State of Ohio Environmental Protection Agency

RE: FINAL PERMIT TO INSTALL MODIFICATION **CERTIFIED MAIL**
FRANKLIN COUNTY

Street Address: 122 S. Front Street
Lazarus Gov. Center **TELE:** (614) 644-3020 **FAX:** (614) 644-2329
Mailing Address: Lazarus Gov. Center P.O. Box 1049

Application No: 01-08555

DATE: 9/17/2002

Ross Laboratories Ross Products Div
Leroy Edwards
585 Cleveland Ave
Columbus, OH 432151724

Enclosed Please find a modification to the Ohio EPA Permit To Install referenced above which will modify the terms and conditions.

You are hereby notified that this action by the Director is final and may be appealed to the Ohio Environmental Review Appeals Commission pursuant to Chapter 3745.04 of the Ohio Revised Code. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based. It must be filed within thirty (30) days after the notice of the Directors action. A copy of the appeal must be served on the Director of the Ohio Environmental Protection Agency within three (3) days of filing with the Commission. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
236 East Town Street, Room 300
Columbus, Ohio 43215

Very truly yours,
Michael W. Ahern
Michael W. Ahern, Supervisor
Field Operations and Permit Section
Division of Air Pollution Control

cc: **USEPA** **CDO**

STATE OF OHIO ENVIRONMENTAL PROTECTION AGENCY

Permit To Install **Issue Date: 9/17/2002**
Terms and Conditions **Effective Date: 9/17/2002**

FINAL ADMINISTRATIVE MODIFICATION OF PERMIT TO INSTALL 01-08555

Application Number:	01-08555
APS Premise Number:	0125040319
Permit Fee:	**$0**
Name of Facility:	Ross Laboratories Ross Products Div
Person to Contact:	Leroy Edwards
Address:	585 Cleveland Ave Columbus, OH 432151724

Location of proposed air contaminant source(s) [emissions unit(s)]:
585 Cleveland Ave
Columbus, **Ohio**

Description of proposed emissions unit(s):
Two aseptic filing lines.

The above named entity is hereby granted a modification to the permit to install described above pursuant to Chapter 3745-31 of the Ohio Administrative Code. Issuance of this modification does not constitute expressed or implied approval or agreement that, if constructed or modified in accordance with the plans included in the application, the above described source(s) of environmental pollutants will operate in compliance with applicable State and Federal laws and regulations, and does not constitute expressed or implied assurance that if constructed or modified in accordance with those plans included in the application, the above described source(s) of pollutants will be granted the necessary operating permits.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Director

Part I - GENERAL TERMS AND CONDITIONS

A. Permit to Install General Terms and Conditions

1. Compliance Requirements

The emissions unit(s) identified in this Permit to Install shall remain in full compliance with all applicable State laws and regulations and the terms and conditions of this permit.

2. Reporting Requirements Related to Monitoring and Record keeping Requirements

The permittee shall submit required reports in the following manner:

a. Reports of any required monitoring and/or record keeping information shall be submitted to the appropriate Ohio EPA District Office or local air agency.

b. Except as otherwise may be provided in the terms and conditions for a specific emissions unit, quarterly written reports of (a) any deviations (excursions) from emission limitations, operational restrictions, and control device operating parameter limitations that have been detected by the testing, monitoring, and record keeping requirements specified in this permit, (b) the probable cause of such deviations, and (c) any corrective actions or preventive measures which have been or will be taken, shall be submitted to the appropriate Ohio EPA District Office or local air agency. If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted quarterly, i.e., by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. (These quarterly reports shall exclude deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06.)

3. Records Retention Requirements

Each record of any monitoring data, testing data, and support information required pursuant to this permit shall be retained for a period of five years from the date the record was created. Support information shall include, but not be limited to, all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit. Such records may be maintained in computerized form.

4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon the premises of this source at any reasonable time for purposes of making inspections, conducting tests, examining records or reports pertaining to any emission of air contaminants, and determining compliance with any applicable State air pollution laws and regulations and the terms and conditions of this permit. The permittee shall furnish to the Director of the Ohio EPA, or an authorized

representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying, reopening or revoking this permit or to determine compliance with this permit. Upon verbal or written request, the permittee shall also furnish to the Director of the Ohio EPA, or an authorized representative of the Director, copies of records required to be kept by this permit.

5. Scheduled Maintenance/Malfunction Reporting

Any scheduled maintenance of air pollution control equipment shall be performed in accordance with paragraph (A) of OAC rule 3745-15-06. The malfunction of any emissions units or any associated air pollution control system(s) shall be reported to the appropriate Ohio EPA District Office or local air agency in accordance with paragraph (B) of OAC rule 3745-15-06. Except as provided in that rule, any scheduled maintenance or malfunction necessitating the shutdown or bypassing of any air pollution control system(s) shall be accompanied by the shutdown of the emissions unit(s) that is (are) served by such control system(s).

