CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-837

ADMINISTRATIVE DOCUMENTS

To: Labeling and Nomenclature Committee
Attention: Dan Boring, Chair (HFD-530), 9201 Corporate Blvd, Room N461

From: Division of Pulmonary Drug Products	**HFD-570**
Attention: Parinda Jani	**Phone:** (301) 827-1064
Date: November 3, 1998	
Subject: Request for Assessment of a Trademark for a Proposed New Drug Product	
Proposed Trademark: XOPENEX Inhalation Solution	**NDA/ANDA#** 20-837
Established name, including dosage form: levalbuterol inhalation solution (several strengths)	
Other trademarks by the same firm for companion products: None	
Indications for Use (may be a summary if proposed statement is lengthy): for the treatment and prevention of [redacted] bronchospasm in patients 12 years of age and older with reversible obstructive airway disease [redacted]	
Initial Comments from the submitter (concerns, observations, etc.): **An approvable letter was sent to the sponsor on July 1, 1998. The name "XOPENEX" was acceptable at that time. Sponsor has submitted a complete response to the AE letter, September 24, 1998. The Division would like to know that the name "XOPEENX" is still acceptable. The due date for this NDA is March 25, 1999.**	

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.

cc: Original 20-837; HFD-570/division file; HFD-570/P.Jani; HFD-570/shahvj, Poochikian, Schumaker

Rev. December 95

APPEARS THIS WAY
ON ORIGINAL

REQUEST FOR TRADEMARK REVIEW

(983)

To: Labeling and Nomenclature Committee
Attention: Dan Boring, Chair (HFD-530), 9201 Corporate Blvd, Room N461.

From: Division of Pulmonary Drug Products	**HFD-570**
Attention: Parinda Jani	**Phone:** (301) 827-1050
Date: January 29, 1998	
Subject: Request for Assessment of a Trademark for a Proposed New Drug Product	
Proposed Trademark: XOPENEX Inhalation Solution	**NDA/ANDA#** 20-837
Established name, including dosage form: levalbuterol inhalation solution (several strengths)	
Other trademarks by the same firm for companion products: None	
Indications for Use (may be a summary if proposed statement is lengthy): for the treatment and prevention of [redacted] bronchospasm in patients 12 years of age and older with reversible obstructive airway disease [redacted]	
Initial Comments from the submitter (concerns, observations, etc.): 1. The sponsor had proposed the names [redacted] and [redacted]", which were unacceptable due to look alike/sound alike names; i.e., Zofran, Zyban, Zosyn etc. 2. In future, [redacted]	

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.

cc: Original 20-837; HFD-570/division file; HFD-570/P.Jani; HFD-570/shahvj, Poochikian, Schumaker

Rev. December 95

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ON ORIGINAL

CDER LABELING AND NOMENCLATURE COMMITTEE

CONSULT # 983	HFD# 570	PROPOSED PROPRIETARY NAME:	PROPOSED ESTABLISHED NAME:
ATTENTION:	PARINDA JANI	XOPENEX Inhalation Solution	Levalbuterol inhalation solution

A. Look-alike/Sound-alike

	Potential for confusion:		
XANAX	XXX Low	____ Medium	____ High
ZOLADEX	XXX Low	____ Medium	____ High
SUPRAX	XXX Low	____ Medium	____ High
ZOFRAN	XXX Low	____ Medium	____ High
	____ Low	____ Medium	____ High

B. Misleading Aspects:

C. Other Concerns:

D. Established Name

XXX Satisfactory

____ Unsatisfactory/Reason

Recommended Established Name

E. Proprietary Name Recommendations:

XXX ACCEPTABLE ____ UNACCEPTABLE

F. Signature of Chair/Date /S/ 5/14/98

CDER Establishment Evaluation Report
for June 25, 1998

Application: **NDA 20837/000**
Stamp: **01-JUL-1997** Regulatory Due: **01-JUL-1998**
Applicant: **SEPRACOR PHARMS**
111 LOCKE DR
MARLBOROUGH, MA 01752

