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July 26, 2002

**BY HAND**

Donald S. Clark, Esq.  
Office of the Secretary  
Federal Trade Commission  
600 Pennsylvania Avenue, N.W.  
Washington D.C. 20580



Re: In the Matter of Biovail Corporation, File No. 011-0094

Dear Mr. Clark:

On behalf of Biovail Corporation ("Biovail"), I write to seek the Federal Trade Commission's approval of Biovail's divestiture of certain patent rights to DOV Pharmaceutical, Inc. ("DOV"), as required by the Agreement Containing Consent Order, executed by Biovail in the above captioned matter on April 5, 2002 ("Order").<sup>1</sup> Paragraph II.A. of the Order requires Biovail to "divest, absolutely, in good faith, and only in a manner that receives the prior approval of the Commission, the Assets To Be Divested to DOV," with Assets To Be Divested meaning "all Exclusive Licenses to the DOV '463 Patent in the Tiazac Field." (Order, Paragraph I.C.)

On July 19, 2002, Biovail and DOV executed an amendment to the parties' license agreement, a copy of which is attached hereto. The amendment modifies the grant of license rights to Biovail by returning the exclusive license to the DOV '463 Patent in the Tiazac Field to DOV. The amendment provides that it will become effective upon notification of Commission approval

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<sup>1</sup>This letter adopts and incorporates by reference all definitions set forth in the Order.

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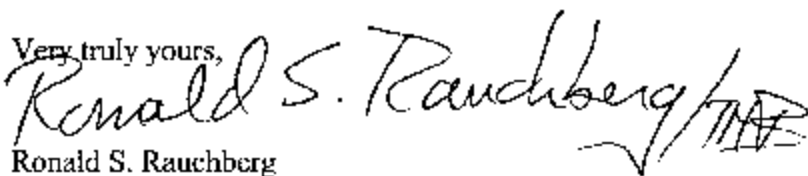
Donald S. Clark

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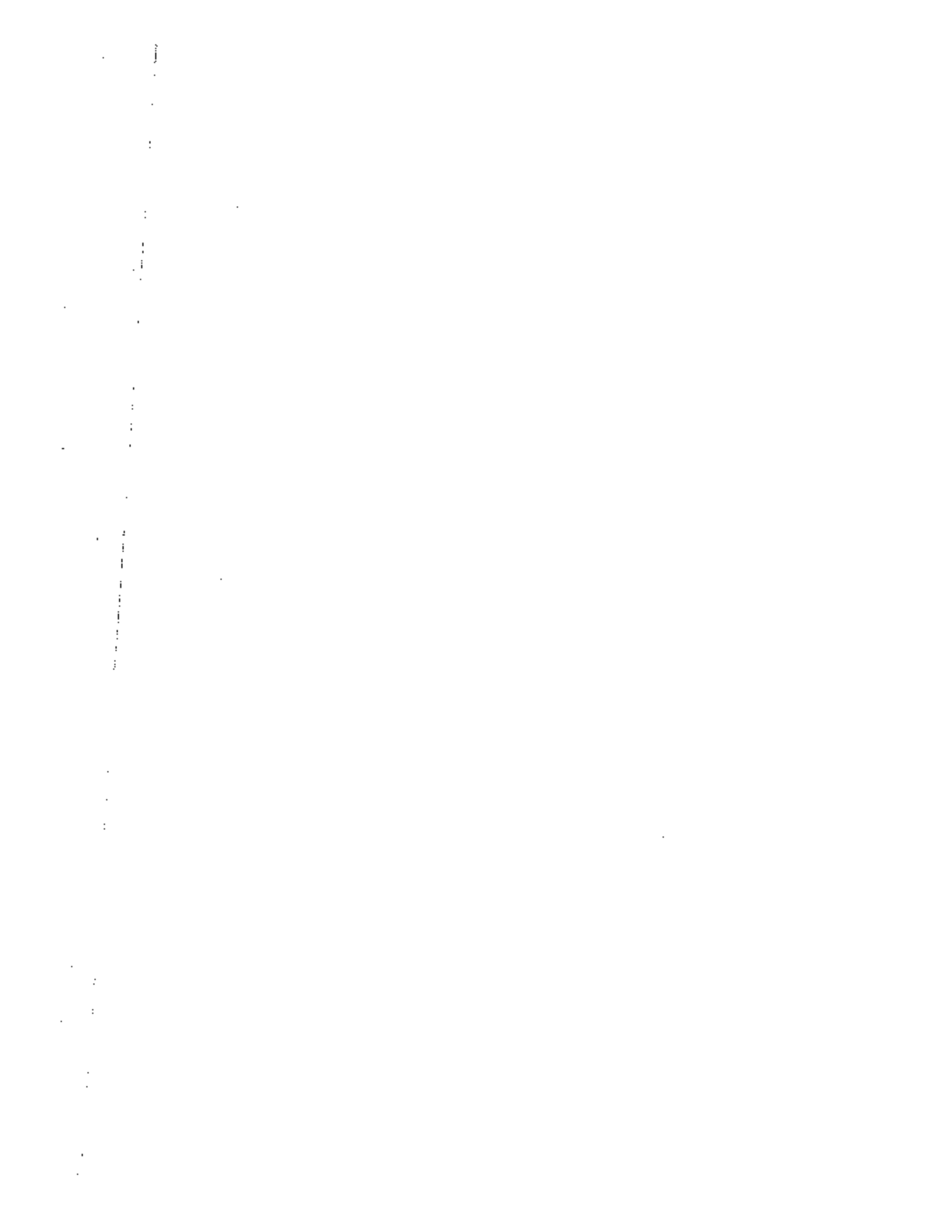
thereof, with no further action by the parties. The amendment fully complies with the divestiture obligations set forth in the Order and therefore merits Commission approval.

