

IN THE UNITED STATES DISTRICT COURT FOR
DISTRICT OF NEBRASKA

UNITED STATES OF AMERICA)

and)

THE CITY OF OMAHA)

Plaintiffs,)

v.)

AMERICAN LABORATORIES, INC.)

Omaha, Nebraska)

Defendant)

Civil Action No. 8:09CV194

CONSENT DECREE

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A. WHEREAS, Plaintiffs, the United States of America, on behalf of the United States Environmental Protection Agency ("EPA"), and the City of Omaha ("Omaha"), a political subdivision of the State of Nebraska, that is authorized to file suit in the name of the State of Nebraska and the Nebraska Department of Environmental Quality ("NDEQ") to enforce both state and federally enforceable environmental protection statutes, regulations, and permits issued by the City of Omaha on behalf of NDEQ, have filed a Complaint in this action concurrently with this Consent Decree, alleging that between 1999 and the filing date of the Complaint, Defendant, American Laboratories, Inc. ("Defendant" or "ALI") is civilly liable for violations of the Clean Air Act ("CAA"), 42 U.S.C. §§ 7401, et seq., the Nebraska Administrative Code Title 129 et seq., and the Omaha Municipal Code Chapter 41 et seq.

B. WHEREAS, at all times relevant to this action, Defendant has owned and/or operated two separate facilities within the City of Omaha, Nebraska, located at 5036 South 33rd St. ("East Facility") and 4410 South 102nd Street ("West Facility").

C. WHEREAS, the Complaint alleges the following violations by Defendant:

1. Violations of the requirements of Section 110 of the CAA, as amended, 42 U.S.C. § 7410, for violations of the CAA and the federally approved and enforceable State Implementation Plan ("SIP") for the State of Nebraska set forth in the Nebraska Administrative Code, Title 129, Chapter 19 and Omaha Municipal Code Chapter 41-2, which adopt and incorporate by reference the federal regulations set forth at 40 C.F.R. § 52.21 (June 30, 1997, edition), pertaining to the "Prevention of Significant Deterioration" ("PSD") of Air Quality under the CAA;

2. Violations of the requirements of Section 112 of the CAA, 42 U.S.C. § 7412, which authorizes the Administrator of EPA to regulate hazardous air pollutants ("HAPs")

that may have an adverse effect on health or the environment. Pursuant to Section 112 of the CAA, 42 U.S.C. § 7412, the Administrator established the National Emission Standards for Hazardous Air Pollutants ("NESHAP") at 40 C.F.R. Part 63. Relevant to the instant case, EPA established National Emission Standards for Pharmaceuticals Production, found at 40 C.F.R. Part 63, Subpart GGG ("Pharmaceutical MACT"), effective October 21, 2002, which are adopted by reference at Nebraska Administrative Code, Title 129, Chapter 27 and Omaha Municipal Code Chapter 41-2; and

3. Violations of Title V of the CAA, 42 U.S.C. §§ 7661-7661f and Nebraska Administrative Code, Title 129, Chapters 5-9,12, which is incorporated by reference at Omaha Municipal Code Chapter 41-2, and requires major sources of air pollutants to obtain and operate pursuant to operating permits which incorporate all applicable requirements of the CAA.

D. WHEREAS, Defendant, ALI, is a corporation organized and existing under the laws of the State of Nebraska, and is authorized to do business in the State of Nebraska.

E. WHEREAS, Defendant does not admit any liability to the United States arising out of the facts alleged in the Complaint;

F. WHEREAS, Defendant has certified by affidavit dated November 16, 2006, that it no longer utilizes HAPs in the production of "pharmaceutical products" as defined by the Pharmaceutical MACT, found at 40 C.F.R. Part 63, Subpart GGG ("Pharmaceutical MACT");

G. WHEREAS, Defendant has been issued a Title V operating permit by Omaha for the West Facility;

H. WHEREAS, Defendant has completed the installation and implementation of the Settlement Control Technologies and Work Practices described in Attachment I to this Consent

Decree and Defendant has submitted to EPA and Omaha written notification that the installation of the control technologies and implementation of the work practices described in Attachment I has been completed and that the control technologies are fully operational at Building 36 of the East Facility.

I. WHEREAS, the Parties recognize, and the Court by entering this Consent Decree finds, that this Consent Decree has been negotiated by the Parties in good faith and will avoid litigation between the Parties, and that this Consent Decree is fair, reasonable, and in the public interest.

NOW, THEREFORE, before taking testimony and without the adjudication or admission of any issue of fact or law except as provided in Section I, below, and with the consent of the Parties, IT IS HEREBY ADJUDGED, ORDERED, AND DECREED as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of the United States' and Omaha's claims in this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1355, and Section 113(b) of the CAA, 42 U.S.C. § 7413(b), because: (1) the action arises in part under the laws of the United States; (2) the United States is a plaintiff; and (3) the action is brought in part to recover penalties incurred under Acts of Congress.

2. The Court has personal jurisdiction over the Parties to this Consent Decree. Venue lies in this District pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b) and pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1395(a), because the claims alleged in the Complaint occurred in this district and because Defendant conducts business at two facilities located in this district. For purposes of this Decree, or any action to enforce this Decree, Defendant consents to the

Court's jurisdiction over this Decree or such action and over Defendant, and consents to venue in this judicial district.

II. APPLICABILITY

3. The obligations of this Consent Decree apply to and are binding upon the United States and Omaha, and upon Defendant, and any successors, assigns, or other entities or persons otherwise bound by law.