Priority: **3S** Org Code: **570**
Action Goal: District Goal: **01-MAR-1998**
Brand Name: **XOPENEX**
Established Name:
Generic Name: **LEVALBUTEROL HCL INHALATION SOL 0.31/0.6**
Dosage Form: **LQI (LIQUID FOR INHALATION)**
Strength: **0.62/0.125 MG/3 ML**

FDA Contacts:

P. JANI	**(HFD-570)**	**301-827-1050**	**, Project Manager**
V. SHAH	**(HFD-570)**	**301-827-1050**	**, Review Chemist**
G. POOCHIKIAN	**(HFD-570)**	**301-827-1050**	**, Team Leader**

Overall Recommendation:

WITHHOLD on 19-JUN-1998 by M. EGAS (HFD-322) 301-594-0095

Establishment: [redacted]
DMF No:
AADA No:

Profile: **SNI** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **05-FEB-1998**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE MANUFACTURER**
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE STERILITY TESTER

Establishment: [redacted]
DMF No: [redacted]
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **29-SEP-1997**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **18-JUN-1998**

Responsibilities: **DRUG SUBSTANCE STABILITY TESTER**
FINISHED DOSAGE STABILITY

TESTER

Decision: **WITHHOLD**
Reason: **EIR REVIEW-CONCUR W/DISTRICT**

Establishment: [redacted] DMF No: [redacted]
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **29-SEP-1997**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

Establishment: [redacted] DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **29-SEP-1997**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **DRUG SUBSTANCE RELEASE TESTER**

Establishment: [redacted] DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **29-SEP-1997**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **FINISHED DOSAGE RELEASE TESTER**
FINISHED DOSAGE STABILITY TESTER

Establishment: DMF No:
AADA No:

SEPRACOR INC
111 LOCKE DRIVE
MARLBOROUGH, MA 01752

Profile: **CTL** OAI Status: **NONE**

Responsibilities: **FINISHED DOSAGE RELEASE**

Last Milestone: **OC RECOMMENDATION**
Milestone Date: **26-JAN-1998**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

TESTER
FINISHED DOSAGE STERILITY TESTER

Establishment:
SEPRACOR INC
24 IVEY LANE
WINDSOR, NOVA SCOTIA, CA

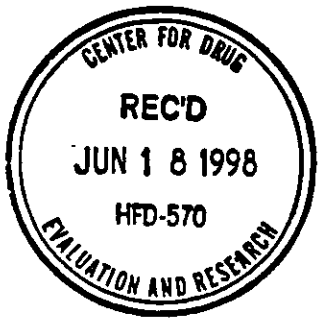
DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **19-JUN-1998**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**
DRUG SUBSTANCE RELEASE TESTER

APPEARS THIS WAY
ON ORIGINAL

SEPRACOR



16 June 1998

John Jenkins, M.D.
Division Director
Division of Pulmonary Drug Products, HFD-570
Attention: Document Control Room, 10B-45
FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857

RE: *AMENDMENT TO NDA NUMBER 20-837, SEPRACOR INC.*
PATENT INFORMATION, U.S. PATENT NO. 5,760,090

Dear Sir/Madam:

This letter is submitted under 21 USC §355(b)(1)(F) and 21 CFR 314.53(d) as an amendment to Sepracor's New Drug Application No. 20-837 for Levalbuterol HCl Inhalation Solution.

The following U.S. Patent, owned by Sepracor Inc., was issued on June 2, 1998, a date which is after the filing date but before approval of NDA No. 20-837:

U.S. Patent No. 5,760,090 expires 5 January 2010

The undersigned declares that U.S. Patent No. 5,760,090 covers the method of use of Levalbuterol HCl Inhalation Solution. This product is the subject of this application for which approval is being sought. A claim of patent infringement could reasonably be asserted with respect to this patent if a person not licensed by the owner engaged in the manufacture, use or sale of the drug for which applicant submitted the application.

