

ILLINOIS POLLUTION CONTROL BOARD
September 19, 2002

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

OPINION AND ORDER OF THE BOARD (by M.E. Tristano):

This matter is before the Board upon a petition for variance (petition) filed by Wallace Pharmaceuticals (Wallace) on May 20, 2002. Wallace is seeking a variance until December 31, 2006, from the volatile organic material (VOM) emission control requirements of 35 Ill. Adm. Code Part 215.482(a). Wallace manufactures pharmaceutical tablets at its facility in Decatur, Macon County. The manufacturing process involves the use of VOM-based wetting agents, and Wallace uses five dryers in this process. Wallace plans to increase production in October, 2002, which would make its five dryers newly-subject to increase VOM control requirements. Section 215.482(a) would require Wallace to reduce VOM emissions from its dryers by 90%. 35 Ill. Adm. Code 215.482(a). During the variance period, Wallace proposes to comply with suggested alternate VOM emission limits, to investigate compliance options, or modify its process to reduce or eliminate its use of the VOM-emitting wetting agents.

Pursuant to the Environmental Protection Act (Act), the Board is charged with the responsibility of granting variances from Board regulations whenever immediate compliance with Board regulations would impose an arbitrary or unreasonable hardship on the petitioner. 415 ILCS 5/35(a). The Illinois Environmental Protection Agency (Agency) is required to appear in hearings on variance petitions. 415 ILCS 5/4(f). The Agency is also charged with the responsibility of investigating each variance petition and making a recommendation to the Board as to the disposition of the petition. 415 ILCS 5/37(a).

In a variance proceeding, the burden is on the petitioner to present proof that immediate compliance with Board regulations would cause an arbitrary or unreasonable hardship which outweighs public interest in compliance with the regulations. Willowbrook Motel v. PCB, 135 Ill. App. 3d 343, 349, 350, 481 N.E.2d 1032, 1036, 1037 (1st Dist. 1977). Pursuant to Section 35(a) of the Act, the Board finds that Wallace has presented adequate proof that immediate compliance with the Board regulations for which relief is being requested would impose such a hardship. 415 ILCS 5/35(a) (1998). Accordingly, the Board will grant the variance request. The variance will expire on December 31, 2006.

PROCEDURAL BACKGROUND

Wallace filed a variance petition on May 20, 2002. The Agency filed its variance recommendation (Rec) on June 26, 2002 recommending the variance be granted subject to conditions. On July 11, 2002, Wallace filed its response to the Agency's recommendation and a hearing officer order issued June 19, 2002.

A hearing was held on July 16, 2002, before Hearing Officer Steven C. Langhoff. Two witnesses were presented by Wallace: Mr. George Brown, representing Wallace, and Mr. Daniel Goodwin, a principal engineer for an environmental consulting firm. The Agency presented one witness, Joe C. Uy. Three members of the public were in attendance, two of who testified: Ms. Barbara Riddle and Ms. Ruth Riddle. Hearing testimony is synopsized below when the subjects to which it is relevant are discussed.

On August 12, 2002, Wallace filed a motion to correct the hearing transcript. The Board grants the motion. On August 19, 2002, Wallace filed its post-hearing brief. The Agency filed its post-hearing brief on August 26, 2002.

FACILITY DESCRIPTION

Wallace's pharmaceutical production and processing facility is located at 434 North Morgan Street, Decatur, Macon County and employs approximately 105 people full time and 20 on a temporary basis. Wallace produces ethical pharmaceutical tablets and liquids that are used to treat respiratory and central nervous system ailments. Pet. at 2-4.

During Wallace's production process, several of the tablet products use a wet granulation process. Two forms of wetting agents are used, water and the VOM at issue here: denatured ethanol. When ethanol is used as the wetting agent, it is evaporated during the drying cycle resulting in VOM emissions from the dryers. Tr. at 18; Pet. at 5-6; Rec. at 3.

REQUESTED VARIANCE

VOM emissions are regulated under 35 Ill. Adm. Code 215.482(a) if Wallace's drying process exceeds the applicable thresholds of Section 215.480(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 less than 2.5 tons/year but more than 100 lbs./day. 35 Ill. Adm. Code 215.480(a). Section 215.482(a) requires at least 90% reduction in VOM emissions from each unit. 35 Ill. Adm. Code 215.482(a).

