BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

WALLACE PHARMACEUTICALS,	)	
	)	
Petitioner,	)	
	)	
v.	)	PCB 02-207
	)	(Air – Variance)
ILLINOIS ENVIRONMENTAL PROTECTION AGENCY,	)	
	)	
	)	
Respondent.	)	

NOTICE OF FILING

TO: Ms. Dorothy M. Gunn
Clerk of the Board
Illinois Pollution Control Board
100 West Randolph Street
Suite 11-500
Chicago, Illinois 60601
(VIA FIRST CLASS MAIL)

(SEE PERSONS ON ATTACHED LIST)

PLEASE TAKE NOTICE that I have today filed with the Office of the Illinois Pollution Control Board an original and nine copies of a **JOINT MOTION TO WITHDRAW VARIANCE,** copies of which are herewith served upon you.

Respectfully submitted,

WALLACE PHARMACEUTICALS,
Petitioner,

By: LaDonna Driver
N. LaDonna Driver

Dated: March 8, 2005

N. LaDonna Driver
HODGE DWYER ZEMAN
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(217) 523-4900

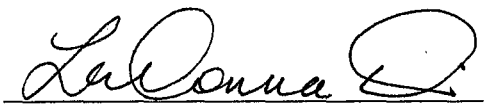
CERTIFICATE OF SERVICE

I, N. LaDonna Driver, the undersigned, hereby certify that I have served the attached JOINT MOTION TO WITHDRAW VARIANCE upon:

Ms. Dorothy M. Gunn
Clerk of the Board
Illinois Pollution Control Board
100 West Randolph Street
Suite 11-500
Chicago, Illinois 60601

Sally Carter, Esq.
Division of Legal Counsel
Illinois Environmental Protection Agency
1021 North Grand Avenue East
Post Office Box 19276
Springfield, Illinois 62794

by depositing said documents in the United States Mail, postage prepaid, in Springfield, Illinois on March 8, 2005.



N. LaDonna Driver

MEDP:001/Fil/NOF-COS – Joint Motion to Withdraw

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

WALLACE PHARMACEUTICALS,	)	
	)	
Petitioner,	)	
	)	
v.	)	**PCB No. 02-207**
	)	**(Variance-Air)**
ILLINOIS ENVIRONMENTAL PROTECTION AGENCY,	)	
	)	
Respondent.	)	

JOINT MOTION TO WITHDRAW VARIANCE

The Illinois Environmental Protection Agency ("Illinois EPA") and MedPointe Pharmaceuticals, formerly Wallace Pharmaceuticals, ("MedPointe") hereby submit this Joint Motion to Withdraw Variance in the above captioned matter pursuant to 35 Ill. Adm. Code 101.500. The Illinois EPA and MedPointe respectfully request that the Board Withdraw the Variance granted to MedPointe on September 19, 2002. In support of this Motion, the Illinois EPA and MedPointe state as follows:

1. MedPointe filed its Petition for Variance ("Petition") on or about May 17, 2002. The Petition requested that the Board grant MedPointe a variance for five dryers in the pharmaceutical tablet manufacturing process from the volatile organic material (VOM) emission control requirements of 35 Ill. Adm. Code 215.482(a). Under the applicable regulations, if the drying process exceeds the applicable threshold at 35 Ill. Adm. Code 215.480(a), VOM emissions are regulated under 215.482(a). Section 215.480(a) regulates VOM emission sources at pharmaceutical manufacturing plants whose emissions exceed 15 lbs./day and 2.5 tons/year, or whose emissions are less than 2.5 tons/year but more than 100 lbs./day. Section 215.482(a) requires at least 90% reduction in VOM emissions from each unit. *See,* Board Order, September 19, 2002.

2. The Petition asserted that the plant sought to shut down its tablet operation for a 10-12 week period in the second half of 2002 to perform plant

improvements. Prior to the shutdown, the plant would have to produce an additional 12 weeks of inventory. In addition, MedPointe anticipated a production and emission increase in 2002 due to the 2001 introduction of two new products and an anticipated introduction of a third new product. The Petitioner alleged that these changes would cause VOM emissions in excess of the thresholds in Section 215.480(a). On or about June 24, 2002, the Illinois EPA filed a response recommending that the Board grant the variance subject to certain conditions.