4. No transfer of ownership or operation of Defendant's East or West Facilities, or assets of Defendant, or any portion thereof, prior to the completion of the Defendant's obligations hereunder, shall relieve Defendant of its obligation to ensure that the terms of the Decree are implemented.

5. Any transfer of ownership or operation of Defendant's East or West Facilities, or assets of Defendant, or any portion thereof, must be conditioned upon:

a. the transferee's agreement to undertake the obligations required by this Consent Decree with respect to the Facilities being transferred, and to intervene as a Defendant in this action for the purpose of being bound by the applicable terms of this Consent Decree;

b. the transferee providing the United States and the Omaha with information sufficient to demonstrate that the transferee has the technical and financial means to comply with the applicable obligations of this Consent Decree; and

c. EPA and Omaha's written consent to the substitution of the transferee for Defendant with respect to such obligations, or as provided in a court order issued at the conclusion of the dispute resolution procedures set forth in Section XI of this Decree.

6. At least thirty (30) days prior to any transfer of ownership or operation of any of the Facilities or any portion thereof, Defendant shall provide a copy of this Consent Decree to the

proposed transferee and shall simultaneously provide written notice of the prospective transfer, together with a copy of the proposed written transfer agreement, to EPA, Region 7, to the United States Department of Justice ("DOJ"), and to Omaha in accordance with Section XV of this Decree (Notices). Any attempt to transfer ownership or operation of the Facility without complying with Paragraphs 5 and 6 constitutes a violation of this Decree.

7. Defendant shall provide a copy of this Consent Decree to all officers, employees, and agents whose duties might reasonably include compliance with any provision of this Decree. Defendant shall condition any contract to perform such work required under this Consent Decree in conformity with the terms of this Consent Decree.

8. In any action to enforce this Consent Decree, Defendant shall not raise as a defense the failure by any of its officers, directors, employees, agents, or contractors to take any actions necessary to comply with the provisions of this Consent Decree.

III. DEFINITIONS

9. Terms used in this Consent Decree that are defined or used in the CAA, or in regulations promulgated thereunder, shall have the meaning assigned to them in such statute or such regulations, unless otherwise provided in this Decree. Whenever the terms set forth below are used in this Consent Decree, the following definitions shall apply:

- a. "Complaint" shall mean the complaint filed by Plaintiffs in this action, unless noted otherwise.
- b. "Consent Decree" or "Decree" shall mean this Decree.
- c. "Day" shall mean a calendar day unless expressly stated to be a working day. In computing any period of time under this Consent Decree, where the last day would fall on a

Saturday, Sunday, or federal holiday, the period shall run until the close of business of the next working day.

d. "Defendant" shall mean American Laboratories, Inc.

e. "East Facility" shall mean the facility owned and operated by ALI located and addressed at 5036 South 33rd St., Omaha, Nebraska.

f. "EPA" shall mean the United States Environmental Protection Agency and any of its successor departments or agencies.

g. "Paragraph" shall mean a portion of this Decree identified by an Arabic numeral.

h. "Parties" shall mean the United States, the City of Omaha, Nebraska, and American Laboratories, Inc.

i. "Plaintiffs" shall mean the United States and the City of Omaha.

j. "Section" shall mean a portion of this Decree identified by a Roman numeral.

k. "West Facility" shall mean the facility owned and operated by ALI located and addressed at 4410 South 102nd Street, Omaha, Nebraska.

l. "United States" shall mean the United States of America, acting on behalf of EPA.

IV. CIVIL PENALTY

10. Defendant shall pay a total civil penalty of \$440,000, which will be paid in two installments of \$220,000 plus interest, each as set forth below in settlement of this action. Interest on the outstanding balance of the civil penalty shall accrue from the date on which this Decree is lodged with the Court, at the rate specified in 28 U.S.C. § 1961. A payment of \$220,000 (plus interest) shall be due and payable within thirty (30) days of the Effective Date as set forth in Section XVI of this Consent Decree and Paragraphs 11 and 12. No later than one year from when

the first installment is due, the Defendant shall pay the second installment of \$220,000 (plus interest) of the civil penalty, as provided in Paragraphs 11 and 12.

11. After Entry of the Consent Decree, instructions shall be provided to Defendant for FedWire Electronic Funds Transfer ("EFT") to the U.S. Department of Justice by the Financial Litigation Unit of the U.S. Attorney's Office for the District of Nebraska. One half of each payment due pursuant to Paragraph 10, above (half being equal to \$110,000 plus accrued

interest), shall be made by Defendant by FedWire Electronic Funds Transfer ("EFT") to the U.S. Department of Justice in accordance with instructions to be provided to Defendant. The payment shall reference the Civil Action Number assigned to this case and DOJ Number 90-5-2-1-08313. Any funds received after 11:00 a.m. Eastern Time shall be credited on the next business day.

12. One half of each payment due pursuant to Paragraph 10, above (half being equal to \$110,000 plus accrued interest), shall be made by Defendant by certified check payable to the Treasurer for Douglas County, Nebraska, and submitted to the Office of the Attorney General, State of Nebraska, State Capitol, Room 2115, P.O. Box 98920, Lincoln, Nebraska, 68509-8920.

13. Within five days of each payment, Defendant shall send written notice of payment and a copy of any transmittal documentation to Plaintiffs in accordance with Section XV of this Decree (Notices).