Wallace is not currently required to comply with the requirements of 35 Ill. Adm. Code Part 215.482(a). But, in October 2002, due to accelerated production and increased demand from new product lines, Wallace expects to exceed the thresholds of Section 215.480(a) and become subject to the Section 215.482(a) control requirements. Pet. at 8; Resp. at 2; Mot. at 2.

Wallace requests the variance to allow it sufficient time to evaluate and implement potential options for controlling VOM emissions from its dryers. Pet. at 1. Increased VOM

emissions are anticipated from accelerated production prior to shutting down its tablet operation to make improvements to its plant. Pet. at 7. In addition, the facility's manufacturing forecast for 2002 represents a production and emissions increase resulting from the introduction of new products. Pet. at 8.

Wallace has requested the variance period end on December 31, 2006. Pet. at 31; Mot. at 2.

ENVIRONMENTAL IMPACT

When deciding to grant or deny a variance petition, the Board is required to balance the petitioner's hardship in complying with Board regulations against the impact that the requested variance will have on the environment. Monsanto Co. v. PCB, 67 Ill. 2d 276, 292, 367 N.E.2d 684, 691 (1977).

The Decatur plant has five dryers: a six-rack Lydon dryer, two double-rack Ross dryers, and two single-rack Ross dryers. To stay below the 100 lb/day threshold, drying batches are limited to one rack per batch. This makes use of the six-rack Lydon dryer inefficient, and the facility has not used the Lydon dryer for these products. As for the Ross dryers, the facility has limited manufacture of VOM-emitting products so as not to exceed the Subpart T thresholds. Accordingly, none of the five dryers have VOM emission control devices. Pet. at 6-7.

Wallace requests a limit of 5 tons of VOM/year per dryer, or up to a total of 25 tons/year. Wallace estimates that if the requested relief is granted, total 2002 emissions will be less than 15 tons. Wallace asserts that no dryer will exceed 100 lbs./day except the Lydon dryer, which will be limited to 280 lbs./day. According to Wallace this will be partially offset from less usage of other dryers. Pet. at 27-28. Wallace states that the increased emission should have no discernable impact on the area's ozone attainment status or the environment. Pet. at 28.

The nearest air quality monitoring station to Wallace's Decatur facility is located about one and three-quarter miles from the Wallace facility. Pet. at 3. There have been no exceedances of the National Ambient Air Quality Standard (NAAQS) for ozone measured at this monitoring station for either the 1-hour standard or the 8-hour standard during the 1999, 2000, and 2001 ozone seasons. Rec. at 7-8.

The Agency agrees that the requested variance should result in no significant environmental harm, as Wallace is not out of compliance at this time and the requested relief will not result in an increase in VOM emissions that will threaten violation of the ozone NAAQS in the area. Rec. at 12.

At the hearing, two witnesses, Ms. Barbara Riddle and Ms. Ruth Riddle both from the Decatur area, testified. Barbara Riddle testified that she is allergic to ethanol and would be opposed to Wallace's ability to emit any additional ethanol. Tr. at 65. Barbara Riddle, however, testified she did not know specifically what the source of the ethanol was that was causing her allergies. In addition, Barbara Riddle states that she lives near other industries in the Decatur area besides Wallace's facility that also emit ethanol. Tr. at 66.

Ruth Riddle testified that she has asthma and allergies, but is not allergic to ethanol. Ruth Riddle did not express opposition to the requested variance, but rather concern as to the level of pollution in the area. Tr. at 70, 71.

HARDSHIP

In its consideration of a variance, the Board is required, pursuant to Section 35(a) of the Act, to determine whether the petitioner has presented adequate proof that it would suffer an arbitrary or unreasonable hardship if required to comply with the Board's regulation at issue. 415 ILCS 5/35(a) (1998).

In 2001, Wallace discovered that the tablet portion of its manufacturing facility needed upgrades. With respect to the processes at issue here, the ventilation system does not meet current FDA standards. Correcting this deficiency will result in the tablet process being shut down for approximately 12 weeks. Tr. at 23. Inventory must be increased prior to the shutdown to meet customer demands. Pet. at 7. The production increase necessitated by the upgrades will lead the dryers to reach or exceed the 2.5 ton per year VOM emission control thresholds under Subpart T. Pet. at 8. Without variance relief, once the threshold is met later this year or in subsequent years with the inability to employ control measures, Wallace will have to cease production until the end of the year. Resp. at 3-4. Ceasing production will result in reduced availability of drug therapies and the loss of jobs. Pet. at 19.

