CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-779

ADMINISTRATIVE DOCUMENTS

Patent Information
On Any Patent Which Claims The Drug

A patent search was performed to locate any drug substance, drug product or method of use patents regarding cefazolin. This search revealed two cefazolin patents, U.S. Patent No. 3,516,997 and U.S. Patent No. 4,898,937. The 3,516,997 patent expired June 23, 1987 and the 4,898,937 patent is not infringed.

Please refer to the letter from Christie, Parker & Hale, LLP Intellectual Property Lawyers that follows. This letter contains details of the patent search and includes copies of the two cefazolin patents referenced above, which support this conclusion.

Patent Certification
With Respect to Any Patent Which Claims the Drug

Reference is made to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 18th Edition and Cumulative Supplements. Cefazolin for Injection USP and Dextrose Injection USP is not listed in the patent and exclusivity tables. The appropriate patent certification follows:

B. Braun Medical Inc. hereby certifies that in our opinion and to the best of our knowledge and of our patent counsel, there are no patents, active or valid, that claim the drug in this application, Cefazolin for Injection USP and Dextrose Injection USP or that claim use of Cefazolin for Injection USP and Dextrose Injection USP have been filed or that such patents have expired.

John G. D'Angelo

8/23/99

John G. D'Angelo, M.S., R.Ph.
Vice President, Regulatory Affairs

Date

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JAMES B. CHRISTIE (1904-1959)
ROBERT L. PARKER (1920-1980)

July 16, 1999

OUR REFERENCE
K163:90.2-18

FAXED 7/16/99

By facsimile with confirmation by mail
(949)660-2730

John D'Angelo
V.P. Regulatory Affairs
B. BRAUN MEDICAL INC.
2525 McGaw Avenue
Irvine, California 92614-4895

Re: Patent Information required under 21 CFR § 314.50

Dear John:

As discussed, you will be filing a New Drug Application (NDA) for cefazolin and will be required to identify in the application any patents that claim the cefazolin drug or the cefazolin drug product or methods of using cefazolin. As is required by statute, for each such patent, you will be required to provide the patent number and to certify that, in your opinion, and to the best of your knowledge, one of the following circumstances:

1. That the patent information has not been submitted to the FDA; or

2. That the patent has expired; or

3. The date on which the patent will expire; or

4. The patent is invalid, or unenforceable or not infringed.

In my discussions with Shari Sandberg, she advised that the cefazolin drug will be used by itself, i.e., there will be no additives or other ingredients associated therewith, except that it will be mixed with a diluent at the time of delivery. Thus, in this case the cefazolin drug is the same as the cefazolin drug product.

You asked that we conduct a search for patents which may cover cefazolin to provide you with information so that you may comply with the FDA reporting requirement.

In view of the foregoing, we conducted a search for patents on cefazolin as well as those directed to its method of use. The results of our study are set forth below.

The original patent for cefazolin issued as U.S. Patent No. 3,516,997, June 23, 1970, to Fujisawa Pharmaceutical Company (Fujisawa). The '97 patent expired June 23, 1987.

U.S. Patent No. 4,898,937, which issued February 6, 1990 to Fujisawa, claims cefazolin in the form of alpha crystals with a water content in the range of 13.0% - 15.8%. Shari Sandberg advised me that while B. Braun will be using alpha crystals of Cefazolin sodium, the maximum water content will be 6%.

The '937 patent discloses that when the water content of the cefazolin alpha crystals is decreased to less than 13.0%, its stability to light is sacrificed. In view of the foregoing, it is our opinion that the B. Braun cefazolin sodium product at 6% water content clearly does not fall within the scope of the claims of '937 patent. Because the 6% value is far outside the scope of the claims and less than half of the 13% claimed value, we are further of the opinion that there is no need to obtain and review the prosecution history of the '937 patent to conclude that there is no infringement.

Given that the cefazolin drug that will be used by B. Braun as an antibiotic and that the original '997 patent discloses the use of cefazolin as a broad-spectrum antibiotic, in our opinion it would not be possible that any U.S. patents claiming the use of cefazolin as an antibiotic would still be in force.