Very truly yours,

A handwritten signature in cursive script that reads "Ronald S. Rauchberg". To the right of the signature, there is a small, stylized mark that appears to be "TRR".

Ronald S. Rauchberg

Attachment



**AMENDMENT TO LICENSE, RESEARCH AND DEVELOPMENT AGREEMENT**

WHEREAS, DOV Pharmaceutical, Inc. ("DOV"), and Biovail Laboratories, Inc. ("Biovail"), entered into a License, Research and Development Agreement (the "Agreement") effective as of January 12, 2001; and

WHEREAS, Biovail has entered into an Agreement Containing Consent Order with the Federal Trade Commission ("FTC") dated April \_\_, 2002 (the "FTC Order"); and

WHEREAS, Biovail and DOV have agreed to amend the Agreement in conformity with the FTC Order;

NOW THEREFORE, Biovail and DOV hereby agree as follows:

**DEFINITIONS**

1. Unless otherwise specified herein, all capitalized terms used in this Amendment to License, Research and Development Agreement (this "Amendment") without a definition shall have the meanings set forth in the Agreement and the FTC Order.

2. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(i).

3. "NDA 20-401" means the FDA-approved New Drug Application that is owned by Biovail for an extended release formulation of diltiazem currently marketed under the brand name Tiazac.

4. "Field" means drug formulations for the treatment, including suppression of angina and hypertension, of any disease or medical condition, except in the Tiazac Field.

5. "Tiazac Field" means any extended release formulation of diltiazem that has been approved by the FDA for sale pursuant to NDA 20-401, or that is described in any ANDA for which approval is sought by referencing NDA 20-401.

**AMENDMENT**

1. The license grant to Biovail found in Section 2.1 of the Agreement is hereby amended to read as follows:

Subject to the terms and conditions of the Agreement,

- (a) Subject to Section (b) below, DOV hereby grants to Biovail an exclusive, worldwide license under the DOV Intellectual Property, including an exclusive license to all substantial rights under the DOV Patent to Manufacture and Market the Product in the Field, with a right to grant Sublicenses in accordance with Section 2.2. Such exclusive license includes the right to bring or defend any legal

action considered necessary by Biovail to protect its interest under the DOV Intellectual Property in the Field.

- (b) Biovail hereby returns to DOV its Exclusive License, and shall not retain a non-exclusive license, under the DOV Intellectual Property in the Tiazac Field. Biovail shall have no rights under the DOV Intellectual Property to Manufacture and Market the Product in the Tiazac Field. DOV may grant worldwide licenses to third parties under the DOV Intellectual Property, including licenses to all substantial rights under the DOV Patent, to Manufacture and Market the Product in the Tiazac Field. DOV shall have the exclusive right to enforce and defend, and Biovail shall not initiate, maintain, or be a party to (other than as a defendant), any legal action to enforce the DOV Patent in the Tiazac Field.

2. In case of conflict between the Agreement or this Amendment and the FTC Order, the latter shall govern.

3. This Amendment shall become effective immediately upon notification of the Federal Trade Commission's approval of this Amendment. It shall be of no force or effect until such notification is received.

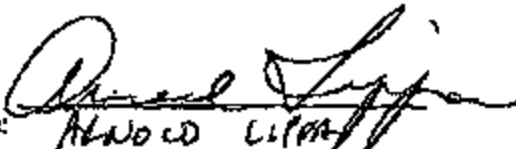
4. This Agreement may be executed in counterparts, and binding signature pages may be delivered by fax.

IN WITNESS WHEREOF, DOV and Biovail have caused this Amendment to be executed by their respective duly authorized officers as of the date stated below.

Dated:

July 18, 2002

DOV PHARMACEUTICAL, INC.

By:   
 Name: Howard Lipman  
 Title: CEO

BIOVAIL LABORATORIES INCORPORATED

By: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_

action considered necessary by Biovail to protect its interest under the DOV Intellectual Property in the Field.

(b) Biovail hereby returns to DOV its Exclusive License, and shall not retain a non-exclusive license, under the DOV Intellectual Property in the Tiazac Field. Biovail shall have no rights under the DOV Intellectual Property to Manufacture and Market the Product in the Tiazac Field. DOV may grant worldwide licenses to third parties under the DOV Intellectual Property, including licenses to all substantial rights under the DOV Patent, to Manufacture and Market the Product in the Tiazac Field. DOV shall have the exclusive right to enforce and defend, and Biovail shall not initiate, maintain, or be a party to (other than as a defendant), any legal action to enforce the DOV Patent in the Tiazac Field.

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IN WITNESS WHEREOF, DOV and Biovail have caused this Amendment to be executed by their respective duly authorized officers as of the date stated below.

DOV PHARMACEUTICAL, INC.

Dated:  
July 18, 2002

By: \_\_\_\_\_  
Name:  
Title:

BIOVAIL LABORATORIES INCORPORATED

By:   
Name: K.C. CAUCBUARA, S.C.  
Title: SVP & GENERAL COUNSEL,  
BIOVAIL CORPORATION

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