



State of Ohio Environmental Protection Agency

Northeast District Office

2110 East Aurora Rd.
Twinsburg, Ohio 44087

TELE: (330) 963-1200 FAX: (330) 487-0769
www.epa.state.oh.us

Ted Strickland, Governor
Lee Fisher, Lieutenant Governor
Chris Korleski, Director

EH+S Bill Contenza, Monday

February 19, 2009

Monica Thayer HR Director

~~██████████~~
~~██████████~~

440/357-3020

Bill Contenza 357-3137

← no longer employed

RE: NPDES PERMIT NO. 31E00004
APPLICATION NO. OH0037982
RICERCA, INC.
LAKE COUNTY
INDUSTRIAL

Mr. Steve Rohrer, Director
Environmental Health & Safety
Ricerca Biosciences, LLC
7528 Auburn Road
Concord, OH 44077

*~~Steve Rohrer~~ or Bill Contenza
(440) 357-3021*

Dear Mr. Rohrer:

On February 18, 2009, this writer conducted a pre-permit inspection of Ricerca, Biosciences Incorporated (Ricerca). The inspection was prompted by the renewal of the National Pollutant Discharge Elimination System (NPDES) permit. You and Mr. William Contenza accompanied this writer during the inspection.

Ricerca provides, on a contractual basis, research and development services primarily to the pharmaceutical industries. There are over 300 employees working at the facility. Potable water is supplied by the City of Painesville. Sanitary and process wastewaters are treated at the Gary L. Kron Water Reclamation Facility. There are three outfalls at the company which discharge to an unnamed tributary of Ellison Creek. All three outfalls, Outfalls 002, 003 and 004 discharge storm water to the creek. The noncontact cooling water discharge which previously discharged from Outfall 003, is now connected to the sanitary sewer.

This writer inspected the Product Development Building (Building B) yard. The yard contains drums that are stored outdoors on skids. These drums are not stored in diked areas. A storm water drain exists in the open area of the yard. In the event of a spill, the drain is covered, by employees, to prevent the spill from entering waters of the state. The drums are inspected on a weekly basis.

One enclosed storage unit housing drums presently exists in the yard. Ricerca has purchased an additional storage unit that will be used to house the remaining drums that are stored outdoors. The additional storage unit should arrive in approximately one month and has a 160 drum storage capacity. Ricerca's goal is to remove from the outdoors, drums that are directly exposed to the elements.

According to the Ricerca's Storm Water Pollution Prevention Plan, employees are provided emergency training when they are first hired and yearly, thereafter. However, no documentation is available supporting the annual training. This is a violation of the

Mr. Steve Rohrer
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NPDES permit that must be corrected. This writer encourages you to carefully read the NPDES permit, particularly Parts IV, V and VI which cover the requirements for storm water discharges.

A review of the plant's Discharge Monitoring Reports (DMRs) revealed the following sampling frequency violations during the period of March 1, 2004 through January 2009:

Station	Reporting Code	Parameter	Sample Frequency	Expected	Reported	Violation Date
003	50050	Flow Rate	1/Month	1	0	01/01/2006
003	50050	Flow Rate	1/Month	1	0	05/01/2007
003	50050	Flow Rate	1/Month	1	0	11/01/2007

Be advised that failure to comply with the effluent limitations or to satisfy the monitoring or reporting and compliance scheduling requirements of your NPDES permit may be cause for enforcement pursuant to Ohio Revised Code Chapter 6111.

The NPDES permit will be drafted soon. When the permit is public noticed, please review it carefully. A 30-day comment period will be provided. All comments must be in writing and directed to this district office.

Within 10 days of the date of this letter, you are directed to notify this office, in writing, outlining the corrective action, either actual or proposed, that will be taken to eliminate the above highlighted deficiencies.

Should you have any questions, please contact the undersigned at (330) 963-1183.

Sincerely,



Marie Underwood, P.E.
Environmental Engineer
Division of Surface Water

MU/mt

We develop drugs...and relationships.

February 28, 2009

Ms. Marie Underwood, P.E.
Environmental Engineer
Ohio EPA
Division of Surface Water
Northeast District Office
2110 East Aurora Road
Twinsburg, OH 44087

RECEIVED
OHIO EPA
MAR - 8 2009

Dear Ms. Underwood:

Thank you for promptly sending us the report on your pre-permit SWPPP inspection of the Ricerca Biosciences campus on February 18, 2009.