6. Permit Transfers

Any transferee of this permit shall assume the responsibilities of the prior permit holder. The appropriate Ohio EPA District Office or local air agency must be notified in writing of any transfer of this permit.

7. Air Pollution Nuisance

The air contaminants emitted by the emissions units covered by this permit shall not cause a public nuisance, in violation of OAC rule 3745-15-07.

8. Termination of Permit to Install

This Permit to Install shall terminate within eighteen months of the effective date of the Permit to Install if the owner or operator has not undertaken a continuing program of installation or modification or has not entered into a binding contractual obligation to undertake and complete within a reasonable time a continuing program of installation or modification. This deadline may be extended by up to 12 months if application is made to the Director within a reasonable time before the termination date and the party shows good cause for any such extension.

9. Construction of New Sources(s)

The proposed emissions unit(s) shall be constructed in strict accordance with the plans and application submitted for this permit to the Director of the Ohio Environmental Protection Agency. There may be no deviation from the approved plans without the express, written approval of the Agency. Any deviations from the approved plans or the above conditions may lead to such sanctions and penalties as provided under Ohio law. Approval of these plans does not constitute an assurance that the proposed facilities will operate in compliance with all Ohio laws and regulations. Additional facilities shall be installed upon orders of the Ohio

Environmental Protection Agency if the proposed sources cannot meet the requirements of this permit or cannot meet applicable standards.

If the construction of the proposed emissions unit(s) has already begun or has been completed prior to the date the Director of the Environmental Protection Agency approves the permit application and plans, the approval does not constitute expressed or implied assurance that the proposed facility has been constructed in accordance with the approved plans. The action of beginning and/or completing construction prior to obtaining the Director's approval constitutes a violation of OAC rule 3745-31-02. Furthermore, issuance of the Permit to Install does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. Approval of the plans in any case is not to be construed as an approval of the facility as constructed and/or completed. Moreover, issuance of the Permit to Install is not to be construed as a waiver of any rights that the Ohio Environmental Protection Agency (or other persons) may have against the applicant for starting construction prior to the effective date of the permit. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed facilities cannot meet the requirements of this permit or cannot meet applicable standards.

10. Public Disclosure

The facility is hereby notified that this permit, and all agency records concerning the operation of this permitted source, are subject to public disclosure in accordance with OAC rule 3745-49-03.

11. Applicability

This Permit to Install is applicable only to the emissions unit(s) identified in the Permit to Install. Separate application must be made to the Director for the installation or modification of any other emissions unit(s).

12. Best Available Technology

As specified in OAC Rule 3745-31-05, all new sources must employ Best Available Technology (BAT). Compliance with the terms and conditions of this permit will fulfill this requirement.

13. Source Operation and Operating Permit Requirements After Completion of Construction

a. If the permittee is required to apply for a Title V permit pursuant to OAC Chapter 3745-77, the permittee shall submit a complete Title V permit application or a complete Title V permit modification application within twelve (12) months after commencing operation of the emissions units covered by this permit. However, if the proposed new or

modified source(s) would be prohibited by the terms and conditions of an existing Title V permit, a Title V permit modification must be obtained before the operation of such new or modified source(s) pursuant to OAC rule 3745-77-04(D) and OAC rule 3745-77-08(C)(3)(d).

b. If the permittee is required to apply for permit(s) pursuant to OAC Chapter 3745-35, the source(s) identified in this Permit To Install is (are) permitted to operate for a period of up to one year from the date the source(s) commenced operation. Permission to operate is granted only if the facility complies with all requirements contained in this permit and all applicable air pollution laws, regulations, and policies. Pursuant to OAC Chapter 3745-35, the permittee shall submit a complete operating permit application within thirty (30) days after commencing operation of the source(s) covered by this permit.

14. Construction Compliance Certification

The applicant shall provide Ohio EPA with a written certification (see enclosed form) that the facility has been constructed in accordance with the Permit to Install application and the terms and conditions of the Permit to Install. The certification shall be provided to Ohio EPA upon completion of construction but prior to startup of the source.

15. Fees

The permittee shall pay fees to the Director of the Ohio EPA in accordance with ORC section 3745.11 and OAC Chapter 3745-78. The permittee shall pay all applicable Permit to Install fees within 30 days after the issuance of this Permit to Install.

B. Permit to Install Summary of Allowable Emissions

The following information summarizes the total allowable emissions, by pollutant, based on the individual allowable emissions of each air contaminant source identified in this permit.