14. Defendant shall not deduct the civil penalties paid under this Section in calculating federal, state, or local income taxes.

V. COMPLIANCE SCHEDULE AND REQUIREMENTS

15. As stated herein, at Building 36 of the East Facility, as of January 2008, Defendant completed the installation of the Settlement Control Technologies and Work Practices described in Attachment I to this Consent Decree. From the Effective Date of this Consent Decree,

Defendant shall continue to operate and implement the Settlement Control Technologies and Work Practices described in Attachment I. From the Effective Date of this Consent Decree, as a means of limiting emissions of isopropyl alcohol ("IPA"), Defendant shall recover and reuse at least 93% of total IPA used at Building 36, calculated on a 12-month rolling average and utilizing data collected by Defendant since the January 2008 startup of the Settlement Control Technologies described in Attachment I. Following the date that a PSD permit required by Paragraph 17 for Defendant's East Facility is issued, fully effective and no longer subject to challenge or appeal, Defendant shall comply with the terms and limits of the PSD permit, which shall require Defendant to recover and reuse at least 93% of total IPA used at Building 36, calculated on a 12-month rolling average basis, in addition to the obligations contained in this Consent Decree.

16. For purposes of calculating the percentage of IPA recovered, Defendant shall propose a method for calculating this percentage to EPA and the City of Omaha for review and approval within fifteen days (15) of the Effective Date of this Consent Decree. Defendant will collect and report the following information monthly by the 15th day of each calendar month to EPA and Omaha in accordance with Section XV (Notices) of this Decree. The basis for Defendant's calculations shall include, but not be limited to, the following information:

- a. The number of batches of pancreatin produced each month;
- b. The amount of IPA put into the pancreatin process each month;
- c. Meter records of IPA into Process Tank 301, recorded pursuant to Manufacturing Instructions;

- d. Monthly measurement of the amount of material and testing of the IPA concentration in Process Tanks 302 and 303, shall occur on dates that material is present in the tanks;
- e. Monthly measurement of spent IPA and testing of IPA concentration in spent IPA Tank 316;
- f. Monthly measurement of recovered IPA and testing of IPA concentration in Recovered IPA Tank 318; and
- g. Monthly measurement of IPA in Virgin IPA Tank 317.
- h. Prior to measurement and testing, spent IPA from the dryers (FD-301 and FD-302) and the solid and fines separation tanks will be pumped into Spent IPA Tank 316. All inventories will be converted and reported on the basis of 99% IPA.
- i. For the prior calendar month, a calculated 12-month average percentage of IPA recovered, as a percentage of total IPA used (Until February 2009, Defendant shall utilize the data for operation for the months between January and September).

EPA and Omaha may provide comment and request additional information be submitted in the monthly reports submitted by Defendant for purposes of development of the PSD permit.

VI. PERMITS

17. Within ninety (90) days of the Effective Date of the Consent Decree as set forth in Section XVI (Effective Date), ALI shall submit an administratively complete PSD permit application to Omaha permitting authority for Building 36 at the East Facility, pursuant to 40 C.F.R. § 52.21 and the State Implementation Plan ("SIP") for the State of Nebraska set forth in the Nebraska Administrative Code, Title 129, Chapter 19, which adopts and incorporates by

reference the federal regulations set forth at 40 C.F.R. § 52.21, pertaining to the PSD of Air Quality under the CAA, to address the modifications to Defendant's East Facility referenced in the United States' Complaint. The PSD permit application shall propose, at a minimum, to utilize the control technologies necessary to achieve the requirement for Best Available Control Technology, as provided in 40 C.F.R. § 52.21, and may include the control technologies described in Attachment I and/or additional control technologies, and emissions limit set forth in Paragraph 15 and the monitoring requirements in Paragraph 16.

18. Defendant hereby waives its jurisdictional objections to the issuance of a PSD permit by the City of Omaha for the East Facility, but reserves any and all rights to object to and/or contest the substantive requirements of any PSD permit to be issued by the City of Omaha in response to Defendant's PSD permit application.

19. Within ninety (90) days of the Effective Date as set forth in Section XVI (Effective Date) of this Consent Decree, Defendant shall submit to Omaha an updated Title V permit application to modify the Title V permit for the East facility, to include the requirements of this Consent Decree and to include a proposed schedule of compliance required to achieve compliance with the terms of the effective PSD permit for the East Facility, and the monitoring requirements described in Section V.

VII. REPORTING REQUIREMENTS

20. In addition to the submittals required in Section V and VI above, Defendant shall submit the following Annual Reports to EPA and Omaha in accordance with Section XV of this Decree (Notices):

a. By February 15th of the year following the Effective Date as set forth in Section XVI of this Consent Decree and by February 15th annually thereafter, Defendant shall submit an

Annual Report fully documenting the performance by Defendant of the tasks required by Sections V and VI, above during the prior calendar year. Defendant also hereby certifies that it is no longer using HAPs at either the East or West facilities, and will provide documentation and notice in each annual report to Omaha and EPA if it begins to use HAPs in the future.

b. Each report submitted by Defendant under this Section shall be signed by a responsible corporate officer of the submitting party and include the following certification:

I certify under penalty of law that I have examined and am familiar with the information submitted in this document and all attachments and that this document and its attachments were prepared either by me personally or under my direction or supervision in a manner designed to ensure that qualified and knowledgeable personnel properly gather and present the information contained therein. I further certify, based on my personal knowledge, or to the best of my knowledge based on my inquiry of those individuals immediately responsible for obtaining the information, that the information is true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowingly and willfully submitting a materially false statement.

