



COMMONWEALTH of VIRGINIA

DEPARTMENT OF ENVIRONMENTAL QUALITY

VALLEY REGIONAL OFFICE

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Secretary of Natural Resources

David K. Paylor
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STATE AIR POLLUTION CONTROL BOARD ENFORCEMENT ACTION

ORDER BY CONSENT AMENDMENT ISSUED TO

Merck & Co., Inc.
Registration #: 80524

SECTION A: Purpose

This is a Consent Order issued under the authority of Va. Code §§ 10.1-1184, -1307(D), -1309, and -1316(C), between the State Air Pollution Control Board and Merck & Co., Inc., for the purpose of resolving certain alleged violations of environmental law and regulations. This Consent Order Amendment amends the Consent Order executed on July 08, 2005.

SECTION B: Definitions

Unless the context clearly indicates otherwise, the following words and terms have the meaning assigned to them below:

1. "Board" means the State Air Pollution Control Board, a permanent citizens' board of the Commonwealth of Virginia as described in Code §§ 10.1-1301 and 10.1-1184.
2. "CFR" means Code of Federal Regulations.
3. "Department" or "DEQ" means the Department of Environmental Quality, an agency of the Commonwealth of Virginia as described in Va. Code § 10.1-1183.
4. "Director" means the Director of the Department of Environmental Quality.
5. "Facility" means Merck's pharmaceutical manufacturing plant, also known as the Stonewall Plant, located at 2778 South East Side Highway, Elkton, Virginia.

6. "Merck" means Merck & Co., Inc., a New Jersey-based pharmaceutical company authorized to conduct business in the Commonwealth of Virginia.
7. "Order" means the Consent Order executed July 08, 2008 between Merck & Co. and the State Air Pollution Control Board.
8. "Order Amendment" means this document, also known as a Consent Order Amendment.
9. "Pharmaceutical MACT" means 40 CFR 63, Subpart GGG.
10. "Va. Code" means the Code of Virginia (1950), as amended.
11. "VRO" means the Valley Regional Office of DEQ, located at 4411 Early Road, P.O. Box 3000, Harrisonburg, Virginia 22801.

SECTION C: Findings of Facts and Conclusions of Law

1. Merck owns and operates a large pharmaceutical manufacturing facility known as the Stonewall Plant located in Elkton, Virginia. The Stonewall Plant manufactures a variety of pharmaceutical products that result in the emission of various hazardous air pollutants (HAPs). The Stonewall Plant has been in continuous operation since 1941.
2. Section 112 of the Clean Air Act directs the U.S. Environmental Protection Agency (EPA) to promulgate Maximum Achievable Control Technology (MACT) standards for industrial source categories in order to control emissions of hazardous air pollutants. MACT requirements apply to all "major" sources in a designated industrial source category, i.e., those sources with the potential to emit 10 tons or more per year of any single HAP or 25 tons or more per year of total HAPs. EPA proposed the MACT requirements for the pharmaceutical industry on April 2, 1997. 62 FR 15754. EPA gave all interested parties, including pharmaceutical manufacturers, the opportunity to comment on the proposed Pharmaceutical MACT.
3. The Stonewall Plant had the potential to emit 10 tons or more per year of certain individual hazardous air pollutants and 25 tons or more per year of total hazardous air pollutants, and was considered a major source of HAP emissions under Section 112 of the Clean Air Act at the time the Pharmaceutical MACT became effective.
4. DEQ issued a Notice of Violation (NOV) to Merck on December 11, 2003, for alleged violations of State Air Pollution Control Law and regulations occurring at Merck's Stonewall Plant based upon information reported to and obtained by DEQ. The NOV listed the alleged violations of the Stonewall Plant's Permit limiting emissions of hazardous air pollutants (HAPs) and other operational deficiencies.
5. After October 2003 performance testing of the Carbidopa manufacturing process air pollution control train, including SCR-634, revealed methyl chloride emissions in excess of the individual HAP limit of 9.9 TPY, Merck conducted an investigation of the process and its

associated air pollution control system. Merck discovered an erroneous modeling assumption that resulted in the underestimation of actual methyl chloride emissions. To increase the capture and destruction of methyl chloride, Merck found that the quantity and temperature of quencher water had to be controlled and that residual methyl chloride had to be purged from the reactor vessel. Merck has completed the necessary process modifications (Letter from Jett to Chewning dated October 31, 2003, Attachment A) and conducted additional performance testing in November 2003. With the process modifications, this testing demonstrated an average methyl chloride control efficiency of 96.3 percent.