OHIO EPA

The report states that documentation was not available demonstrating that employees had received the annual NPDES and SWPPP training. Ricerca will take the following corrective actions regarding this violation:

1. By June 1, 2009 the EH&S Director will prepare training material, (lecture notes, PowerPoint slides, and handout), that covers the following topics:
 - a. Purpose, contents and location of Ricerca's SWPPP.
 - b. Employee responsibilities and proper storage/process practices.
 - c. Emergency response for spills so material does not enter the storm system.
 - d. Housekeeping requirements for storage and process areas.
 - e. Inspections of storage and process areas.
2. By November 1, 2009 all Ricerca employees will have received the above training via classroom or intranet computer-based training.
3. By December 1, 2009 records for each trained employee will be on file in the EH&S Office or on the QA Training Database.

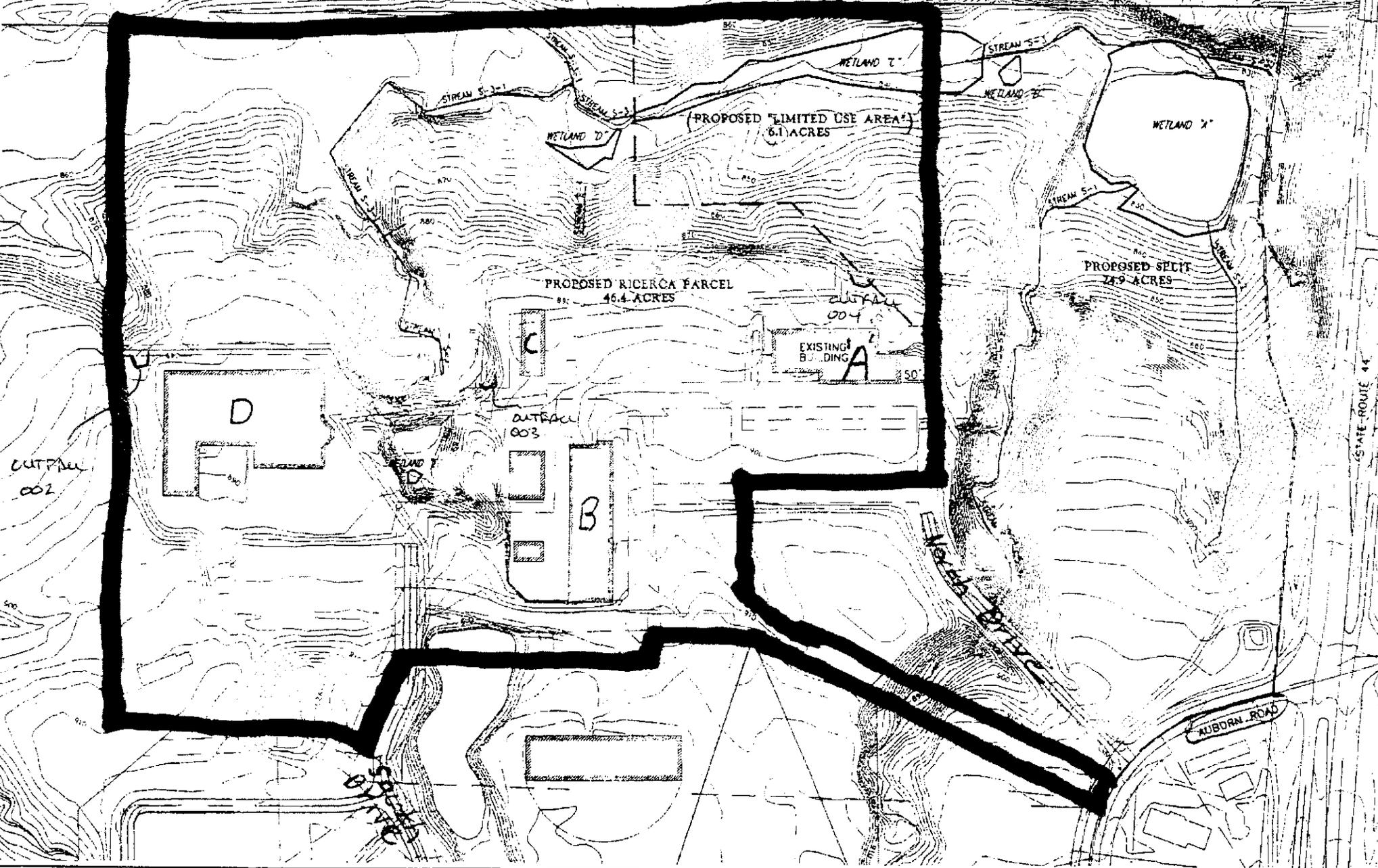
Call me at 440-357-3021 if you have any questions or need additional information.

Steve Rohrer

Steve Rohrer, Ph.D.
EH&S Director
Ricerca Biosciences

srh

Ricerca Biosciences, LLC • 7528 Auburn Road, Concord, OH 44077 USA
www.ricerca.com • Phone 440-357-3300 • Fax 440-354-6276



REV	DESCRIPTION	DATE	BY	CHK'D BY