Sepracor Inc., 111 Locke Drive, Marlborough, MA 01752 Tel: (508) 481-6700 Fax: (508) 481-7683

Sepracor respectfully requests that, upon approval of the application, the above patent information be published in the "Prescription and OTC Drug Product Patent and Exclusivity Data" section of the U.S. Department of Health and Human Services publication *APPROVED DRUG PRODUCTS with Therapeutic Equivalence Evaluations.*

Very truly yours,

Douglas E. Reedich, Ph.D.
Chief Patent Counsel

DER:jdp

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**APPEARS THIS WAY
ON ORIGINAL**

SEPRACOR

23 May, 1997

Central Document Room
Center for Drug Evaluation Research
FOOD AND DRUG ADMINISTRATION
12420 Parklawn Drive
Park Building, rm 2-14
Rockville, Maryland 20857

Re: NDA Number 20-837, Sepracor Inc
Patent Information, U.S. Pat. No. 5,362,755

Dear Sir/Madam:

This letter is submitted under 21 USC 355(b)(1) in connection with Sepracor's New Drug Application number 20-837 for Levalbuterol HCl Inhalation Solution.

The following U.S. Patent is owned by Sepracor Inc.

U.S. Patent No. 5,362,755, expires 8 November 2011

The undersigned declares that U.S. Pat. No. 5,362,755 covers the method of use of Levalbuterol HCl Inhalation Solution. This product is the subject of this application for which approval is being sought.

A claim of patent infringement could reasonably be asserted with respect to this patent if a person not licensed by the owner engaged in the manufacture, use or sale of the drug for which applicant submitted the application.

Sepracor respectfully requests that, upon approval of the application, the above patent information be published in the "Prescription and OTC Drug Product Patent and Exclusivity Data" section of the U.S. Department of Health and Human Services publication *APPROVED DRUG PRODUCTS with Therapeutic Equivalence Evaluations.*

Very truly yours,

Douglas E. Reedich

Douglas E. Reedich, Ph.D.
Chief Patent Counsel

DER/jd
fda4.doc

Sepracor Inc., 111 Locke Drive, Marlborough, MA 01752 Tel: (508) 481-6700 Fax (508) 481-7683

SEPRACOR

23 May, 1997

Central Document Room
Center for Drug Evaluation Research
FOOD AND DRUG ADMINISTRATION
12420 Parklawn Drive
Park Building, rm 2-14
Rockville, Maryland 20857

Re: NDA Number 20-837, Sepracor Inc
Patent Information, U.S. Pat. No. 5,547,994

Dear Sir/Madam:

This letter is submitted under 21 USC 355(b)(1) in connection with Sepracor's New Drug Application number 20-837 for Levalbuterol HCl Inhalation Solution.

The following U.S. Patent is owned by Sepracor Inc.

U.S. Patent No. 5,547,994, expires 20 August 2013

The undersigned declares that U.S. Pat. No. 5,547,994 covers the method of use of Levalbuterol HCl Inhalation Solution. This product is the subject of this application for which approval is being sought.

A claim of patent infringement could reasonably be asserted with respect to this patent if a person not licensed by the owner engaged in the manufacture, use or sale of the drug for which applicant submitted the application.

Sepracor respectfully requests that, upon approval of the application, the above patent information be published in the "Prescription and OTC Drug Product Patent and Exclusivity Data" section of the U.S. Department of Health and Human Services publication *APPROVED DRUG PRODUCTS with Therapeutic Equivalence Evaluations.*

Very truly yours,

Douglas E. Reedich

Douglas E. Reedich, Ph.D.
Chief Patent Counsel

DER/jd
fda4.doc

Sepracor Inc., 111 Locke Drive, Marlborough, MA 01752 Tel: (508) 481-6700 Fax: (508) 481-7683

SEPRACOR

23 May, 1997

Central Document Room
Center for Drug Evaluation Research
FOOD AND DRUG ADMINISTRATION
12420 Parklawn Drive
Rockville, Maryland 20857

Re: NDA Number 20-837, Sepracor Inc.
Patent Certification

Dear Sir/Madam:

This letter is submitted under 21 USC 355(b)(2) and 21 CFR 314.50(i)(1)(ii) in connection with Sepracor's New Drug Application number 20-837 for Levalbuterol HCl Inhalation Solution.