VIII. REVIEW AND APPROVAL OF

EMISSIONS MONITORING PLAN, IF REQUESTED

21. If determined to be necessary for purposes of developing the required PSD permit, EPA and Omaha may request that Defendant submit an Emissions Monitoring Plan (Monitoring Plan) for review and approval to monitor the effectiveness of the Settlement Control Technologies and Practices set forth in Attachment I to this Consent Decree. If such a Plan is requested, Defendant shall submit the Monitoring Plan to Plaintiffs within sixty (60) days of receipt of the request. EPA, in consultation with Omaha, may approve or decline to approve the Monitoring Plan and provide written comments. Within sixty (60) days of receiving written comments from EPA, Defendant shall either: (i) revise the Monitoring Plan consistent with the written comments and

provide the revised Monitoring Plan for final approval to EPA and the Omaha; or (ii) submit the matter for dispute resolution, including the period for informal negotiations under Section XI (Dispute Resolution) of this Consent Decree. Upon receipt of EPA's final approval of the Monitoring Plan or upon completion of the Monitoring Plan pursuant to dispute resolution, Defendant shall implement the Monitoring Plan in accordance with its terms.

IX. STIPULATED PENALTIES

22. If Defendant fails to timely and completely make the payments required under Section IV (Civil Penalty) when due, Defendant shall be liable for a stipulated penalty of five thousand dollars (\$5,000) to the United States per day for each day that the payment or any portion thereof, including interest, is late.

23. Except as set forth specifically in Paragraphs 22, 24, and 25, Defendant shall be liable for stipulated penalties to the United States for all other violations of this Consent Decree, as set forth below. A violation includes failing to perform any obligation required by the terms of this Decree, including any obligations under Sections IV, V, VI or VII (unless specifically addressed elsewhere), according to all applicable requirements of this Decree and within the specified time schedules established by or approved under this Decree.

<u>Penalty Per Violation Per Day:</u>	<u>Period of Noncompliance:</u>
\$750	1 st through 14 th day
\$1,000	15 th through 30 th day
\$2,250	31 st day and beyond

24. Failure to comply with the 12-month rolling average limit of 93% of recovery of total IPA used, where the violation is recovery of less than 93% but greater than 91% recovery of

total IPA used, shall be subject to a penalty of \$1,000 per day (amount of IPA recovered is between 91% and 93% of total IPA used). A violation of the 12-month rolling average recovery limit for IPA is a violation on every day of the month on which the average is based.

25. Failure to comply with the 12-month rolling average limit for IPA, where the violation is recovery of less than 91% of total IPA used shall be subject to a penalty of \$2,500 per day. A violation of the 12-month rolling average recovery limit for IPA is a violation of every day of the month on which the average is based.

26. Stipulated penalties shall begin to accrue on the day after performance is due, and shall continue to accrue until performance is satisfactorily completed. Stipulated penalties shall accrue simultaneously for separate violations of this Consent Decree. Defendant shall pay any stipulated penalty assessed within thirty (30) days of receiving a written demand from the United States. The United States may, in the unreviewable exercise of its discretion, reduce or waive stipulated penalties otherwise due under this Consent Decree.

27. Stipulated penalties shall continue to accrue during any Dispute Resolution, with interest on accrued penalties payable and calculated at the rate established by the Secretary of the Treasury, pursuant to 28 U.S.C. § 1961, but need not be paid until the following:

a. If the dispute is resolved by agreement, Defendant shall pay accrued penalties determined to be owed, together with interest, to the United States within thirty (30) days of the effective date of that agreement;

b. If the dispute is submitted to the Court and the United States prevails in whole or in part, Defendant shall pay all accrued penalties determined by the Court to be owing, together with interest, within sixty (60) days of receiving the Court's decision or order, except as provided in Subparagraph c, below;

c. If either the United States or Defendant appeals the District Court's decision, Defendant shall pay all accrued penalties determined to be owed, together with interest, within fifteen (15) days of receiving the final appellate court decision.

28. Defendant shall, as directed by the United States in its demand, pay stipulated penalties owing to the United States by EFT or by certified or cashier's check in the amount due, payable to the U.S. Treasury, referencing the civil action number assigned to this case, DOJ

Number 90-5-2-1-08313. Payments by certified or cashier's check shall be delivered to the office of the United States Attorney, District of Nebraska in accordance with Section XV of this Consent Decree (Notices).

29. Defendant shall not deduct stipulated penalties paid under this Section in calculating federal, state or local income taxes.

30. If Defendant fails to pay stipulated penalties according to the terms of this Consent Decree, Defendant shall be liable for interest on such penalties, as provided for in 28 U.S.C. § 1961, accruing as of the date payment became due.

31. Subject to the provisions of Section XII of this Consent Decree (Effect of Settlement/Reservation of Rights), the stipulated penalties provided for in this Consent Decree shall be in addition to any other rights, remedies, or sanctions available to Plaintiffs for Defendant's violation of this Consent Decree or applicable law.

X. FORCE MAJEURE

32. A "force majeure event" is any event beyond the control of Defendant, its contractors, or any entity controlled by any Defendant that delays the performance of any obligation under this Consent Decree despite Defendant's best efforts to fulfill the obligation. "Best efforts" includes anticipating any potential force majeure event and addressing the effects

of any such event (a) as it is occurring and (b) after it has occurred, to prevent or minimize any resulting delay to the greatest extent possible. "Force Majeure" does not include Defendant's financial inability to perform any obligation under this Consent Decree.