In summary, the only patents developed by our search which are relevant to the NDA are the '997 patent, which expired long ago, and the '937 patent, which is clearly not infringed. (Copies of the '997 and '937 patents are enclosed).

Please contact me if you have any questions regarding this analysis.

Very truly yours,

William P. Christie

WPC/jfc
Enclosure: via mail only
cc: Shari Sandberg (w/o encl.)
Charles A. DiNardo, Esq. (w/o encl.)
MLM IRV21550.1-*-7/16/99 9:42 am

Debarment Certification

B. Braun Medical Inc. 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.

John G. D'Angelo, M.S., R.Ph.
Vice President, Regulatory Affairs

8/23/99
Date

Field Copy Certification

B. Braun Medical Inc. hereby certifies that the field copy is a true copy of the technical section described in paragraph (d)(1) of Title 21 CFR § 314.50 contained in the archival and review copies of this application.

John G. D'Angelo, M.S., R.Ph.
Vice President, Regulatory Affairs

8/23/99
Date

EXCLUSIVITY SUMMARY FOR NDA # 50-779 SUPPL #_____

Trade Name none Generic Name Cefazolin for Injection and Dextrose Injection in the DUPLEX Container

Applicant Name B. Braun Medical Inc. HFD # 520

Approval Date If Known 7/27/00

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

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

a) Is it an original NDA?

YES /✓/ NO /___/

b) Is it an effectiveness supplement?

YES /___/ NO /___/

If yes, what type? (SE1, SE2, etc.) _____

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.

waiver of evidence to demonstrate in vivo bioavailability (21 CFR 320.22(b)(1)) granted. See Pelsor memo

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?

no

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such)

YES /✓/ NO /___/

If yes, NDA # 50-461. Drug Name _____.

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /___/

IF THE ANSWER TO QUESTION 3 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. IF "YES" GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S 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"):

_____ _____

_____ _____

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

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 /___/ Explain _____ NO /___/ Explain _____

_____ _____

_____ _____

Investigation #2

YES /___/ Explain _____ | NO /___/ 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: _____

/S/
Signature
Title: Project Manager

7/25/00
Date

/S/
Signature of Office/
Division Director

7/25/2000
Date

cc:
Original NDA
HFD-520/Division File
HFD-520/CSO/B. Duvall-Miller
HFD-93/Mary Ann Holovac

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA Number:	050779	**Trade Name:**	CEFAZOLIN SODIUM/DEXTROSE 1GM/500MG INJ
Supplement Number:	000	**Generic Name:**	CEFAZOLIN SODIUM/DEXTROSE 1GM/500MG INJ
Supplement Type:	N	**Dosage Form:**	
Regulatory Action:	PN	**COMIS Indication:**	FOR TREATMENT OF SERIOUS INFECTIONS DUE TO SUSCEPTIBLE ORGANISMS
Action Date:	8/25/99		

Indication # 1 Respiratory Tract Infections

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
30 kg	18 years	Completed	

Comments: For mild to moderate infections adult dose is 500 mg every 8 hours and minimum pediatric dose is 25-50 mg/kg/day; so this product could be used for pediatric patients from 30 kg up to adults

Indication # 2 Urinary Tract Infections

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
40 kg	18 years	Completed	

Comments: Adult dose for UTI is 1 gram every 12 hours and pediatric dose is 25-50 mg/kg/day; so this product could be used for pediatric patients from 40 kg up to adults

Indication # 3 Skin and Skin Structure Infections

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
30 kg	18 years	Completed	

Comments: For mild to moderate infections adult dose is 500 mg every 8 hours and minimum pediatric dose is 25-50 mg/kg/day; so this product could be used for pediatric patients from 30 kg up to adults

Indication # 4 Biliary Tract Infections

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
40 kg	18 years	Completed	

Comments: For moderate to severe infections adult dose is 500 mg to 1 gram every 6-8 hours and pediatric dose is 50 mg/kg/day every 6-8 hours; so this product could be used for pediatric patients from 40 kg up to adults

Indication # 5 Bone and Joint Infections

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
40 kg	18 years	Completed	

Comments: For moderate to severe infections adult dose is 500 mg to 1 gram every 6-8 hours and pediatric dose is 50 mg/kg/day every 6-8 hours; so this product could be used for pediatric patients from 40 kg up to adults

