9-30-94

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UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

REGION III

IN THE MATTER OF	)	AMENDED ADMINISTRATIVE ORDER ON CONSENT
Merck & Co., Inc. including its unincorporated division, Merck, Sharp & Dohme, N/K/A Merck Manufacturing Division Sumneytown Pike West Point, Montgomery County, Pennsylvania	)	U.S. EPA Docket No. RCRA-III-002TH
EPA I.D. Number: PAD 00 238 7926	)	Proceeding under Section 7003 of the Resource Conservation and Recovery Act, as amended, 42 U.S.C. § 6973.
Respondent	)	

I hereby certify that the within is a true and correct copy of the original Amended Administrative Order filed in this matter.

Cynthia J. Maddalone
Attorney for EPA

AMENDMENT TO ADMINISTRATIVE ORDER ON CONSENT

The above referenced Administrative Order on Consent ("Consent Order" or "Order") is hereby amended in accordance with paragraph 2 of Section XXIV, "EFFECTIVE DATE AND SUBSEQUENT MODIFICATION", in the following manner:

Section II "FINDINGS" is hereby amended to include Paragraph 17 as follows:

17. Merck has fulfilled the requirements stated in paragraphs 1 through 7 of Section VII of the Order. EPA approved Respondent's performance of the work required by paragraph 7 of Section VII by letter dated September 21, 1993. Specifically, Merck fulfilled the requirements of the site-wide environmental investigation by submitting the reports entitled "Phase II Final Report, Hydrogeologic Investigation at the West Point Site" and attachments and "Site-Wide Risk Assessment, Merck & Co., Inc., West Point Site, November 25, 1993 and Addenda". These reports received written approval by EPA on February 24, 1993. Merck & Co., Inc. then submitted a remedial plan entitled Corrective Measures Study Phase III Report for the Hydrogeologic Investigation at the West Point Site, Revision 1, July 1993. This report received written approval by EPA on September 21, 1993. On September 30, 1993, EPA issued a "Final Decision And Response To Comments On Proposed Corrective Measures Under RCRA Section 7003" ("FDRTC") document concerning the final remedy at this Facility. EPA's FDRTC documents the Selected Remedy which will be protective of human health and the environment. The FDRTC is appended to this Order as Attachment A and incorporated by reference as if fully set forth herein.

Section VII "WORK TO BE PERFORMED" is hereby amended to include the following Paragraphs 11 through 35.

11. Within sixty (60) calendar days of the effective date of this Amendment to this Consent Order, Merck shall submit to EPA for approval a Draft Corrective Measures Implementation Work Plan ("CMI Work Plan") in accordance with the requirements set forth in Task I of the Scope of Work for a Corrective Measures Implementation Program in Attachment B to this Consent Order, which describes the manner in which Merck shall implement and attain all requirements of the FDRTC including, but not limited to, the Media Cleanup Standards for Contaminated Groundwater, dated September 30, 1993 and any amendments thereto.

12. Within forty-five (45) calendar days of receipt of EPA's comments on the Draft CMI Work Plan submitted pursuant to Section VII, Paragraph 11, above, Merck shall submit to EPA for approval a Revised Draft CMI Work Plan which addresses EPA's comments and remedies any deficiencies in the Draft CMI Work Plan identified by EPA.

13. Concurrent with the submission of the Draft CMI Work Plan, Merck shall submit to EPA a CMI Health and Safety Plan in accordance with the requirements set forth in the Scope of Work for Health and Safety Plan in Attachment D to this Consent Order.

14. In accordance with the schedule in the EPA-approved CMI Work Plan, Merck shall submit a Draft CMI Report to EPA for approval. The Draft CMI Report shall describe activities performed during construction, provide actual specifications of the implemented remedy, and provide a preliminary assessment of the performance of the corrective measures, in accordance with the requirements set forth in Attachment B to this Consent Order.

15. Within ninety (90) calendar days of receipt of EPA's comments on the Draft CMI Report, Merck shall submit to EPA for approval a Revised Draft CMI Report which responds to EPA's comments on, and remedies any deficiencies in the Draft CMI Report which have been identified by EPA.

16. EPA shall determine, on the basis of the EPA-approved CMI Report and any other relevant information, whether the constructed project is consistent with the design specifications and whether the corrective measures are achieving the requirements set forth in the FDRTC. If EPA determines that the constructed project is consistent with the design specifications and that the corrective measures are achieving the requirements set forth in the FDRTC, EPA shall notify Merck of such determination in writing as soon as reasonably possible.