33. Defendant shall provide written notice to Plaintiffs as provided in Section XV (Notices) as soon as practicable, but not later than three (3) business days after the time Defendant first knew of, or by the exercise of due diligence, should have known of, a claimed force majeure event. The notice shall state the anticipated duration of any delay; its cause(s); Defendant's past and proposed actions to prevent or minimize any delay; a schedule for carrying out those actions; and Defendant's rationale for attributing any delay to a force majeure event. If Defendant fails to comply with the notice requirements herein, the United States may void Defendant's claim for force majeure as to the specific event for which Defendant has failed to comply with such notice requirement.

34. If the United States agrees that a force majeure event has occurred, the United States may agree to extend the time for Defendant to perform the affected requirements for the time necessary to complete those obligations. An extension of time to perform the obligations affected by a force majeure event shall not, by itself, extend the time to perform any other obligation. Where the United States agrees to an extension of time, the appropriate modification shall be made pursuant to Section XVIII of this Consent Decree (Modification) and is not a material change under that Section.

35. If the United States does not agree that a force majeure event has occurred, or does not agree to the extension of time sought by Defendant, the United States' position shall be binding, unless Defendant invokes Dispute Resolution under Section XI of this Consent Decree. In any such dispute, Defendant bears the burden of proving, by a preponderance of the evidence,

that each claimed force majeure event is a force majeure event, that Defendant gave the notice required by Paragraph 33, that the force majeure event caused any delay Defendant claims was attributable to that event, and that Defendant exercised its best efforts to prevent or minimize any delay caused by the event.

XI. DISPUTE RESOLUTION

36. Unless otherwise expressly provided for in this Consent Decree, the dispute resolution procedures of this Section shall be the exclusive method available to resolve disputes arising under or with respect to this Consent Decree. However, such procedures shall not apply to actions by Plaintiff(s) to enforce obligations of Defendant under this Consent Decree that have not been disputed in accordance with this Section.

37. Any dispute subject to dispute resolution under this Consent Decree shall first be the subject of informal negotiations between the United States, which will act as designated representative of Plaintiffs in dispute resolution, and Defendant. The dispute shall be considered to have arisen when Defendant sends a written notice of dispute, as provided in Section XV of this Decree (Notices). Such notice of dispute shall state clearly the matter in dispute. The period of informal negotiations shall not exceed thirty (30) days from the date the dispute arises, unless that period is modified by written agreement between the Defendant and Plaintiffs. If informal negotiations are unsuccessful, then the United States' position shall control unless Defendant files with the Court a petition to resolve the dispute within thirty (30) days after the conclusion of the informal negotiation period. In any dispute under this Paragraph, Defendant shall bear the burden of demonstrating that its position complies with this Consent Decree and the CAA, and that Defendant is entitled to relief under applicable law.

38. The invocation of dispute resolution procedures under this Section shall not extend, postpone, or affect in any way any obligation of Defendant under this Consent Decree, not directly in dispute. Stipulated penalties with respect to the disputed matter shall continue to accrue from the first day of noncompliance, but payment shall be stayed pending resolution of the dispute as provided herein. If Defendant does not prevail on the disputed issue, stipulated penalties shall be assessed and paid as provided in Section IX (Stipulated Penalties).

XII. INFORMATION COLLECTION AND RETENTION

39. The Plaintiffs and their representatives, including attorneys, contractors, and consultants, shall have the right of entry into any of the Facilities covered by this Consent Decree, at all reasonable times, upon presentation of credentials, to: monitor the progress of activities required under this Consent Decree; verify any data or information submitted to a Plaintiff in accordance with the terms of this Consent Decree; obtain samples and, upon request, splits of any samples taken by Defendant or its representatives, contractors, or consultants; obtain documentary evidence, including photographs and similar data; and assess Defendant's compliance with this Consent Decree.

40. Until at least three years after the termination of this Consent Decree, Defendant shall retain, and shall instruct its contractors and agents to preserve, all non-identical copies of all documents, records, or other information (including documents, records, or other information in electronic form) in its or its contractors' or agents' possession or control, or that come into its or its contractors' or agents' possession or control, and that relates in any manner to Defendant's performance of its obligations under this Consent Decree. This information-retention requirement shall apply regardless of any contrary corporate or institutional policies or procedures. At any

time during this information-retention period, the United States or a Plaintiff may request copies of any documents, records, or other information required to be maintained under this Paragraph.

41. At the conclusion of the information retention period specified in the preceding paragraph, Defendant shall notify the Plaintiffs at least 90 days prior to destroying any document(s), record(s), or other information subject to the requirements of the preceding paragraph and, upon request by a Plaintiff, Defendant shall deliver any such document(s), record(s), or other information to the requesting Plaintiff or Plaintiffs. Defendant may assert that certain documents, records, or other information are privileged under the attorney-client privilege or any other privilege recognized by federal law. If Defendant asserts such a privilege, it shall provide the following: (1) the title of the document, record, or information; (2) the date of the document, record, or information; (3) the name and title of each author of the document, record, or information; (4) the name and title of each addressee and recipient; (5) a description of the subject of the document, record, or information; and (6) the privilege asserted by Defendant. However, no documents, records, data, or other information created or generated pursuant to the requirements of this Consent Decree shall be withheld on grounds of privilege.