6. On July 08, 2005, Merck and the Air Pollution Control Board executed an Order resolving Merck's alleged violations of the Air Pollution Control Law, and provided for completion of certain remedial actions, payment of a civil charge, and completion of certain Supplemental Environmental Projects (SEPs).
7. As of December 17, 2007, Merck appears to have satisfied the terms of the original Order, including payment of the civil charge and completion of the requirements specified in Appendices A and B. The SEP detailed in the original Appendix B was completed below cost estimates, this Order is being amended to include terms for the expenditure of the remaining SEP funds.

SECTION D: Agreement and Order

1. Accordingly the State Air Pollution Control Board, by virtue of the authority granted it pursuant to Va. Code §§ 10.1-1186(2), 10.1-1309, and 10.1-1316(C), orders Merck, and Merck voluntarily agrees to comply with the terms and conditions set forth in **Appendix A** to this Order and to complete a **SEP** pursuant to Va. Code § 10.1-1186.2 as described in **Appendix A** of this Order.

SECTION E: Administrative Provisions

1. The Board may modify, rewrite, or amend the Order with the consent of Merck, for good cause shown by Merck, or on its own motion after notice to Merck and its opportunity to be heard.
2. This Order addresses and resolves only those violations specifically identified herein. This Order shall not preclude the Board or the Director from taking any action authorized by law, including but not limited to taking any action authorized by law regarding any additional, subsequent, or subsequently discovered violations or taking subsequent action to enforce this Order. This Order shall not preclude appropriate enforcement actions by federal, state, or local regulatory authorities for matters not addressed herein. Merck does not waive any rights it may have to object to enforcement actions by other federal, state, or local authorities arising out of the same or similar facts alleged in this Order.
3. For purposes of this Order and subsequent actions with respect to this Order, Merck admits the jurisdictional allegations but does not admit the factual findings and conclusions of law contained herein.

4. Merck consents to venue in the Circuit Court of the City of Richmond for any civil action taken to enforce the terms of this Order.
5. Merck declares it has received fair and due process under the Administrative Process Act, Va. Code §§ 2.2-4000 *et seq.*, and the Air Pollution Control Law and it waives the right to any hearing or other administrative proceeding authorized or required by law or regulation, and to any judicial review of any issue of fact or law contained herein, except that Merck reserves its right to a hearing or other administrative proceeding authorized or required by law or to judicial review of any issue of fact or law contained in any subsequent amendments to this Order issued by the Board without the consent of Merck. Nothing herein shall be construed as a waiver of the right of Merck to any administrative proceeding for, or to judicial review of, any action taken by the Board to enforce this Order.
6. Failure by Merck to comply with any of the terms of this Order shall constitute a violation of an order of the Board. Nothing herein shall waive the initiation of appropriate enforcement actions or the issuance of additional orders as appropriate by the Board or the Director as a result of such violations. Nothing herein shall affect appropriate enforcement actions by any other federal, state, or local regulatory authority. Merck does not waive any rights it may have to object to enforcement actions by federal, state, or local authorities arising out of the same or similar facts alleged in this Order.
7. If any provision of this Order is found to be unenforceable for any reason, the remainder of the Order shall remain in full force and effect.
8. Merck shall be responsible for failure to comply with any of the terms and conditions of this Order unless compliance is made impossible by earthquake, flood, other acts of God, war, strike, or such other occurrence. Merck shall show that such circumstances were beyond its control and not due to a lack of good faith or diligence on its part. Merck shall notify the DEQ Regional Director in writing when circumstances are anticipated to occur, are occurring, or have occurred that may delay compliance or cause noncompliance with any requirement of the Order. Such notice shall set forth:
 - a. the reasons for the delay or noncompliance;
 - b. the projected duration of any such delay or noncompliance;
 - c. the measures taken and to be taken to prevent or minimize such delay or noncompliance; and
 - d. the timetable by which such measures will be implemented and the date full compliance will be achieved.

Failure to so notify the Regional Director within 24 hours of learning of any condition above, which Merck intends to assert will result in the impossibility of compliance, shall constitute a waiver of any claim to inability to comply with a requirement of this Order.

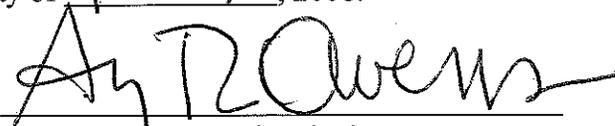
9. This Order is binding on the parties hereto, their successors in interest, designees and assigns, jointly and severally.