Indication # 6 Genital Infections

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
40 kg	18 years	Completed	

Comments: For moderate to severe infections adult dose is 500 mg to 1 gram every 6-8 hours and pediatric dose is 50 mg/kg/day every 6-8 hours; so this product could be used for pediatric patients from 40 kg up to adults

Indication # 7 Septicemia

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
40 kg	18 years	Completed	

Comments: For severe, life-threatening infections adult dose is 1 to 1.5 grams every 6 hours and pediatric dose is 50-100 mg/kg/day every 6 hours; so this product could be used for pediatric patients from 40 kg up to adults

Indication # 8 Endocarditis

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
40 kg	18 years	Completed	

Comments: For severe, life-threatening infections adult dose is 1 to 1.5 grams every 6 hours and pediatric dose is 50-100 mg/kg/day every 6 hours; so this product could be used for pediatric patients from 40 kg up to adults

Indication # 9 Perioperative Prophylaxis

Label Adequacy: Adequate for ALL pediatric age groups

Forumulation Needed: Other

Comments (if any): July 26, 2000: This product is designed to deliver a 500 mg or 1 gram dose of cefazolin in 50 mL of dextrose. Use of this product poses a risk of overdose in pediatric patients who require less than the full adult dose of cefazolin. Cefazolin is available in preparations from other sponsors, that are appropriate for pediatric use. This product's pediatric use section states that it should not be used in pediatric patients who require less than the full adult dose.

Lower Range	Upper Range	Status	Date
40 kg	18 years	Completed	

Comments: For perioperative infections, the adult dose is 1 gram pre-operatively and 500 mg to 1 gram every 6-8 hours and pediatric dose is about 50 mg/kg/day every 6-8 hours; so this product could be used for pediatric patients from 40 kg up to adults

This page was completed based on information from Elizabeth Duvall miller/ Dr. John Alexander

/S/

Signature - Elizabeth Duvall miller

7/27/00

Date

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 50779/000
Stamp: 25-AUG-1999 Regulatory Due: 25-JUN-2000
Applicant: B BRAUN
2525 MCGAW AVE
IRVINE, CA 92714

Priority: 5S Org Code: 520
Action Goal: District Goal: 26-APR-2000
Brand Name: CEFAZOLIN SODIUM/DEXTROSE 1GM/500MG INJ
Established Name:
Generic Name: CEFAZOLIN SODIUM/DEXTROSE 1GM/500MG INJ
Dosage Form: FIJ (FOR INJECTION)
Strength: 1GM/500MG

FDA Contacts: A. YU (HFD-520) 301-827-2143 , Review Chemist
D. KATAGUE (HFD-520) 301-827-2174 , Team Leader

Overall Recommendation:

Establishment: [redacted]
DMF No:
AADA No:

Profile: CSS OAI Status: OAI ALERT
Last Milestone: ASSIGNED INSPECTION TO IB
Milestone Date: 15-SEP-1999

Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE STERILIZER

Establishment: 2021236
B BRAUN MEDICAL INC
2525 MCGAW AVE
IRVINE, CA 92614

DMF No:
AADA No:

Profile: SVL OAI Status: NONE
Last Milestone: ASSIGNED INSPECTION TO IB
Milestone Date: 17-SEP-1999

Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE STABILITY TESTER

APPEARS THIS WAY
ON ORIGINAL

Application: NDA 50779/000
Stamp: 25-AUG-1999
Regulatory Due: 25-JUN-2000
Applicant: B BRAUN
2525 MCGAW AVE
IRVINE, CA 92714
Priority: 5S
Org Code: 520

Action Goal:
District Goal: 26-APR-2000
Brand Name: CEFAZOLIN SODIUM/DEXTROSE 1GM/500MG INJ
Estab. Name:
Generic Name: CEFAZOLIN SODIUM/DEXTROSE 1GM/500MG INJ

Dosage Form: (FOR INJECTION)
Strength: 1GM/500MG

Application Comment [redacted]

FDA Contacts: A. YU (HFD-520) 301-827-2143 , Review Chemist
D. KATAGUE (HFD-520) 301-827-2174 , Team Leader