42. Defendant may also assert that information required to be provided under this Section is protected as Confidential Business Information ("CBI") under 40 C.F.R. Part 2. As to any information that Defendant seeks to protect as CBI, Defendant shall follow the procedures set forth in 40 C.F.R. Part 2.

43. The information retention requirements of Paragraphs 38 and 39 shall survive termination of this Consent Decree and shall be enforceable by this Court even after such termination. This Consent Decree in no way limits or affects any right of entry and inspection, or any right to obtain information, held by the Plaintiffs pursuant to applicable federal or state laws,

regulations, or permits, nor does it limit or affect any duty or obligation of Defendant to maintain documents, records, or other information imposed by applicable federal or state laws, regulations, or permits.

XIII. EFFECT OF SETTLEMENT/RESERVATION OF RIGHTS

44. This Consent Decree resolves the civil claims of the United States and Omaha for the violations alleged in the Complaint filed in this action.

45. Plaintiffs reserve all legal and equitable remedies available to enforce the provisions of this Consent Decree. This Consent Decree shall not be construed to prevent or limit the rights of the United States and/or Omaha to obtain penalties, damages, response costs or injunctive relief under the CAA and/or under other federal or state laws, regulations, or permit conditions, except as expressly specified herein.

46. In any subsequent administrative or judicial proceeding reserved herein and initiated by the United States and/or Omaha for injunctive relief or civil penalties relating to Defendant's violations at the facilities covered by the Consent Decree, Defendant shall not assert, and may not maintain, any defense or claim based upon the principles of waiver, res judicata, collateral estoppel, issue preclusion, claim-splitting, or other defenses based upon any contention that the claims raised by the United States in the subsequent proceeding were or should have been brought in the instant case; provided, however, that nothing in this Paragraph is intended to, or shall, affect the validity of Paragraph 36 of this Consent Decree.

47. This Consent Decree is not a permit, or a modification of any permit, under any federal, state, or local laws or regulations. Defendant is responsible for achieving and maintaining complete compliance with all applicable federal, state, and local laws, regulations, and permits; and Defendant's compliance with this Consent Decree shall be no defense to any

action commenced pursuant to said laws, regulations, or permits. Plaintiffs do not, by their consent to the entry of this Decree, warrant or aver in any manner that Defendant's compliance with any aspect of this Consent Decree will result in compliance with provisions of the CAA, or with any other provisions of federal, state, or local laws, regulations, or permits.

48. This Consent Decree does not limit or affect the rights of Defendant, the United States or Omaha against any third parties not party to this Consent Decree, nor does it limit the rights of third parties not party to this Consent Decree, against Defendant, except as otherwise provided by law.

49. This Consent Decree shall not be construed to create rights in, or grant any cause of action to, any third party not party to this Consent Decree.

50. Defendant hereby covenants not to sue the Plaintiffs and agrees not to assert any claims against the Plaintiffs related to the claims set forth in the Complaint.

51. This Consent Decree is without prejudice to the rights of the Plaintiffs against Defendant with respect to all matters other than those expressly specified in Paragraph 36, above, including, but not limited to, the following:

- a. claims based on a failure of Defendant to meet a requirement of this Consent Decree;
- b. any and all criminal liability; and
- c. past, present, or future violations of the CAA other than the violations described in the Complaint.

XIV. COSTS

52. The Parties shall bear their own costs of this action, including attorneys' fees.

XV. NOTICES

53. Unless otherwise specified herein, whenever notifications, submissions, reports or communications are required by this Consent Decree, they shall be made in writing and addressed to all parties as follows:

As to the United States:

As to the U.S. Department of Justice:

Section Chief
Environmental Enforcement Section
Environment and Natural Resources Division
U.S. Department of Justice
P.O. Box 7611
Washington, D.C. 20044-7611

Re: DOJ Number 90-5-1-2-08313

As to EPA Region 7:

Angela Catalano
U.S. Environmental Protection Agency, Region 7
AWMD/APCO
901 North 5th Street
Kansas City, Kansas 66101

Phone: (913) 551-7411

Fax: (913) 551-7925

As to the United States Attorney, District of Nebraska:

To provide verbal notification as required by this Decree: (913) 551-7411

As to the City of Omaha:

Chester Black, Air Quality Control Manager
City of Omaha
Public Works Department
Air Quality Control Division
5600 South 10th Street
Omaha, Nebraska 68107

Phone: (402) 444-6015

Fax: (402) 444-6016

As to Defendant:

Kenny Soejoto
Chief Operating Officer
American Laboratories Inc.
4410 South 102nd Street
Omaha, Nebraska 68127

Phone: (402) 339-2494
Fax: (402) 339-0801

and

Mr. Douglas Curran, Esq. and
Ms. Stacy Stotts, Esq.
Stinson Morrison Hecker LLP
1201 Walnut, Suite 2900.
Kansas City, Missouri 64106

Phone: (816) 842-8600
Fax: (816) 691-3945

54. Any Party may, by written notice to the other Parties, change its designated notice recipient or notice address provided above.

55. Notices submitted pursuant to this Section shall be deemed submitted upon mailing, unless otherwise provided in this Consent Decree or by mutual agreement of the Parties in writing.

XVI. EFFECTIVE DATE

56. The Effective Date of this Consent Decree shall be the date upon which this Consent Decree is entered by the Court.

XVII. RETENTION OF JURISDICTION

57. The Court shall retain jurisdiction over this case until termination of this Consent Decree, for the purpose of resolving disputes arising under this Decree or entering orders

modifying this Decree, pursuant to Sections XI (Dispute Resolution) and XVIII (Modification), or effectuating or enforcing compliance with the terms of this Decree.

