------------------------------------|

COMMENTS / SPECIAL INSTRUCTIONS: Please provide a microsterility review for the above referenced 505(b)(2) application. This application is located in EDR under NDA 50-821. If you have questions, contact me at (301) 796-0702.

SIGNATURE OF REQUESTOR
J. Christopher Davi, MS, RPM

METHOD OF DELIVERY (Check one)
 DFS EMAIL MAIL HAND

PRINTED NAME AND SIGNATURE OF RECEIVER

PRINTED NAME AND SIGNATURE OF DELIVERER

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/s/

Janice Pohlman
12/10/2008 03:46:02 PM

Davi, Christopher

From: Davi, Christopher
Sent: Monday, November 17, 2008 3:28 PM
To: 'Susan.Olinger@bbraun.com'
Subject: Comments for NDA 50-821 (505(b)(2) Cefepime for Injection in the Duplex Container)

Ms. Olinger,

The Filing date for your application is November 24, 2008. Please be advised of the following issues we identified as part of the filing review:

1. Cefepime for Injection, provided for in the drug substance sections of the NDA, is a drug product with a USP monograph. The drug substance is cefepime hydrochloride. The application provides information on the drug substance, cefepime hydrochloride only by indirect reference. No direct reference to such information is provided for the cefepime hydrochloride drug substance. Without a direct reference, one of the potential consequences is that changes may be made to the drug substance without notification to the NDA holder. Some of these potential changes could have an impact on the final drug product. It is strongly recommended that you obtain direct reference to the manufacture of the drug substance.

2. Several PDF files in the electronic NDA submission are not paginated. It is recommended that these files be resubmitted with pagination.

If you have questions, please contact me.

Regards,

Chris Davi

J. Christopher Davi, MS
Regulatory Project Manager
Food and Drug Administration (FDA)
Division of Anti-Infective and Ophthalmology Products
christopher.davi@fda.hhs.gov
(301) 796-0702

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/s/

Christopher Davi
11/17/2008 03:49:12 PM
CSO



NDA 50-821

NDA ACKNOWLEDGMENT

B. Braun Medical, Inc.
Attention: Susan Olinger, J.D.
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Olinger:

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: Cefepime for Injection, USP and Dextrose Injection, USP in the Duplex® container

Date of Application: September 25, 2008

Date of Receipt: September 25, 2008

Our Reference Number: NDA 50-821

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 November 24, 2008 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/oc/datacouncil/spl.html>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

Please note that you are 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). Title VIII of FDAAA amended the PHS Act by adding new section 402(j) (42 USC § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices.

FDAAA requires that, at the time of submission of an application under section 505 of the FDCA, the application must be accompanied by a certification that all applicable requirements of 42 USC § 282(j) have been met. Where available, the certification must include the appropriate National Clinical Trial (NCT) control numbers. 42 USC 282(j)(5)(B). You did not include such certification when you submitted this application. You may use Form FDA 3674, *Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank*, to comply with the certification requirement. The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/default.html>.

In completing Form FDA 3674, you should review 42 USC § 282(j) to determine whether the requirements of FDAAA apply to any clinical trials referenced in this application. Additional information regarding the certification form is available at: http://internet-dev.fda.gov/cder/regulatory/FDAAA_certification.htm. Additional information regarding Title VIII of FDAAA is available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>. Additional information on registering your clinical trials is available at the Protocol Registration System website <http://prsinfo.clinicaltrials.gov/>.

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 Anti-Infective and Ophthalmology 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/cder/ddms/binders.htm>.

If you have any questions, call J. Christopher Davi, MS, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Frances LeSane
Chief, Project Management Staff
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

Frances LeSane
10/3/2008 01:58:43 PM



Pre-NDA 50-821

B. Braun Medical, Inc.
Attention: Susan Olinger
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Olinger:

Please refer to your May 9, 2008, correspondence, received May 9, 2008, requesting a meeting to discuss a potential 505(b)(2) filing for Cefepime for Injection and Duplex Injection in the Duplex[®] Container.

Based on the statement of purpose, objectives, and proposed agenda, we consider the meeting a type B meeting as described in our guidance for industry titled *Formal Meetings with Sponsors and Applicants for PDUFA Products* (February 2000). The teleconference is scheduled for:

Date: July 14, 2008

Time: 3:30 to 4:30 PM, EST

Phone Arrangements: Sponsor to provide phone number and access code.

CDER Participants: Division of Anti-Infective and Ophthalmology Products (DAIOP):

Wiley A. Chambers, MD, Acting Director

Katherine A. Laessig, MD, Deputy Director

Sumathi Nambiar, MD, MPH, Medical Team Leader

Alma Davidson, MD, Clinical Reviewer

Charles Bonapace, PharmD, Clinical Pharmacology Team Leader

Wendelyn Schmidt, PhD, Acting Pre-Clinical Pharmacology Team Leader

Amy Ellis, PhD, Pre-Clinical Pharmacology Reviewer

Frederic J. Marsik, PhD, Clinical Microbiology Team Leader

Avery Goodwin, PhD, Clinical Microbiology Reviewer

Thamban Valappil, PhD, Biometrics Team Leader

David L. Roeder, MS, Associate Director, Regulatory Affairs

J. Christopher Davi, MS, Regulatory Project Manager

Provide the background information for this teleconference (three copies to the Pre-NDA and 14 desk copies to me) at least one month prior to the meeting. If the materials presented in the information package are inadequate to justify holding a teleconference, or if we do not receive the package by June 13, 2008, we may cancel or reschedule the teleconference.

If you have any questions, call J. Christopher Davi, MS, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Frances LeSane
Chief, Project Management Staff
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

Frances LeSane
5/20/2008 02:58:16 PM