- 10. This Order shall become effective upon execution by both the Director or his designee and Merck. Notwithstanding the foregoing, Merck agrees to be bound by any compliance date which precedes the effective date of this Order.
- 11. This Order shall continue in effect until:
 - a. Merck petitions the Regional Director to terminate this Order after Merck has completed all of the requirements of the Order, including the requirements of Appendices A and B, and the Regional Director has acknowledged in writing to Merck that all of those requirements have been satisfied. The Regional Director's determination that Merck has satisfied all the requirements of this Order is a "case decision" within the meaning of the Virginia Administrative Process Act.
 - b. The Director or Board may terminate this Order earlier in his or its sole discretion upon 30 days written notice to Merck.

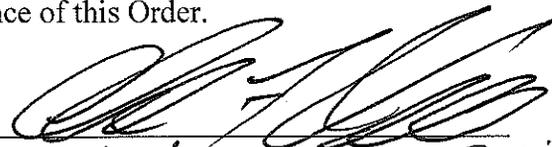
Termination of this Order, or any obligation imposed in this Order, shall not operate to relieve Merck from its obligation to comply with any statute, regulation, permit condition, other order, certificate, certification, standard, or requirement otherwise applicable.

- 12. By its signature below, Merck voluntarily agrees to the issuance of this Order.

And it is so ORDERED this day of March 11, 2008.


 Amy T. Owens, Regional Director
 Department of Environmental Quality

Merck & Co., Inc. voluntarily agrees to the issuance of this Order.

By: 
 Date: 3/4/08
 City / County of Rockingham
 Commonwealth/State of Virginia
 The foregoing instrument was acknowledged before me this 4th day of March 2008, by Charles F. Vencill
(name of person seeking acknowledgement)
 Notary Public ama fare # 7131432
 My commission expires: 02-28-2011 day of

Commonwealth of Virginia
City/County of _____

The foregoing document was signed and acknowledged before me this _____ day of _____



Please see previous page.

_____, 2008, by _____, who is
(Name)

_____ of Merck & Co., Inc., on behalf of Merck & Co., Inc.
(Title)

Notary Public

My commission expires: _____.

There are six (6) items required for the notary to state on each document being notarized:

1. The name of the county or independent city in which the document is signed (do not put in this space the street or name of business where the signing occurred).
2. The date it is signed.
3. An acknowledgement that it was signed in the presence of the notary.
4. The notary's signature.
5. The date that the notary's commission expires.
6. Notary registration number

This statement must be on the same page as the signatures being notarized. Never notarize a signature that is on a different page than the notary statement. If this information is handwritten, it must be legible.

A Virginia notary may notarize a document to be filed and used outside of Virginia if it is signed and notarized in Virginia, but a document that is to be filed or used outside of Virginia or by the federal government will probably be required to include a notary's official seal.

A notary's seal is not required, but may be used, on documents notarized in Virginia for use or filing within Virginia (unless it is for the federal government).

A Virginia notary's seal must contain the name of the notary exactly as it appears on the notary's commission, words "Notary Public" and "Commonwealth of Virginia."

If a notary has any question or concern regarding any act of a Notary Public, he or she should contact the Notary Section of the Office of the Secretary of the Commonwealth BEFORE performing that act.

If a notary violates any law or regulation governing notaries public, the Secretary of the Commonwealth may revoke his or her commission. A notary may be sued for his or her misconduct. A notary will be criminally prosecuted for willful misconduct and may be fined up to \$500 per offense. It is a felony to act as a notary without having a valid commission and doing so may result in imprisonment for up to five years and a \$2,500 fine for each offense.

APPENDIX A

Supplemental Environmental Project

The Virginia State Air Pollution Control Board orders Merck to undertake, and Merck agrees to implement, a Supplemental Environmental Project in accordance with the following terms and conditions:

1. Based upon the submittal of any and all receipts and/or invoices to the Department to date, the SEP referenced in the July 08, 2005 Order appears to have been completed below cost estimates. Department records indicate \$122,269.00 of the original \$300,000.00 remains, pending submittal of any outstanding receipts or invoices. The remaining funds will be dispersed to the City of Harrisonburg Public Works Department, the Lord Fairfax Soil and Water Conservation District, and the Shenandoah Valley Soil and Water Conservation District to implement Best Management Practices in watersheds with completed Total Maximum Daily Load Implementation Plans. Funds will be disbursed at the discretion of the Department based on scopes of work and contractual agreements with the listed parties, with all expenditures appropriately documented.
2. In the event that Merck publicizes the SEP or the results of the SEP, Merck shall state in a prominent manner that the project is part of a settlement for an enforcement action with DEQ.