In addition, Wallace stated that due to pressure from generic manufacturers, it began to develop new products in 2001. This required a build-up of inventory for distribution to wholesalers and stores prior to introduction to physicians. About six months of inventory must be manufactured in a short amount of time in preparation for launching the new products. Tr. at 21.

Wallace stated that investigation into three different approaches to compliance has uncovered technical feasibility, timing and or economic problems with each option. Options investigated included: formulations and/or process revisions to eliminate VOM solvent use, pollution control devices, and outsourcing. Pet. at 19.

Wallace also argues that the facility cannot immediately change the process to eliminate the VOM solvent. The products must undergo a very methodical process for any change to meet the Food and Drug Administration guidelines and documentation for everything that is done, including stability studies. This approach would take approximately four years. Therefore, a process change or reformulation cannot occur in time to comply with the threshold limitations of Subpart T. Pet. at 10, 18.

As to the second approach, Wallace asserts that the facility cannot install pollution control equipment before the emission thresholds for Subpart T are reached. Because of space constraints, any control equipment would have to be installed on the roof, which would require significant engineering and structural reinforcement to support the equipment. Pet. at 9. By the

time that this would be completed, it would be at least ten months before the control equipment would be operational. Pet. at 18, 19.

Dan Goodwin, consultant for Wallace, testified on evaluating alternatives for pollution control equipment for Subpart T compliance. Tr. at 46. Mr. Goodwin explained that in addition to the solvent substitution option, he identified four control technology options: absorption, adsorption, condensation and oxidation. Absorption was eliminated from consideration because it would require a large volume of water that would have to be disposed of and would be prone to freezing while on the roof. Tr. at 47-48; Pet. at 12-13. Adsorption also presented challenges with respect to rooftop location. Tr. at 48-49; Pet. at 13. Condensation was also eliminated because the refrigeration capacity needed for it would be problematic, due to weight, for the location on the roof and electrical requirements. Tr. at 49-50; Pet. at 14.

Mr. Goodwin suggested oxidation as the most technically feasible control technology option, however, he expressed concern as to the cost effectiveness of this technology. To reduce emissions below the Subpart T threshold level of 12.5 tons, Mr. Goodwin estimated a cost effectiveness ratio of \$87,000 to \$102,000 per ton VOM reduced. Using a more conservative approach for estimating costs to achieve a 90 percent reduction in VOM emitted, Mr. Goodwin estimated a cost effectiveness ratio of \$16,000 to \$19,000 per ton of VOM reduced. Tr. at 50-54; Pet. at 15. Reviewing the Board's previous rulemaking in Subpart T, Mr. Goodwin recalled that the Board used \$5,000 per ton as a benchmark for reasonable costs. Tr. at 53.

As to the third option, Wallace also argues that once the Subpart T emission thresholds are met, halting production at the Decatur facility cannot be easily replaced with production elsewhere. Pet. at 16. Wallace estimated that the process of finding a qualified outside contractor could take several months. Besides the time and costs associated with this approach, moving the process out of the Decatur facility would result in loss of jobs there. Pet. at 17, 19.

COMPLIANCE PLAN

During the variance, Wallace proposes to evaluate the possible use of control equipment and the elimination of VOM from its tablet products or process. Wallace would perform preliminary research on non-VOM solvents. Pet. at 22. If bench-top evaluations are successful, Wallace would undertake pilot scale testing of the non-VOM solvents or process modifications. If bench-top evaluations reveal no suitable non-VOM solvent or process modification, Wallace will assess suitable add-on control technology. Pet. at 23. If the control technology assessment reveals no reasonably available control technology for the VOM emissions, Wallace will confer with the Agency on the potential of a site-specific rulemaking. Pet. at 24-25. Throughout the variance period, Wallace will submit progress reports to the Agency on a semi-annual basis. Resp. at Att. B. The compliance plan and a schedule are included in the variance conditions proposed by Wallace and the Agency.