17. No later than two (2) years from EPA's determination pursuant to Section VII, Paragraph 16, above, and continuing until receipt of notice from EPA that the requirements of the FDRTC have been met, Merck shall submit to EPA for approval a Draft O&M Assessment Report every two years in accordance with the requirements set forth in Task III of the Scope of Work for a Corrective Measures Implementation Plan in Attachment B to this Consent Order.

18. At any time after EPA's determination pursuant to Section VII, Paragraph 16, above, Merck may petition EPA for a determination that Merck has achieved the requirements specified in the FDRTC. Merck shall provide information to support such petition. EPA shall notify Merck of its determination, and the basis therefor, in writing as soon as reasonably possible. If EPA agrees that Merck has achieved the requirements specified in the FDRTC, Merck may cease operation of the remediation systems. However, Merck must continue the ground water monitoring in accordance with the EPA-approved O&M plan submitted pursuant to Task III of Attachment B to this Consent Order until Merck can demonstrate that the media cleanup standards have not been exceeded for a period of three consecutive years.

19. If at any time during the pendency of this Consent Order Merck obtains or discovers information concerning a release of any hazardous waste or hazardous constituent at or from the Facility into the environment, in addition to or different from that described in Section II ("FINDINGS") above, Merck shall immediately notify EPA orally of such release, and shall notify EPA in writing within three (3) calendar days of providing oral notification. The notifications shall describe the nature and extent of the release and any threat or potential threat to human health or the environment posed by such release. If EPA determines that corrective action for such release is necessary to protect human health or the environment, EPA shall notify Merck.

20. Within ten (10) calendar days of receipt of such notice from EPA, or within such other time period as may be specified by EPA, Merck shall submit to EPA for approval a Draft Interim Measures ("IM") Work Plan which identifies Interim Measures which will protect human health and the environment from such release and which are, to the extent practicable, consistent with and integrated into the corrective measures set forth in the FDRTC. Said Draft IM Work Plan shall be developed in accordance with the requirements set forth in Task I of the IM Scope of Work in Attachment C to this Consent Order. The Draft IM Work Plan shall document the procedures to be used by Merck for the implementation of the Interim Measures and shall include, but not be limited to, an Interim Measures Project Management Plan (including a Preliminary Project Schedule), a Data Collection Quality Assurance Plan, a Data Management Plan, and a Community Relations Plan.

21. Concurrent with the submission of the Draft IM Work Plan, Respondent shall submit to EPA an IM Health and Safety Plan in accordance with the requirements set forth in the Scope of Work for a Health and Safety Plan in Attachment D to this Consent Order.

22. Upon receipt of EPA approval of the Draft IM Work Plan submitted pursuant to paragraph 20 above, Merck shall implement the EPA-approved IM Work Plan in accordance with the requirements and schedules set forth therein.

23. EPA will review all documents which Merck submits pursuant to Section VII, Paragraphs 11 - 35 of this Amended Consent Order ("Submissions") and will notify Merck in writing of EPA's approval or disapproval of each such Submission, with the exception of the CMI and IM Health and Safety Plans and progress reports. In the event of EPA's disapproval, EPA shall specify in writing any deficiencies in the Submission. Such disapproval shall not be subject to the dispute resolution procedures of Section XIV, below. EPA may, at its discretion, direct Merck to implement non-deficient portions of a Submission.

24. Within thirty (30) calendar days of receipt of EPA's comments on the Submission, or ten (10) calendar days or other time period as may be specified by EPA in the case of an IM Workplan, Merck shall submit to EPA for approval a revised Submission, which responds to EPA's comments on and corrects as appropriate any deficiencies identified by EPA. In the event EPA disapproves the revised Submission, EPA reserves the right to revise such Submission and seek to recover from Merck the costs thereof, in accordance with the Comprehensive Environmental Response, Compensation and Liability Act of 1980 ("CERCLA"), 42 U.S.C. § 9601 et seq., as amended by the Superfund Amendments and Reauthorization Act of 1986, and any other applicable laws, and/or to take any other appropriate action under RCRA, CERCLA, or any other legal authority. Any Submission approved or revised by EPA under this Consent Order shall be deemed incorporated into and made an enforceable part of this Consent Order.