Sepracor's NDA Number 20-837 is submitted under 21 USC 355(b)(2), and relies upon certain investigations not conducted by or for Sepracor and for which Sepracor has not obtained a right of reference. The drug on which such investigations were conducted is the subject of NDA Number 19243.

In the opinion and to the best knowledge of Sepracor Inc., there are no patents that claim the drug or drugs on which investigations that are relied upon in this application were conducted or that claim a use of such drug or drugs.

Very truly yours,

Douglas E. Reedich, Ph.D.
Chief Patent Counsel

DER/efa

FDA3.doc

Sepracor Inc., 111 Locke Drive, Marlborough, MA 01752 Tel: (508) 481-6700 Fax: (508) 481-7683

SEPRACOR

6, June 1997

Central Document Room
Center for Drug Evauation Research
FOOD AND DRUG ADMINISTRATION
12420 Parklawn Drive
Rockville, Maryland 20857

Re: NDA Number 20-837, Sepracor Inc.
Request for New Drug Product Exclusivity

Dear Sir/Madam:

This letter is submitted in connection with Sepracor's New Drug Application Number 20-837 for Levalbuterol HCl Inhalation Solution.

Levalbuterol HCl Inhalation Solution contains no active moiety that has been approved by FDA in any other application submitted under 21 USC 355(b). Accordingly, Sepracor respectfully requests that FDA grant a five (5) year period of New Product Exclusivity under 21 USC 355(c)(3)(ii), and 314.108(b)(2).

Very Truly Yours

Douglas E Reedich

Douglas E Reedich
Chief Patent Counsel

DER/efa

fad6.doc

Sepracor Inc., 111 Locke Drive, Marlborough, MA 01752 Tel: (508) 481-6700 Fax: (508) 481-7683

V0011-059

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number:	20837	**Trade Name:**	XOPENEX
Supplement Number:		**Generic Name:**	LEVALBUTEROL HCL INHALATION SOL
Supplement Type:		**Dosage Form:**	Solution; Inhalation
Regulatory Action:	PN	**Proposed Indication:**	Xopenex Inhalation Solution is inicated for the treatment or prevention of bronchospasm in adults and adolescents 12 years of age and older with reversible obstructive airway disease.

IS THERE PEDIATRIC CONTENT IN THIS SUBMISSION?

YES, Pediatric data exists for at least one proposed indication which supports pediatric approval

What are the INTENDED Pediatric Age Groups for this submission?

____NeoNates (0-30 Days)____Children (25 Months-12 years)

____Infants (1-24 Months) _X_Adolescents (13-16 Years)

Label Adequacy	Adequate for SOME pediatric age groups
Formulation Status	NO NEW FORMULATION is needed
Studies Needed	STUDIES needed. Applicant has COMMITTED to doing them
Study Status	

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

COMMENTS:

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER, PARINDA JANI

/S/ 3-24-99

Signature Date

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ON ORIGINAL

SEPRACOR

Debarment Certification

In accordance with Section 306(k) of the Food Drug and Cosmetic Act, Sepracor Inc. hereby certifies that we did not and will not use in any capacity the services of any person debarred under Section 306(a) or 306(b) of the Act.

Pauliana C. Hall

Pauliana C. Hall, R.A.C.
Vice President
Worldwide Regulatory Affairs

June 30, 1997

APPEARS THIS WAY
ON ORIGINAL

Sepracor Inc., 111 Locke Drive, Marlborough, MA 01752 Tel: (508) 481-6700 Fax: (508) 481-7683

V001P061