

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 50-746

ADMINISTRATIVE DOCUMENTS

Confidential



Mupirocin Calcium Cream

BRL 4910F

ITEM 13/14. PATENT INFORMATION

000190

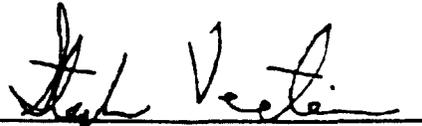
SB
SmithKline Beecham

Stephen Venetianer
Vice President & Patent Counsel
Corporate Intellectual Property - U.S.

The patent information for the NDA covering mupiricin calcium is as follows:

<u>Patent #</u>	<u>Owner</u>	<u>Type</u>	<u>Expires</u>
5,436,266	Beecham Group plc	Composition of Matter	April 10, 2007
5,569,672	Beecham Group plc	Method of Treatment	October 29, 2013

The undersigned declares that Patent Nos. 5,436,266 and 5,569,672 cover the formulation, composition and method of use of crystalline calcium pseudomonate for the treatment of bacterial or mycoplasmal infections. This product is the subject of this application for which approval is being sought.



Stephen Venetianer
Vice President & Patent Counsel

October 31, 1996
Date

000191

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

NDA/PLA/PMA # 50-746 Supplement # Circle one: SE1 SE2 SE3 SE4 SE5
SE6

HFD-520 Trade and generic names/dosage form: Bactroban[®] (mupirocin Calcium Cream, 2%) Cream Action: (AP) AE NA

Applicant SmithKline Beecham Therapeutic Class Topical

Indication(s) previously approved none

Pediatric information in labeling of approved indication(s) is adequate inadequate

Indication in this application treatment of secondarily infected small traumatic skin lesions (For supplements, answer the following questions in relation to the proposed indication.) due to susceptible strains of Staphylococcus aureus + Streptococcus pyogenes.

 1. **PEDIATRIC LABELING IS ADEQUATE FOR ALL PEDIATRIC AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric age groups. Further information is not required.

X 2. **PEDIATRIC LABELING IS ADEQUATE FOR CERTAIN AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for certain pediatric age groups (e.g., infants, children, and adolescents but not neonates). Further information is not required.

 3. **PEDIATRIC STUDIES ARE NEEDED.** There is potential for use in children, and further information is required to permit adequate labeling for this use.

 a. A new dosing formulation is needed, and applicant has agreed to provide the appropriate formulation.

 b. A new dosing formulation is needed, however the sponsor is either not willing to provide it or is in negotiations with FDA.

 c. The applicant has committed to doing such studies as will be required.

 (1) Studies are ongoing,

 (2) Protocols were submitted and approved.

 (3) Protocols were submitted and are under review.

 (4) If no protocol has been submitted, attach memo describing status of discussions.

 d. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

 4. **PEDIATRIC STUDIES ARE NOT NEEDED.** The drug/biologic product has little potential for use in pediatric patients. Attach memo explaining why pediatric studies are not needed.

 5. If none of the above apply, attach an explanation, as necessary.

ATTACH AN EXPLANATION FOR ANY OF THE FOREGOING ITEMS, AS NECESSARY.

Signature of Preparer and Title

Proj Mgr

Date

11/25/97

cc: Orig NDA/PLA/PMA # 50-746

HFD-520 /Div File

NDA/PLA Action Package

HFD-0067 SOLmstead (plus, for CDER/CBER APs and AEs, copy of action letter and labeling)

NDA 50-746

Bactroban[®] Cream

Mupirocin Calcium Cream

DEBARMENT STATEMENT

SMITHKLINE BEECHAM PHARMACEUTICALS HEREBY CERTIFIES THAT SAID APPLICANT DID NOT USE IN ANY CAPACITY THE SERVICES OF ANY PERSON DEBARRED UNDER SUBSECTION (A) OR (B) [SECTION 306(A) OR (B) OF THE ACT], IN CONNECTION WITH THE NEW DRUG APPLICATION FOR BACTROBAN[®] CREAM (MUPIROCIN CALCIUM CREAM). THE APPLICANT FURTHER CERTIFIES THAT NO SUCH PERSON DEBARRED BY THE FOOD AND DRUG ADMINISTRATION WILL BE USED IN ANY CAPACITY IN FUTURE INVESTIGATIONS INVOLVING THIS DRUG PRODUCT. AT SUCH TIME AS SAID DEBARMENT BECOMES KNOWN TO THE SPONSOR.

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REQUEST FOR TRADEMARK REVIEW

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TO: Labeling and Nomenclature Committee
Attention: DAN Boring, Ph.D.

FROM: Division of Anti-Infectives HFD- 520
Attention: MILTON SLOAN R.D. Phone 927-2182

DATE: April 21, 1997

SUBJECT: Request for Assessment of a Trademark for a Proposed Drug Product

Proposed Trademark: Bactroban® Cream NDA/ANDA# 50-746

Company Name: Smithkline Beecham

Established name, including dosage form: mupirocin
calcium cream

Other trademarks by the same firm for companion products:
Bactron® Nasal Ointment, Bactron® Topical Ointment

Indications for Use (may be a summary if proposed statement is lengthy): Antibacterial; treatment of secondarily infected traumatic skin lesions

Initial comments from the submitter: (concerns, observations, etc.)

Applicant has approved product 2% Bactroban® Nasal Ointment as calcium salt.

NOTE: Meetings of the Committee are scheduled for the 4th Tuesday of the month. Please submit this form at least one week ahead of the meeting. Responses will be as timely as possible.

Rev Oct. 93

Consult #799 (HFD-520)

BACTROBAN

mupirocin cream

BACTROBAN is an already approved product available as a nasal and topical ointment. The sponsor is seeking a new cream formulation. The Committee has no concerns about the use of the name BACTROBAN for the new dosage form.

The Committee has no reason to find the proposed proprietary name unacceptable.

D. Boins 6/23/97, Chair
CDER Labeling and Nomenclature Committee