Overall Recommendation: WITHHOLD on 22-MAR-2000 by S. FERGUSON (HFD-324) 301-827-0

Establishment: [redacted]

DMF No: [redacted] AADA:
Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE STERILIZER
Profile: CSS OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	02-FEB-2000				DAMBROG
SUBMITTED TO DO	02-FEB-2000	10D			DAMBROG
DO RECOMMENDATION	07-FEB-2000			ACCEPTABLE BASED ON FILE REVIEW	EGASM
BASED ON EI OF 11/6/98 OC RECOMMENDATION	08-FEB-2000			ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

Establishment [redacted]

DMF No: [redacted] AADA: [redacted]
Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE STERILIZER
Profile: CSS OAI Status: NONE
Estab. Comment: E-MAIL DATED 2/2/2000 B BRAUN CLARIFIED THAT THIS WAS THE INCORRECT SITE. THE CORRECT SITE [redacted] WHICH WAS SUBMITT TO EES 2/2/2000. (on 02-FEB-2000 by J. D AMBROGIO (HFD-324) 3(827-0062)

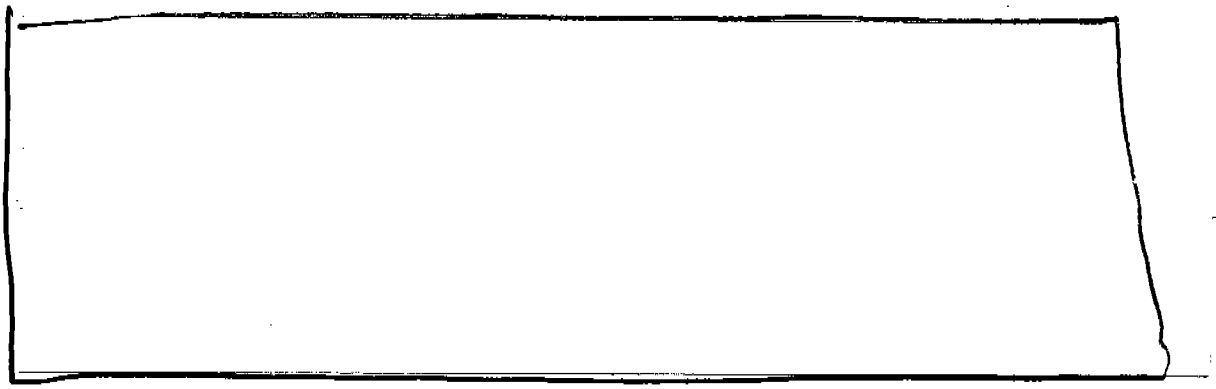
Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creato
SUBMITTED TO OC	10-SEP-1999				YUA
SUBMITTED TO DO	13-SEP-1999	GMP			EGASM
ASSIGNED INSPECTION	15-SEP-1999	GMP			EGASM

DO RECOMMENDATION 06-JAN-2000 ACCEPTABLE EGASM
BASED ON FILE REVIEW
BASED ON EI OF 3/15-18/99
OC RECOMMENDATION 06-JAN-2000 ACCEPTABLE EGASM
DISTRICT RECOMMENDATION
OC RECOMMENDATION 02-FEB-2000 WITHHOLD DAMBROG
FACILITY NOT DOING FUNCT.
B. BRAUN CLARIFIED PER E-MAIL DATED 2/2/2000 THAT THEY SUBMITTED THE APPLICATION WITH THE INCORRECT SITE [redacted]. THE CORRECT SITE IS [redacted] WHICH WAS ADDED TO THE APPLICATION BY OC 2/2/2000