25. Beginning with the first day of the third full month following the effective date of this Consent Order, and every three months thereafter on the first day of the month, Merck shall provide EPA with quarterly (every three months) progress reports. The quarterly progress reports shall contain the information set forth in Task IV of the Scope of Work for a Corrective Measures Implementation Program in Attachment B to this Consent Order.

26. Four (4) copies of all Submissions required by this Consent Order shall be hand-delivered or sent by Certified Mail, Return Receipt Requested, to the Project Coordinator designated pursuant to Section VIII ("DESIGNATED PROJECT COORDINATORS"), below.

27. Any notice, report, certification, data presentation, or other document submitted by Merck pursuant to this Consent Order which discusses, describes, demonstrates, supports any finding or makes any representation concerning Merck's compliance or noncompliance with any requirement of this Consent Order shall be certified by a responsible corporate officer or a duly authorized representative of a responsible corporate officer. A "responsible corporate officer" means: (a) a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or (b) the manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding $35 million (in 1987 dollars when the Consumer Price Index was 345.3), if authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures. A person is a "duly authorized representative" only if: (1) the authorization is made in writing by a person described above; (2) the authorization specifies either an individual or position

having responsibility for overall operation of the regulated facility or activity (a duly authorized representative may thus be either a named individual or any individual occupying a named position); and (3) the written authorization is submitted to the Project Coordinator designated by EPA in Section VIII ("DESIGNATED PROJECT COORDINATORS") of this Consent Order.

28. The certification required by Paragraph 27, above, shall be in the following form:

> I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.
>
> Signature: _____
>
> Name: _____
>
> Title: _____

29. EPA may determine that certain tasks are necessary in addition to or in lieu of the tasks included in any EPA-approved work plan in order to protect human health and the environment. EPA will notify Merck of this determination and the basis for the same which will include a technical justification addressing the need to add to or modify the EPA-approved work plan.

30. Within fifteen (15) calendar days after the receipt of such determination, Merck shall have the opportunity to meet or confer with EPA to discuss the additional work. If required by EPA, Merck shall submit for EPA's approval a work plan for the additional work. Such work plan shall be submitted within thirty-five (35) days of receipt of EPA's determination that additional work is necessary, or according to an alternative schedule established by EPA. Upon EPA approval of a work plan, Merck shall implement it in accordance with the schedule and provisions contained therein.

31. If Merck fails to perform the additional work, EPA reserves the right to perform such additional work itself and seek to recover all costs of performing such additional work from

Merck, and/or to disapprove of the CMI Work Plan and the CMI Report.

32. At any time during or after the implementation of the corrective measures specified in the FDRTC, EPA may determine that the requirements of the FDRTC including, but not limited to, the media cleanup standards set forth in the FDRTC have not been met and/or that the continued implementation of the corrective measures are not likely to achieve said requirements. In that event, EPA may select supplemental and/or alternative corrective measures pursuant to RCRA, applicable EPA regulations and/or guidance. If both parties agree to the supplemental and/or alternative corrective measures, this Consent Order may be modified pursuant to Section XXIV ("EFFECTIVE DATE AND SUBSEQUENT MODIFICATION") of this Consent Order. If both parties do not agree, EPA reserves its rights to: require Merck to implement such supplemental and/or alternative corrective measures in accordance with RCRA and regulations promulgated pursuant thereto; implement the supplemental and/or alternative corrective measures itself and seek to recover the cost of such implementation from Merck; and/or take any other appropriate action under RCRA, CERCLA, or any other legal authority.

33. All work performed pursuant to this Consent Order shall be under the direction and supervision of a professional engineer or geologist with expertise in hazardous waste site investigation and remediation. Within (10) calendar days after the effective date of this Consent Order, Merck shall submit to EPA, in writing, the name, title and qualifications of the supervising professional engineer or geologist and of any major contractor(s) to be used in carrying out the terms of this Consent Order. For the purposes of this Consent Order, major contractor shall mean any contractor who has contracts to perform work whose total value exceeds $50,000.00. Within ten (10) calendar days of retaining any other major contractor(s) to be used in carrying out the terms of this Consent Order, Merck shall submit to EPA, in writing, the names, titles and qualifications of those additional major contractors. Notwithstanding Merck's selection of a professional engineer, geologist or major contractor, nothing herein shall relieve Merck of its obligation to comply with the terms and conditions of this Consent Order.

