

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
BROWARD DIVISION

ANDRX PHARMACEUTICALS, INC.,
Plaintiff,

v.

CASE NO.: 01-6194-CIV-DIMITROULEAS
Magistrate Judge Johnson

BIOVAIL CORPORATION
INTERNATIONAL,
Defendant,
and

PLAINTIFF, ANDRX
PHARMACEUTICAL, INC.'S NOTICE OF
FILING DECLARATION OF
DIANE SERVELLO

TOMMY G. THOMPSON, Secretary, U.S.
Department of Health and Human Services,
BERNARD A. SCHWETZ, D.V.M., Ph.D.,
Acting Principal Deputy Commissioner, U.S.
Food and Drug Administration, and U.S.
FOOD AND DRUG ADMINISTRATION.

Additional Defendants,

Plaintiff, Andrx Pharmaceuticals, Inc. ("Andrx") hereby gives notice of filing the attached Declaration of Diane Servello in connection with Andrx's Motion for Summary Judgment Declaring Additional 30-Month Stay Inapplicable or Eliminated.

Dated: April 9, 2001

Respectfully submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP
Louis M. Solomon, Esq.
Colin A. Underwood, Esq.
Jennifer R. Scullion, Esq.
45 Rockefeller Plaza
New York, New York 10111
(212) 956-3700
Attorneys for Andrx Pharmaceuticals, Inc.

HOULIHAN & PARTNERS
Gerald J. Houlihan, Esq.
2600 Douglas Road, Suite 600
Miami, FL 33134
(305) 460-4091
Attorneys for Andrx Pharmaceuticals, Inc.

ISICOFF & RAGATZ, P.A.
Eric D. Isicoff, Esq.
Teresa Ragatz, Esq.
James A. Weinkla, Esq.
1101 Brickell Avenue
Suite 800 South Tower
Miami, Florida 33131
(305) 373-3222

By: 

Eric D. Isicoff
Florida Bar No. 372201

Attorneys for Andrx Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
BROWARD DIVISION

ANDRX PHARMACEUTICALS, INC.,

Plaintiff,

v.

CASE NO.:01-6194-CIV-DIMITROULEAS
MAGISTRATE JUDGE JOHNSON

BIOVAIL CORPORATION,

Defendant,

And

TOMMY G. THOMPSON, Secretary, U.S.
Department of Health and Human Services,
BERNARD A. SCHWETZ, D.V.M., Ph.D.,
Acting Principal Deputy Commissioner, U.S.
Food and Drug Administration, and U.S.
FOOD AND DRUG ADMINISTRATION,

Additional Defendants,

DECLARATION OF DIANE SERVELLO

DIANE SERVELLO, pursuant to 28 U.S.C. § 1746, declares as follows:

1. I am Director, Regulatory Affairs for Andrx Pharmaceuticals, Inc. ("Andrx") I have extensive experience in the regulatory process required to obtain FDA approval of a generic drug. In my position at Andrx, I am responsible for Andrx's compliance with the regulatory requirements governing generic drug manufacturers, including the submission of Abbreviated New Drug Applications ("ANDAs") containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"). I submit this declaration in support of Andrx's Motion for Summary Judgment Declaring Additional 30-Month Stay Inapplicable Or Eliminated. Except where indicated, I make this declaration on the basis of personal knowledge or based on my review of company records kept in the ordinary and regular course of business.

CASE NO.:01-6194-CIV-DIMITROULEAS
MAGISTRATE JUDGE JOHNSON

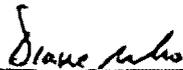
2. Andrx submitted its ANDA for a generic version of Tiazac to FDA in June 22, 1998. The ANDA contained a paragraph IV certification addressing United States Patent Number 5,529,791 (the "'791 patent"), which was listed in the Orange Book as "claiming" Tiazac. Andrx gave Biovail notice of the certification, which Biovail received on August 25, 1998.

