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

<table>
<thead>
<tr>
<th>From: Division of Pulmonary Drug Products</th>
<th>HFD-570</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention: Parinda Jani</td>
<td>Phone: (301) 827-1064</td>
</tr>
<tr>
<td>Date: November 3, 1998</td>
<td></td>
</tr>
<tr>
<td>Subject: Request for Assessment of a Trademark for a Proposed New Drug Product</td>
<td></td>
</tr>
<tr>
<td>Proposed Trademark: XOPENEX Inhalation Solution</td>
<td>NDA/ANDA# 20-837</td>
</tr>
<tr>
<td>Established name, including dosage form: levalbuterol inhalation solution (several strengths)</td>
<td></td>
</tr>
<tr>
<td>Other trademarks by the same firm for companion products: None</td>
<td></td>
</tr>
</tbody>
</table>

Indications for Use (may be a summary if proposed statement is lengthy): for the treatment and prevention of reversible obstructive airway disease in patients 12 years of age and older with bronchospasm.

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/shahv, Poochikian, Schumaker

Rev. December 95

APPEARS THIS WAY ON ORIGINAL
REQUEST FOR TRADEMARK REVIEW

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

<table>
<thead>
<tr>
<th>From:</th>
<th>Division of Pulmonary Drug Products</th>
<th>HFD-570</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention:</td>
<td>Parinda Jani</td>
<td>Phone: (301) 827-1050</td>
</tr>
</tbody>
</table>

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 bronchospasm in patients 12 years of age and older with reversible obstructive airway disease.

Initial Comments from the submitter (concerns, observations, etc.):
1. The sponsor had proposed the names ______ and _____", which were unacceptable due to look alike/sound alike names; i.e., Zofran, Zyban, Zosyn etc.  
2. In future, ______

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
## A. Look-alike/Sound-alike

<table>
<thead>
<tr>
<th>Drug</th>
<th>Potential for confusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>XANAX</td>
<td>XXX Low Medium High</td>
</tr>
<tr>
<td>ZOLADEX</td>
<td>XXX Low Medium High</td>
</tr>
<tr>
<td>SUPRAX</td>
<td>XXX Low Medium High</td>
</tr>
<tr>
<td>ZOFRAN</td>
<td>XXX Low Medium High</td>
</tr>
</tbody>
</table>

## B. Misleading Aspects:

|                      |

## C. Other Concerns:

|                      |

## D. Established Name

- Satisfactory
- Unsatisfactory/Reason

Recommended Established Name

## E. Proprietary Name Recommendations:

- ACCEPTABLE
- UNACCEPTABLE

## F. Signature of Chair/Date

1S/ 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 Action Goal: Org Code: 570
Established Name: XOPENEX
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. POOCHEIKIAN (HFD-570) 301-827-1050, Team Leader

Overall Recommendation:

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

Profile: SNI OAI Status: NONE Responsibilities: FINISHED DOSAGE MANUFACTURER
Last Milestone: OC RECOMMENDATION
Milestone Date: 05-FEB-1998
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

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

Profile: CTL OAI Status: NONE Responsibilities: DRUG SUBSTANCE STABILITY TESTER
Last Milestone: OC RECOMMENDATION
Milestone Date: 18-JUN-1998
FINISHED DOSAGE STABILITY
Decision: WITHHOLD
Reason: EIR REVIEW-CONCUR W/DISTRICT

Establishment:  
DMF No:  
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:  
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:  
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: SEPRACOR INC  
111 LOCKE DRIVE  
MARLBOROUGH, MA 01752

Profile: CTL  
OAI Status: NONE  
Responsibilities: FINISHED DOSAGE RELEASE
### CDER Establishment Evaluation Report

**for June 25, 1998**

<table>
<thead>
<tr>
<th>Last Milestone:</th>
<th>OC RECOMMENDATION</th>
<th>TESTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milestone Date:</td>
<td>26-JAN-1998</td>
<td>FINISHED DOSAGE STERILITY</td>
</tr>
<tr>
<td>Decision:</td>
<td>ACCEPTABLE</td>
<td>TESTER</td>
</tr>
<tr>
<td>Reason:</td>
<td>DISTRICT RECOMMENDATION</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Establishment:</th>
<th>DMF No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEPRACOR INC</td>
<td></td>
</tr>
<tr>
<td>24 IVEY LANE</td>
<td>AADA No:</td>
</tr>
<tr>
<td>WINDSOR, NOVA SCOTIA, CA</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Profile:</th>
<th>CSN</th>
<th>OAI Status:</th>
<th>DRUG SUBSTANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Milestone:</td>
<td>OC RECOMMENDATION</td>
<td>MANUFACTURER</td>
<td></td>
</tr>
<tr>
<td>Milestone Date:</td>
<td>19-JUN-1998</td>
<td>DRUG SUBSTANCE RELEASE</td>
<td></td>
</tr>
<tr>
<td>Decision:</td>
<td>ACCEPTABLE</td>
<td>TESTER</td>
<td></td>
</tr>
<tr>
<td>Reason:</td>
<td>DISTRICT RECOMMENDATION</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**APPEARS THIS WAY ON ORIGINAL**
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 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,

[Signature]

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

DER:jdp

[C:\WINWORD\FDA JUNE 2 1998.DOC]

APPEARS THIS WAY ON ORIGINAL
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  

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, Ph.D.  
Chief Patent Counsel  

DER/jd  

FDA6.doc
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,

[Signature]
Douglas E. Reedich, Ph.D.
Chief Patent Counsel

DER/jd
fda4.doc
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
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.  
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  
Chief Patent Counsel

DER/efa

fadd.doc
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 indicated 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 Formulation Status Studies Needed
Adequate for SOME pediatric age groups NO NEW FORMULATION is 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 JAN

Signature /S/  Date 3-24-99

APPEARS THIS WAY ON ORIGINAL

3/23/99  11:59:25 AM
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, R.A.C.
Vice President
Worldwide Regulatory Affairs

June 30, 1997