34. EPA shall have the right to disapprove at any time the use of any professional engineer, geologist or major contractor selected by Merck. EPA's disapproval shall not be subject to review under Section XIV of this Consent Order ("DISPUTE RESOLUTION") or otherwise. Within fifteen (15) calendar days of receipt from EPA of written notice disapproving the use of any professional engineer, geologist, or major contractor, Merck shall notify EPA, in writing, of the name, title and qualifications of the personnel who will replace the personnel disapproved by EPA.

35. Merck shall notify EPA ten (10) calendar days prior to changing voluntarily its engineer or geologist, and/or major contractors to be used in carrying out the terms of this Consent Order, and shall submit to EPA, in writing, the name, title, and qualifications of such person(s).

Section VIII "DESIGNATED PROJECT COORDINATORS" is hereby amended as follows. Paragraph 1 of the Consent Order is deleted in its entirety and the following text is inserted therein as Paragraph 1.

1. EPA hereby designates Kai Hon Shum as the EPA Project Coordinator. Within ten (10) calendar days of the effective date of this Amended Consent Order, Merck shall notify EPA, in writing, of the Project Coordinator it has selected. Merck's legal counsel shall not serve as Merck's Project Coordinator. The EPA Project Coordinator will be EPA's primary designated representative at the Facility.

Section IX "NOTICE" is hereby amended to delete the text beginning "As to EPA:" up to, but not including, "As to DER" and inserting therein

As to EPA

Kai Hon Shum (3HW64)
Pennsylvania Corrective Action Section
RCRA Enforcement/UST Branch
Hazardous Waste Management Division
U.S. Environmental Protection Agency - Region III
841 Chestnut Building
Philadelphia, PA 19107
(215) 597-2381

Section XV "DELAY IN PERFORMANCE AND STIPULATED PENALTIES" is hereby amended as follows. Paragraph 1 is deleted in its entirety and the following text is inserted therein as Paragraph 1:

1. Except as subject to the provisions of Section XVI, for each week that Respondent fails to submit any report or document or otherwise fails to comply with any requirement of this Consent Order at the time and in the manner set forth herein, Respondent shall be liable upon demand by EPA to EPA for the sums set forth below as stipulated penalties. Payments shall be made by certified or cashier's check made payable to the Treasurer, United States of America and remitted to:

EPA Region III
Regional Hearing Clerk
P.O. Box 360515
Pittsburgh, PA 15251-6515

With a simultaneous copy to:

EPA Region III
Regional Hearing Clerk (3RC00)
841 Chestnut Building
Philadelphia, PA 19107

If Respondent objects to the imposition of penalties, Respondent may invoke the dispute resolution procedures under Section XIV.

The Consent Order is hereby amended to include the following in the last sentence of the first paragraph of Section XXI - "RELATIONSHIP OF THIS ORDER TO OTHER LAWS"

Notwithstanding the foregoing, EPA acknowledges that Merck's satisfactory completion of the activities required by this Consent Order is equivalent to the performance by Merck of corrective action requirements pursuant to §3004(u) and §3004(v) of RCRA.

The Consent Order is hereby amended to add Section XXV. The text of Section XXV is as follows:

XXV. FINANCIAL RESPONSIBILITY

1. Concurrent with the submission of the Draft CMI Work Plan, Merck shall also submit to EPA for approval an assurance of its financial ability to meet the current cost estimate for the corrective measures selected in the FDRTC and any amendments thereto, including both capital and operation and maintenance costs ("Current Cost Estimate"). Merck shall update this assurance of its financial ability to meet the Current Cost Estimate ("Financial Assurance") annually to take into account the rate of inflation, as set forth in Paragraph 4, below. Merck's Financial Assurance shall be in one (or a combination of) the following forms:

a. A surety bond guaranteeing performance of the corrective measures;

b. One or more letters of credit equalling the Current Cost Estimate;

c. A trust agreement establishing a trust fund equalling the Current Cost Estimate;

d. A demonstration that Merck satisfies the requirements of the financial test set forth in Paragraph 2 of this Section; or

e. A guarantee to perform the corrective measures by one or more parent corporations or subsidiaries, or by one or more unrelated corporations that have a substantial business relationship with Merck, as set forth in Paragraph 3 of this Section.