SUMMARY (for informational purposes only)
TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

Pollutant	Tons Per Year
Hydrogen Peroxide	1.92

Emissions Unit ID: **P015**

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
P015 - Aseptic filling line w/wet scrubber (CAM 1)	OAC rule 3745-31-05(A)(3)	Hydrogen peroxide (H2O2) emissions shall not exceed 0.22 lb/hr and 0.96 ton/yr. See section A.2.a below.

2. Additional Terms and Conditions

2.a Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by the use of a wet scrubber and compliance with the parametric monitoring described in section B.1-3.

2.b The aseptic filling line shall employ an electrical lock-out system to ensure maximum capture and control of hydrogen peroxide emissions during production. A malfunction of either the scrubber blower fan or recirculating liquid pump shall cause an electrical lockout to prevent production.

B. Operational Restrictions

1. The pressure drop across the packed-bed scrubber shall be maintained within an acceptable range of no less than 0.2 and no greater than 1.4 inches of water, while the emissions unit is in operation.

2. The liquid level in the recycle tank of the wet scrubber shall be maintained at depth of no less than 4 inches, while the emissions unit is in operation.

3. In the event of a pressure drop alarm, the permittee shall evaluate the solids concentration in the recycle tank to ensure that solids are not depositing within the recycle tank or on the bed packing. The permittee shall clean or replace the bed packing annually.

C. Monitoring and/or Record keeping Requirements

1. The permittee shall properly operate and maintain equipment to monitor the pressure drop across the packed bed scrubber, while the emissions unit is in operation. The monitoring equipment shall be calibrated, operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals. The permittee shall record the following in an operations log on daily basis:

a. The pressure drop across the packed-bed scrubber for each day when the emission unit was in operation;

b. A log or record of the downtime for the control device and monitoring equipment, when the emissions unit was in operation;

c. The liquid level, in inches within the scrubber water reservoir tank; and

d. In the event of a pressure drop alarm, the permittee shall record a probable cause and any actions taken to return the packed-bed scrubber to an acceptable operating range.

2. The permit to install for these emissions units in this permit was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutants: hydrogen peroxide
TLV (ug/m^3): 1,389
Maximum Hourly Emission Rate (lbs/hr): 0.22 lb/hr
Predicted 1-Hour Maximum Ground-Level Concentration (ug/m^3): 29
MAGLC (ug/m^3): 33

Physical changes to or changes in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air Toxic Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will

still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in applying the "Air Toxic Policy" include the following:

a. Changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;

b. Changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and

c. Physical changes to the emissions unit or its exhaust parameters (e.g., increased/ decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

3. If the permittee determines that the "Air Toxic Policy" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01(VV)(1)(a)(ii), and a modification of the existing permit to install will not be required. If the change(s) is (are) defined as a modification under other provisions of the modification definition (other than (VV)(1)(a)(ii)), then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will still satisfy the "Air Toxic Policy":

a. A description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);

b. Documentation of its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and

c. Where computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

D. Reporting Requirements

1. In accordance with the General Terms and Conditions of this permit, the permittee shall submit quarterly deviation (excursion) reports that identify any periods of time during which the pressure drop across the packed-bed scrubber did not comply with the allowable range specified above and, if the pressure drop alarm sounds, a probable cause and any actions taken to return the packed-bed scrubber to an acceptable operating range..

E. Testing Requirements

1. Compliance with the emission limitations in section A..1 of these terms and conditions shall be determined in accordance with the following methods:

a. Emissions Limitation:
Hydrogen peroxide emissions shall not exceed 0.22 lb/hr.

Applicable Compliance Method:
The permittee shall demonstrate compliance with the hourly allowable emissions limitation through calculation using the ideal gas law: n(moles) = PV/RT; where: P = 1 atm; V= 3200 ft3/min; R = 0.02518 atm-ft3/ lb-R; T= 539 R (80 F) and n = 8.12 moles air/min * 29 lbs/mol = 235.5 lbs/min = 106.8 kg air/min * 1,000,000 mg/ 1 kg * 1 part/1,000,000 parts, therefore 1 ppm H2O2 = 106.8 mg air/min/453,600 mg/lb = 0.00024 lb/min and 14.8 ppm H2O2 highest hourly reading * 0.00024 lb/min = 0.0036 lb/min * 60 min/hr = 0.22 lb/hr.

b. Emissions Limitation:
Hydrogen peroxide emissions shall not exceed 0.96 ton/yr.

Applicable Compliance Method:
Compliance with the annual limitation shall be assumed as long as compliance with the hourly limitation is maintained (the annual limitation was calculated by multiplying the hourly emission rate by 8760 hours per year and dividing by 2000 pounds per ton).