XVIII. MODIFICATION

58. The terms of this Consent Decree may be modified only by a subsequent written agreement signed by all the Parties. Where the modification constitutes a material change to any term of this Decree, it shall be effective only upon approval by the Court.

XIX. TERMINATION

59. Three (3) years after Defendant has completed the performance of its obligations required by this Decree, including payments under Section IV of this Decree and any accrued Stipulated Penalties under Section IX, as well as the items required under Section V (Compliance Schedule and Requirements) and Section VI (Permits), Defendant may submit to Plaintiffs a written request for termination, stating that Defendant has satisfied the requirements of the Consent Decree, together with all documentation necessary to support Defendant's claim and request for termination.

60. If the Plaintiffs agree that the Decree may be terminated, the United States shall file a motion or a joint stipulation for termination of the Decree.

61. If the Plaintiffs do not agree that the Decree may be terminated, the Defendant may invoke Dispute Resolution under Section XI of this Decree. However, Defendant shall not seek Dispute Resolution of any dispute, under Section XI, until ninety (90) days after service of its Request for Termination.

XX. PUBLIC PARTICIPATION

62. This Consent Decree shall be lodged with the Court for a period of not less than thirty (30) days for public notice and comment, consistent with the procedures set forth in 28

C.F.R. § 50.7. The United States reserves the right to withdraw or withhold its consent if the comments regarding the Consent Decree disclose facts or considerations indicating that the Consent Decree is inappropriate, improper, or inadequate. Defendant agrees not to oppose entry of this Consent Decree by the Court or to challenge any provision of the Decree, unless the United States has notified Defendant in writing that it no longer supports entry of the Decree. Defendant consents to entry of this Consent Decree without further notice.

XXI. SIGNATORIES / SERVICE

63. The Assistant Attorney General for the Environment and Natural Resources Division of the Department of Justice, on behalf of the United States, and each undersigned representative of Defendant, certifies that he or she is fully authorized to enter into the terms and conditions of this Consent Decree and to execute and legally bind the Party he or she represents to the terms of this Decree.

64. This Consent Decree may be signed in counterparts, and such counterpart signature pages shall be given full force and effect.

65. Defendant agrees to accept service of process by mail with respect to all matters arising under or relating to this Consent Decree and to waive the formal service requirements set forth in Rule 4 of the Federal Rules of Civil Procedure and any applicable Local Rules of this Court including, but not limited to, service of a summons.

XXII. INTEGRATION

66. This Consent Decree constitutes the final, complete, and exclusive agreement and understanding among the Parties with respect to the settlement embodied in the Decree and supersedes all prior agreements and understandings, whether verbal or written. No other document, nor any representation, inducement, agreement, understanding, or promise, constitutes

any part of this Decree or the settlement it represents, nor shall it be used in construing the terms of this Decree.

XXIII. FINAL JUDGMENT

67. Upon approval and entry of this Consent Decree by the Court, this Consent Decree shall constitute a final judgment between the United States and Defendant.

68. The Court finds that there is no just reason for delay and therefore enters this judgment as a final judgment.

Upon execution of this document, the original Consent Decree shall be returned to the United States Attorney's Office and a copy of the Consent Decree shall be maintained in the Clerk's Office.

This Consent Decree is dated and entered this ____ day of _____, 2009.

UNITED STATES DISTRICT JUDGE
District of Nebraska

Signature Page to Consent Decree in U.S. v. American Laboratories, Inc.

FOR PLAINTIFF UNITED STATES OF AMERICA:

June 8, 2009
DATE

ELLEN M. MAHAN
Deputy Section Chief
Environmental Enforcement Section
Environment and Natural Resources Division
United States Department of Justice
Washington, D.C. 20530

June 9, 2009
DATE

~~SARAH DIMMELHOCH, ESQ.~~
Trial Attorney
Environmental Enforcement Section
Environment & Natural Resources Division
United States Department of Justice
P.O. Box 7611
Washington, D.C. 20044-7611

Signature Page to Consent Decree in U.S. v. American Laboratories, Inc.

FOR PLAINTIFF UNITED STATES OF AMERICA (continued):

6/16/09
DATE

JOE W. STECHER
United States Attorney
District of Nebraska

6/16/09
DATE

Laurie A. Kelly
Assistant United States Attorney, Mass. Bar No.
557575
District of Nebraska
1620 Dodge Street
Suite 1400
Omaha, Nebraska 68102-1506
Telephone: (402) 661-3700
Fax: (402) 661-3081

Signature Page to Consent Decree in U.S. v. American Laboratories, Inc.
FOR PLAINTIFF UNITED STATES OF AMERICA (continued):

5/7/09
DATE

William Rice
Acting Regional Administrator
U.S. Environmental Protection Agency, Region 7
Kansas City, Kansas 66101

4/28/09
DATE

Howard C. Bunch, Esq.
Sr. Assistant Regional Counsel
U.S. Environmental Protection Agency, Region 7
901 North 5th Street
Kansas City, Kansas 66101

Signature Page to Consent Decree in U.S. v. American Laboratories, Inc.

**FOR PLAINTIFF, CITY OF OMAHA,
NEBRASKA**

4/27/09
DATE

[Signature]
ROBERT HAMER, ATTORNEY
City of Omaha,
Deputy City Attorney,
Nebraska Bar Number 11666

Signature Page to Consent Decree in U.S. v. American Laboratories, Inc.