2. If Merck seeks to demonstrate Financial Assurance through the financial test, as discussed in Subparagraph 1.d of this Section, it shall provide EPA with a letter from its chief financial officer (supported by its most recent audited financial statements prepared in accordance with Generally Accepted Accounting Principles ("GAAP")) certifying that Merck meets the criteria of either 2.a or 2.b of this Section:

a. Merck must have:

(1) Either a ratio of total liabilities to net worth of less than 1.5; or a ratio of the sum of net income plus depreciation, depletion and amortization, minus $10 million, to total liabilities greater than 0.10; and

(2) Tangible net worth greater than the sum of the current closure, post-closure care, corrective action cost estimate and any other environmental obligations covered by a financial test plus $10 million; and

(3) Assets located in the United States amounting to at least the sum of the current closure, post-closure care, corrective action cost estimate and any other environmental obligations covered by a financial test plus $10 million; or

b. Merck must have:

(1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, A or Baa as issued by Moody's; and

(2) Tangible net worth greater than the sum of the current closure, post-closure care, corrective action cost estimate and any other environmental obligations covered by a financial test plus $10 million; and

(3) Assets located in the United States amounting to at least the sum of the current closure, post-closure care, corrective action cost estimate and any other environmental

obligations covered by a financial test plus $10 million.

For purpose of making the calculations set forth in this Paragraph 2, if any portion of the sum of the current closure, post-closure care, corrective action cost estimate and any other environmental obligations covered by a financial test is included in "total liabilities" on Merck's most recently audited financial statements prepared in accordance with GAAP, the amount of such portion may be deducted from the total liability amount of such financial statements and added to Merck's tangible net worth.

3. If Merck seeks to demonstrate Financial Assurance through a guarantee by a third party pursuant to Subparagraph 1.e of this Section, Merck shall demonstrate that the guarantor satisfies the requirements of the financial test set forth in Paragraph 2 of this Section.

4. Annually, on the anniversary of Merck's receipt of notification of EPA approval of the Financial Assurance required in Paragraph 1 of this Section, Merck shall submit to EPA for approval an updated form(s) of Financial Assurance which takes into account the rate of inflation. If Merck uses the financial test or corporate guarantee pursuant to Subparagraphs 1.d or 1.e of this Section, the Current Cost Estimate for the corrective measures must be updated for inflation within 30 days after the close of the firm's fiscal year and before submission of the updated form(s) of Financial Assurance to EPA. The adjustment for inflation shall be made by either recalculating the Current Cost Estimate for the corrective measures in current dollars or by using an inflation factor derived from the most recent annual Implicit Price Deflator for Gross Domestic Product published by the U.S. Department of Commerce in its monthly publication, Survey of Current Business. The inflation factor is derived by dividing the latest published annual Deflator by the annual Deflator for the previous year. (Both figures are currently set forth in Table 7.14 in the Survey of Current Business). The adjustment to the Current Cost Estimate for inflation is then made by multiplying the Current Cost Estimate by the latest inflation factor.

5. In the event that EPA determines that Merck shall modify the specified corrective measures, Merck shall revise the Current Cost Estimate for the corrective measures no later than 30 days after this receipt of notification of such EPA determination, if the change in the corrective measures increases the cost or the expected duration of the CMI. This revision shall reflect any changes in the total number of years to perform the CMI and any changes in the estimated costs for each year of the corrective measures shall also be adjusted for inflation as specified in Paragraph 4 of this Section.

6. If Merck determines at any time that it is unable, or reasonably expects that it will be unable, to maintain the Financial Assurance provided pursuant to this Section, Merck shall obtain and submit to EPA for approval one (or a combination of) the other forms of Financial Assurance listed in Paragraph 1 of this Section within thirty (30) calendar days of the earlier of (a) the event that causes such inability, or (2) receipt of information that gives rise to the reasonable expectation of such inability.

7. If EPA determines at any time that the Financial Assurance provided pursuant to this Section is inadequate, Merck shall, within thirty (30) days of its receipt of notification of such determination, obtain and present to EPA for approval one (or a combination of) the other forms of Financial Assurance listed in Paragraph 1 of this Section.

8. Merck's inability to demonstrate financial ability to meet the Current Cost Estimate for the corrective measures shall not excuse performance of any activities required under this Order.

In accordance with Section XXIV, Paragraph 2 of this Consent Order these amendments to this Consent Order shall become effective upon Respondent's receipt of a fully executed true and correct copy of such amendments.

IT IS SO ORDERED AND AGREED:

LEGAL APPROVAL 9/11/94 RK

9/29/94

Dr. Michael L. King
Executive Vice-President
North American Operations
Merck & Co., Inc.

Date

9/30/94

Peter H. Kostmayer
Regional Administrator
U. S. EPA - Region III

Date