3. In the Board's September 19, 2002, Order ("Order"), the Board granted MedPointe's Petition. In the Order, the Board allowed the variance subject to the following conditions:

a. The petitioner must begin preliminary research on the search for a non-VOM solvent or process modification immediately and finish such research by June 1, 2003. Petitioner must notify the Illinois EPA of such results.

b. The petitioner must begin the add-on control technology assessment, as well as the bench-top evaluation of non-VOM solvents or process modifications selected from preliminary research by June 1, 2003. Wallace must complete the assessment of suitable add-on control technology and the bench-top evaluation of non-VOM solvents or process modification by April 1, 2004. Petitioner must notify the Illinois EPA of such results.

c. Should the bench-top evaluations prove successful for one or more non-VOM solvents or process modifications, petitioner must proceed to pilot scale testing by April 1, 2004, with completion by February 1, 2005. Petitioner must notify the Illinois EPA of such results. If the pilot scale technology proves successful, petitioner must proceed to full scale manufacturing evaluation and stability testing which will be completed by December 1, 2005. Petitioner must notify the Agency of such results. If this phase of process development is successful, full implementation of the chosen option must be completed by December 1, 2006.

d. At three points throughout the testing process Wallace must evaluate the success of its attempts to find a non-VOM solvent or process modification. These three points must be at the conclusion of bench-top testing, pilot testing and manufacturing and stability testing. At each point, if the tests have been unsuccessful, Wallace must proceed with either the search for suitable add-on control technology, file a petition for a site-specific rulemaking or choose to operate below the Subpart T VOM emission threshold.

e. If add-on control technology is to be installed, the necessary structural engineering evaluations for add-on control technology, and the design of the control systems be completed within 4 months from the date that the Petitioner determines that add-on control technology will be utilized. An application for a construction permit must be submitted to the Illinois EPA within a month. Control equipment shall then be ordered one month after issuance of the construction permit and must be delivered and installed within an additional four months. The control system must be started up, go through shake down, and be operating satisfactorily no longer than two months from this point. Final compliance must be reported to the Agency no later than December 31, 2006.

f. If the control technology assessment reveals that there is no reasonably available control technology for the VOM emissions from the dryers, the petitioner must report this in the next scheduled report, as listed below. Petitioner must then confer the Illinois EPA about whether they will seek a site-specific rule to increase Subpart T control thresholds for the Decatur facility. In the alternative, the petitioner may choose to operate below the Subpart T control threshold.

g. Petitioner must provide semi-annual reports indicating progress made towards the development of a suitable alternative to usage of ethanol in their process, and the development of a suitable add-on control technology device to achieve compliance with 35 Ill. Adm. Code 215, Subpart T, according to the compliance plan contained herein.

h. Petitioner's progress reports must be filed as follows:

4/30/03	for the period	9/1/02 - 3/31/03
10/30/03	for the period	4/1/03 - 9/30/03
4/30/04	for the period	10/1/03 - 3/31/04
10/30/04	for the period	4/1/04 - 9/30/04
4/30/05	for the period	10/1/04 - 3/31/05
10/30/05	for the period	4/1/05 - 9/30/05
4/30/06	for the period	9/1/05 - 3/31/06
10/30/06	for the period	4/1/06 - 9/30/06

unless compliance is achieved prior to the reports date.

i. Each of the five dryers at the Wallace facility is to be limited to 5.0 tons/year of VOM emissions. The Ross dryers is limited to VOM emissions of 100 lbs./day while the Lydon dryer is limited to 280 lbs/day.

4. On December 14, 2004, MedPointe representatives met with Illinois EPA representatives to discuss its status under Section 215.480(a) and the September 19, 2002, variance. In the meeting, MedPointe indicated that the products that involved the use of VOM, that were the subject of the variance, have all but ceased production.

Production at the facility has instead shifted to different products using processes that do not involve VOM. Based on this shift in its operations, MedPointe represented that it has been emitting VOM far below the thresholds in 35 Ill. Adm. Code 215.480(a), for the duration of the variance to date. In its annual emission report for 2002, MedPointe reported plant-wide VOM emissions of 6.87 ton/year. In its 2003 annual emission report, MedPointe reported plant-wide VOM emissions of 1.22 ton/year. This is well below Subpart T's VOM emission threshold of 12.5 ton/year (2.5 ton/year x 5 dryers). MedPointe expects this situation to continue for the foreseeable future.

5. The Order does not provide clear guidance on the current factual scenario, where Med Pointe represents that the production at issue in the variance has virtually ceased. Paragraph 3(h) of the Board's Order provides that progress reports must be filed by certain identified dates unless compliance is achieved prior to the report due date. While MedPointe has been filing semi-annual reports under the schedule in the Board's Order, Med Pointe's reported emissions have been below the VOM emission threshold of 12.5 ton/year; thus, progress reports are arguably not required by the Board' s Order. However, due to the requirements of paragraphs 3(a) through 3(f) of the Board's Order concerning the continuing evaluation and testing of add-on control technology and the evaluation and testing of the use of non-VOM solvents, the parties consulted on the best course of action. After consultation between the Illinois EPA and MedPointe, the parties believe that the variance should simply be withdrawn.

7. Due to the petitioner's reported emission below the VOM emission threshold of 12.5 tons/year, the withdrawal of the variance will have no impact on Macon County's attainment status and, if anything, will benefit the environment by eliminating the previously allowed increase in daily and annual VOM emissions from the facility.

WHEREFORE, the Illinois EPA and MedPointe jointly request that the Board withdraw MedPointe's Variance.

Respectfully submitted,

MEDPOINTE PHARMACEUTICALS,

LaDonna Driver
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