F. Miscellaneous Requirements

None

Emissions Unit ID: **P016**

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
P016 - Aseptic filling line w/wet scrubber (CAM2)	OAC rule 3745-31-05(A)(3)	Hydrogen peroxide (H2O2) emissions shall not exceed 0.22 lb/hr and 0.96 ton/yr. See section A.2.a below.

2. Additional Terms and Conditions

2.a Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by the use of a wet scrubber and compliance with the parametric monitoring described in section B.1-3.

2.b The aseptic filling line shall employ an electrical lock-out system to ensure maximum capture and control of hydrogen peroxide emissions during production. A malfunction of either the scrubber blower fan or recirculating liquid pump shall cause an electrical lockout to prevent production.

B. Operational Restrictions

1. The pressure drop across the packed-bed scrubber shall be maintained within an acceptable range of no less than 0.2 and no greater than 1.4 inches of water, while the emissions unit is in operation.

2. The liquid level in the recycle tank of the wet scrubber shall be maintained at no less than 4 inches, while the emissions unit is in operation.

3. In the event of a of a pressure drop alarm, the permittee shall evaluate the solids concentration in the recycle tank to ensure that solids are not depositing within the recycle tank or on the bed packing. The permittee shall clean or replace the bed packing annually.

C. Monitoring and/or Record keeping Requirements

1. The permittee shall properly operate and maintain equipment to monitor the pressure drop across the packed bed scrubber, while the emissions unit is in operation. The monitoring equipment shall be calibrated, operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals. The permittee shall record the following in an operations log on daily basis:

a. The pressure drop across the packed-bed scrubber for each day when the emission unit was in operation;

b. A log or record of the downtime for the control device and monitoring equipment, when the emissions unit was in operation;

c. The liquid level, in inches below the cover, within the scrubber water reservoir tank; and

d. In the event of a pressure drop alarm, the permittee shall record a probable cause and any actions taken to return the packed-bed scrubber to an acceptable operating range.

2. The permit to install for the emissions unit in this permit was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutants: hydrogen peroxide
TLV (ug/m^3): 1,389
Maximum Hourly Emission Rate (lbs/hr): 0.22 lb/hr
Predicted 1-Hour Maximum Ground-Level Concentration (ug/m^3): 29
MAGLC (ug/m^3): 33

Physical changes to or changes in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air

Toxic Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in applying the "Air Toxic Policy" include the following:

a. Changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;

b. Changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and

c. Physical changes to the emissions unit or its exhaust parameters (e.g., increased/ decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

3. If the permittee determines that the "Air Toxic Policy" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01(VV)(1)(a)(ii), and a modification of the existing permit to install will not be required. If the change(s) is (are) defined as a modification under other provisions of the modification definition (other than (VV)(1)(a)(ii)), then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will still satisfy the "Air Toxic Policy":

a. A description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);

b. Documentation of its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and

c. Where computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

Emissions Unit ID: **P016**

D. Reporting Requirements

1. In accordance with the General Terms and Conditions of this permit, the permittee shall submit quarterly deviation (excursion) reports that identify any periods of time during which the pressure drop across the packed-bed scrubber did not comply with the allowable range specified above and if the pressure drop alarm sounds, a probable cause and any actions taken to return the packed-bed scrubber to an acceptable operating range.

E. Testing Requirements

1. Compliance with the emission limitations in section A..1 of these terms and conditions shall be determined in accordance with the following methods:

a. Emission Limitation:
Hydrogen peroxide emissions shall not exceed 0.22 lb/hr.

Applicable Compliance Method:
The permittee shall demonstrate compliance with the hourly allowable emissions limitation through calculation using the ideal gas law: n(moles) = PV/RT; where: P = 1 atm; V= 3200 ft3/min; R = 0.02518 atm-ft3/ lb-R; T= 539 R (80 F) and n = 8.12 moles air/min * 29 lbs/mol = 235.5 lbs/min = 106.8 kg air/min * 1,000,000 mg/ 1 kg * 1 part/1,000,000 parts, therefore 1 ppm H2O2 = 106.8 mg air/min/453,600 mg/lb = 0.00024 lb/min.
14.8 ppm H2O2 highest hourly reading * 0.00024 lb/min = 0.0036 lb/min * 60 min/hr = 0.22 lb/hr.

b. Emission Limitation:
Hydrogen peroxide emissions shall not exceed 0.96 ton/yr.

Applicable Compliance Method:
Compliance with the annual limitation shall be assumed as long as compliance with the hourly limitation is maintained (the annual limitation was calculated by multiplying the hourly emission rate by 8760 hours per year and dividing by 2000 pounds per ton).

F. Miscellaneous Requirements

None