FOR Defendant

American Laboratories, Inc.

By: _____
~~Jeff Jackson, President and CEO~~

ATTACHMENT I - CIVIL ACTION NO.
SETTLEMENT CONTROL TECHNOLOGY AND WORK PRACTICES

American Laboratories Inc.
Pancreatin Process – Building 36
East Facility – 5020 South 33rd Street
Omaha, Nebraska

I. Introduction

The Parties have determined that improvements to certain equipment and existing work practices should result in significant reductions of volatile organic compound (“VOC”) emissions in the pancreatin process at Building 36 at the East Facility and shall constitute the Settlement Control Technologies and Work Practices for purposes of the Consent Decree. The current pancreatin process equipment along with the improvements being implemented for emissions reductions are described herein.

II. Current Pancreatin Process and Improvements Being Implemented

The area where pancreatin is produced is located in a room referred to as the “wet processing” area within Building 36. The wet processing area contains a freezer and a cooler as well as the storage, process tanks and vessels, two dryers, a distillation column, pumps and other equipment used for the production of pancreatin. There is also a large exhaust fan in the north exterior wall of the wet processing area that is monitored from the control area in room 107. The fan is a variable speed unit that maintains a negative two (2) inches water column vacuum on the room. When the control senses a drop to negative 1.8 inches, for example, when a door is opened, the fan speed increases. The response is nearly immediate. The maximum airflow rate in the room has been determined to be approximately 9,000 cfm.

A. Process Tanks

1. Current Process

Pancreatin production is a batch operation. Process Tanks 301, 302 and 303 are used in the process and solvent and other materials are contained in these tanks during the batch operation. Spent solvent is removed from Tank 302 and Tank 303, and is pumped to the spent solvent tank (Tank 316).

2. Improvements Being Implemented

Each of the process vessel tanks (Tank 301, 302 and 303) is equipped with a lid opening on the top and permanently attached piping for the addition of solvent and product. Solvent resistant gaskets will be placed on metal to metal contact points (lids) on process vessels where possible to further reduce VOC emissions from enclosed process tanks. The gaskets will be included in the Plant's preventive maintenance program.

B. Solids Separation

1. Current Process

The liquid/solids separator separates solids received from the process tanks. Once separated, solids exit from the discharge points at the sides of the screener into primarily unenclosed bag filtering equipment that is stored on the process floor and in the cooler until ready to dry. During and after the separation process the spent solvent is collected and pumped to spent solvent Tank 316. After separation, the material is loaded into dryer pans and placed into a dryer or stored in the cooler until dryer capacity is available.

2. Improvement Being Implemented

The unenclosed bag filtering equipment will be replaced with covered tanks to reduce VOC emissions. The tanks will be mobile so they can be moved between the fines tank, the cooler, and the spent isopropyl alcohol ("IPA") recovery tank (Tank 316) as needed. Each tank will separate the solids (both course and fines) and IPA/water will drain to portable receivers in the cooler. The IPA/water will then be transferred to a pump system and will be pumped into Tank 316 as was previously done with the bag filter system. The tanks will be covered as much as possible during the filling process and completely during storage in the cooler.

Replacement of the dryer pans with larger pans will allow for more efficient drying and with other operational changes, will eliminate the need to store the pans in the cooler until they can be placed in the dryer. As a result, the pans will no longer be stored in the cooler before drying, thus reducing VOC loss associated with storing dryer pans in the cooler.

The discharge points off the screener will be modified. Currently, material is allowed to fall from discharge points on each side (course and fines) of the screener. The coarse material discharge point will be fitted with a flexible rubber boot that will allow the tub to be more effectively covered during the course separation tank filling operation. The fines discharge point will be fitted with another flexible boot that can be clamped to the screener. The fines collection tank will be covered during the transfer of fines to Tank 303. To further reduce emissions from the enclosed separator/screener, the placement of IPA resistant gaskets will be used on metal to metal contact points (lids) on process vessels where possible.

C. Dryers

1. Current Process

Dryers numbered FD301 and FD302 are each equipped with a condenser where vapors are condensed and spent solvent is recovered. The temperature in both dryers is monitored during the drying process with hand-held bi-metal dial thermometers. The recovered solvent is pumped into Tank 316. The vacuum pumps from the condensers exhaust to a pipe that extends along an interior wall across the length of the Plant to the emission point outside on the south wall.

2. Improvements Being Implemented

None required by this Attachment.

D. Distillation of Recovered Solvent and Solvent Storage

1. Current Process

Liquid from Tank 316 is subsequently pumped to the distillation column where it is distilled and the solvent is recovered. Recovered solvent is stored in the recovered solvent Tank 318. The column, which is entirely enclosed, extends through the Plant's roof. The distillation column controls are in the control area in room 107. The top temperature and the bottom temperature is monitored. An audible alarm sounds throughout the Plant if the bottom temperature drops below the set point. There is a level alarm on the reflux drum, and flow alarms on the feed and steam streams. These alarms sound at the control panel in room 107 if readings are either over or under the set points.

The virgin, recovered, and spent solvent storage tanks are equipped with emergency relief valves and flame arrestors on the stacks that extend through the Plant

roof. The distillation column has an emergency rupture disk on the portion of the column extending through the roof.

2. Improvements Being Implemented

None required by this Attachment.