3. By facsimile dated February 2, 2001, FDA notified Andrx was required to provide a new patent certification addressed to United States Patent Number 6,162,463 (the "'463 patent"). A true and correct copy of the FDA's facsimile is attached hereto as Exhibit A.

4. On February 16, 2001 Andrx executed an amendment to its ANDA adding a paragraph IV certification claiming that the '463 patent was invalid and would not be infringed by Andrx's product. Andrx sent notice of the amended certification to Biovail. Andrx's notice to Biovail was made under protest and without waiving Andrx's claims that no certification was required and that Andrx's certification would not delay final FDA approval. A true and correct copy of the notice to Biovail is attached hereto as Exhibit B. On information and belief based on United States Postal Service Express Mail receipts, Biovail received the notice, through an agent for service of process, on February 20, 2001.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 6, 2001 in Davis, Florida.



Diane Servello

EXHIBIT A

OFFICE OF GENERIC DRUGS, CDER, FDA
 Document Control Room, Metro-Park North II
 7500 Standish Place, Room 150
 Rockville, MD 20855-2773 (301-594-0320)

cc: Chih-Ming
 Scott Lodin
 Jake Chan
 Steve Jan



TO: APPLICANT: Andrx Pharmaceuticals, Inc

TEL: 954-581-7500

ATTN: Dianne Servello

FAX: 954-587-1054

FROM: Bonnie McNeal

PROJECT MANAGER: 301-827-5849

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated June 22, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Diltiazem Hydrochloride Extended-release Capsules USP, 120 mg, 180 mg, 240 mg, 300 mg and 360 mg.

Reference is also made to your amendment dated: December 13, 2000.

Attached are 2 pages of minor deficiencies and/or comments that should be responded to within 30 calendar days from the date of this document. This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed. Your complete response should be (1) faxed directly to our document control room at 301-827-4337, (2) mailed directly to the above address, and (3) the cover sheet should be clearly marked a FAX AMENDMENT.

Please note that if you are unable to provide a complete response within 30 calendar days, the file on this application will be closed as a MINOR AMENDMENT and you will be required to take an action described under 21 CFR 314.120 which will either amend or withdraw the application. Accordingly, a response of greater than 30 days should be clearly marked MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. Facsimiles or incomplete responses received after 30 calendar days will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. You have been/will be notified in a separate communication from our Division of Bioequivalence of any deficiencies identified during our review of your bioequivalence data. Further if a major deficiency is cited in the bioequivalence review, the subsequent Not Approvable letter will request that this reply be declared a MAJOR AMENDMENT.

SPECIAL INSTRUCTIONS:

Patent information only requested. Bioequivalence comments are included.

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action in the absence of the authorization is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

B. J. C.
 2/2/01

Chemistry Comments to be Provided to the Applicant

ANDA: 75-401

APPLICANT: Andrx Pharmaceuticals, Inc.

DRUG PRODUCT:

Diltiazem Hydrochloride Extended-release
Capsules USP, 120 mg, 180 mg, 240 mg, 300 mg and
360 mg

The deficiency below represents a fax deficiency.

Please provide a patent certification to patent #6162463, which expires on April 28, 2018.

Sincerely yours,



Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 75-401

APPLICANT: Andrx Pharmaceuticals

DRUG PRODUCT: Diltiazem Hydrochloride ER Capsules, USP
120 mg, 180 mg, 240 mg, 300 mg, 360 mg
Amendment dated 12/12/00

The Division of Bioequivalence has completed its review and has no further questions at this time.

We acknowledge that the following dissolution testing has been incorporated into your stability and quality control programs:

The dissolution testing should be conducted in 900 mL of pH 7.5 phosphate buffer, at 37°C using USP Apparatus II (paddle) at 75 rpm. The test product should meet the following specifications:

2h	NMT 25%
4h	20%-40%
8h	60%-85%
12h	NLT 70%
16h	NLT 80%

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,



Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research