AGENCY RECOMMENDATION

The Agency agrees with Wallace that due to sales increases and a production shutdown required by upgrades, Wallace must increase its production to a point that it will meet or exceed

the thresholds for Subpart T controls. Without relief, the Agency argues, Wallace will be forced to shut down its production and lay off employees. Wallace cannot quickly employ control technology, reformulate its product, or shift production elsewhere. A variance is the only avenue for continuing Wallace's production. Accordingly, the Agency argues it would be arbitrary and unreasonable not to grant the requested variance. Rec. at 4. The Agency recommends a grant of the variance subject to conditions similar to conditions proposed and later revised by the Petitioner. Rec. at 13-14; Resp. Att. B.

CONSISTENCY WITH FEDERAL LAW

Wallace and the Agency agree that the variance would be consistent with federal law. In accordance with Section 35 of the Act, the Board may grant variances only where they are consistent with federal law. 415 ILCS 5/35 (2000). There is no provision of the Clean Air Act (CAA) or its associated regulations, that would prohibit the relief requested. This facility is currently not a major source of VOM or hazardous air pollutants (HAP), nor would it be under the requested variance. Therefore, the parties believe that variance relief would not implicate any issues concerning Title I, or Title V of the CAA. Because Part 215 has been approved by the United States Environmental Protection Agency (USEPA) as part of the Illinois state implementation plan (SIP), the variance, if granted, will need to be submitted to USEPA as a SIP revision.

CONCLUSION

In determining whether any variance is to be granted, the Act requires the Board to determine whether a petitioner has presented adequate proof that immediate compliance with the Board regulations at issue would impose an arbitrary and unreasonable hardship upon the petitioner.

The Board finds that, if the variance is not granted, Wallace will incur an arbitrary or unreasonable hardship. Wallace has demonstrated that denial of variance would impose an economic hardship. Even with increased production, Wallace's VOM emissions will have additional controls, and its addition to the VOM emissions in the area will be minimal. Accordingly, the variance request will be granted for the period of approximately 4 and a half years, subject to conditions.

This opinion constitutes the Board's findings of fact and conclusions of law.

ORDER

1. The Board grants Wallace a variance from 35 Ill. Adm. Code 215.482(a) to allow it to continue production of ethical pharmaceutical tablets at its facility located in Decatur.
2. This variance begins on the date of this order and terminates no later than December 31, 2006.
3. This variance is 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 Environmental Protection Agency 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 Environmental Protection Agency 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 Environmental Protection Agency 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 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 Environmental Protection Agency 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 Environmental Protection Agency 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 plain 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.

IT IS SO ORDERED.

If petitioner chooses to accept this variance, within 45 days after the date of this opinion and order, petitioner shall execute and forward to:

Charles E. Matoesian
 Division of Legal Counsel
 Illinois Environmental Protection Agency
 1021 North Grand Avenue East
 Post Office Box 19276
 Springfield, Illinois 62794

A certificate of acceptance and agreement to be bound by all the terms and conditions of the granted variance. The 45-day period shall be held in abeyance during any period that this matter

is appealed. Failure to execute and forward the certificate within 45 days renders this variance void. The form of the certificate is as follows:

I (We), _____, having read the opinion and order of the Illinois Pollution Control Board, in PCB 02-207, dated September 19, 2002, understand and accept the said opinion and order, realizing that such acceptance renders all terms and conditions thereto binding and enforceable.

Petitioner

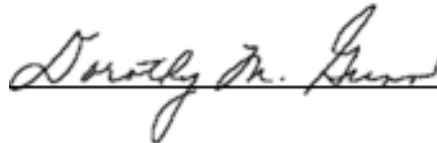
By: Authorized Agent

Title

Date

Section 41(a) of the Environmental Protection Act provides that final Board orders may be appealed directly to the Illinois Appellate Court within 35 days after the Board serves the order. 415 ILCS 5/41(a) (2000); *see also* 35 Ill. Adm. Code 101.300(d)(2), 101.906, 102.706. Illinois Supreme Court Rule 335 establishes filing requirements that apply when the Illinois Appellate Court, by statute, directly reviews administrative orders. 172 Ill. 2d R. 335. The Board's procedural rules provide that motions for the Board to reconsider or modify its final orders may be filed with the Board within 35 days after the order is received. 35 Ill. Adm. Code 101.520; *see also* 35 Ill. Adm. Code 101.902, 102.700, 102.702.

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above opinion and order on September 19, 2002, by a vote of 7-0.



Dorothy M. Gunn, Clerk
Illinois Pollution Control Board