Establishment: 2021236
B BRAUN MEDICAL INC
2525 MCGAW AVE
IRVINE, CA 92614
DMF No: AADA:
Responsibilities: FINISHED DOSAGE LABELER
FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE STABILITY TESTER
FINISHED DOSAGE STERILITY TESTER
Profile: SVL OAI Status: NONE
Estab. Comment: SINCE THIS IS A PRODUCT WITH A SPECIAL PACKAGE, I WOULD BE WIL TO ACCOMPANY THE INSPECTOR FOR PAI.
THE SPONSOR LISTED TWO ADDRESSES WITH ONE CFN# 2021236. THEY INFORMED ME THAT THEY ARE THE SAME CAMPUS: 2525 MCGAW AVENUNE IRVINE, CA 92614, AND 2206 ALTON PARKWAY IRVINE, CA92614.
(on 20-SEP-1999 by A. YU (HFD-520) 301-827-2143)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creato
SUBMITTED TO OC	10-SEP-1999				YUA
SUBMITTED TO DO	13-SEP-1999	GMP			EGASM
ASSIGNED INSPECTION	17-SEP-1999	PS			CEVERL
INSPECTION SCHEDULED	01-OCT-1999		19-NOV-1999		CEVERL
INSPECTION PERFORMED	26-NOV-1999		19-NOV-1999		TDODDS
DO RECOMMENDATION	26-NOV-1999			WITHHOLD	TDODDS
				COMPUTER VALIDATION	
				MEDIA FILLS	
				RECORDS/REPORTS	

[redacted]



ACTING DISTRIC

EIR RECEIVED BY OC 22-MAR-2000

OC RECOMMENDATION 22-MAR-2000 FERGUSO

WITHHOLD FERGUSO

EIR REVIEW-CONCUR W/DISTRICT

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 50775/000
Stamp: 25-AUG-1999 Regulatory Due: 25-JUN-2000
Applicant: B BRAUN
2525 MCGAW AVE
IRVINE, CA 92714

Priority: 5S
Org Code: 520
Action Goal:
District Goal: 26-APR-2000
Brand Name: CEFAZOLIN SODIUM/DEXTROSE 1GM/500MG INJ
Established Name:
Generic Name: CEFAZOLIN SODIUM/DEXTROSE 1GM/500MG INJ
Dosage Form: FIJ (FOR INJECTION)
Strength: 1GM/500MG

FDA Contacts: A. YU (HFD-520) 301-827-2143 , Review Chemist
D. KATAGUE (HFD-520) 301-827-2174 , Team Leader

Overall Recommendation:

ACCEPTABLE on 22-JUN-2000 by S. FERGUSON (HFD-324) 301-827-0062
WITHHOLD on 22-MAR-2000 by S. FERGUSON (HFD-324) 301-827-0062

Establishment: [redacted]
DMF No:
AADA No:

Profile: CSS
Last Milestone: OC RECOMMENDATION
Milestone Date 08-FEB-2000
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
OAI Status: NONE
Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE STERILIZER

Establishment: [redacted]
DMF No:
AADA No:

Profile: CSS
Last Milestone: OC RECOMMENDATION
Milestone Date 02-FEB-2000
Decision: WITHHOLD
Reason: FACILITY NOT DOING FUNCTION
OAI Status: NONE
Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE STERILIZER

Establishment: 2021236
B BRAUN MEDICAL INC
2525 MCGAW AVE
IRVINE, CA 92614
DMF No:
AADA No:

Profile: SVS
Last Milestone: OC RECOMMENDATION
OAI Status: NONE
Responsibilities: FINISHED DOSAGE LABELER
FINISHED DOSAGE

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Milestone Date 22-JUN-2000
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE STABILITY TESTER
FINISHED DOSAGE STERILITY TESTER

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

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

PHILADELPHIA DISTRICT
SCIENCE BRANCH

MEMORANDUM

DATE: March 7, 2000

FROM: Director, Science Branch
Philadelphia District, HFR-CE160

SUBJECT: NDA 50-779: Cefazolin for Injection, 500 mg/container, and Drug Substance
B. Braun Medical, Irvine, CA 92623

TO: Andrew Yu, Ph.D., Review Chemist
CDER, Division of New Drug Chemistry I, HFD-830

The Philadelphia District Laboratory performed the analysis of Cefazolin for Injection, 500 mg/container, and Drug Substance using the firm's method and samples provided. Attached are the summary of results, worksheets, and comments for the subject NDA.

Based on the analytical results, the NDA method appears to be suitable for regulatory control of this product. All results were within the firm's specifications.

/S/

W. Charles Becoat

cc: HFR-CE100
HFC-140
HFR-PA250 (Los Angeles District Investigations Branch)
Lab A: Hart
File

REN:WCB
ATTACHMENTS