



CORDENPHARMA COLORADO

ENVIRONMENTAL PROGRAMS STATUS REPORT

June 2021



Introduction

Status Report History and Purpose

The annual Environmental Programs Status Report (Status Report), which was first issued in 1998, is part of the voluntary pollution prevention program at CordenPharma Colorado. The Status Report serves as an update to the City of Boulder and Boulder County on the current status and results of CordenPharma Colorado's pollution prevention activities. The Status Report also meets the requirements of City of Boulder municipal code 10-7.7-8(a)(1). The goal is to provide our stakeholders and the general public with an understanding of CordenPharma Colorado's environmental footprint. The Status Report also demonstrates CordenPharma Colorado's commitment to continuous improvement in our operations, both benefitting the patients who depend on the medicines CordenPharma Colorado produces and also protecting the environment. As always, a copy of the latest Environmental Programs Status Report is available for general public review on our website, www.cordenpharma.com/facilities/colorado.

Status Report Summary

In 2020, CordenPharma Colorado increased the production of bulk pharmaceuticals and pharmaceutical intermediates by 8 percent from 2019. As a result, there were negative trends in several environmental figures that directly correlate to production rates. However, because of the different environmental impacts of each process, some environmental figures reflect positive trends due to changes in the mix of products produced as well as pollution prevention efforts. Particularly noteworthy are the Process Waste Minimization Goals achieved, which have resulted in significant process improvements to reduce hazardous waste generation from processes with complex chemistry that requires more solvent than historical processes.

From 2019 to 2020, total bulk liquid sent offsite increased by 97 percent, however, the percentage sent offsite for the beneficial purposes of recycling or energy recovery improved from 92 percent to 97 percent. Additional changes from 2019 to 2020 include a 2 percent decrease in energy usage and a 35 percent increase in volatile organic compound emissions. Details can be found in the Summary Tables, beginning on page 12.

Status Report Outline

The remainder of this Status Report includes the following sections:

- **2020 Activity Background**
- **Environmental Compliance and Regulatory Status Changes**
- **Pollution Prevention Goals and Objectives**
- **2020 Summary Tables**

2020 Activity Background

This section of the Environmental Programs Status Report details the production and technical development activities at CordenPharma Colorado and the voluntary environmental performance programs in which the company participates.

Production Activities Summary

CordenPharma Colorado is a member of the CordenPharma Group. The CordenPharma Group includes a network of international companies that manufacture bulk intermediates, active ingredients, and final prescription and over-the-counter medicines.

The current focus of CordenPharma Colorado's activities is the contract production of therapeutic peptides, highly active compounds, and complex small molecules. CordenPharma Colorado sends the compounds it produces to other manufacturing sites for formulation into finished pharmaceutical products. As a multi-purpose facility that can handle small and large scale production, the medicinal compounds that CordenPharma Colorado manufactures frequently change in response to market demand and the development of new therapeutic innovations.

Technical Development Activities

CordenPharma Colorado's technical development activities include designing of manufacturing processes for intermediates and APIs that produce high purity medicinal compounds, while optimizing cost, reliability and safety. These same development activities also have environmental benefits:

- Improving the inherent safety of our manufacturing processes often entails the discovery and development of chemical synthesis routes that minimize or eliminate the use of environmentally undesirable materials.
- The improved synthesis routes that CordenPharma Colorado scientists design also can help avoid high pressure and high temperature process conditions, with both safety benefits and energy savings.
- Starting with the simplest materials as building blocks for our products and improving the efficiency of our manufacturing processes minimizes the demand for raw materials.
- Maximizing the ability of our existing equipment to manufacture pharmaceutical products minimizes the need to construct and operate new facilities.

CordenPharma Colorado's technical development facilities include both laboratories for process research and pilot scale production facilities for manufacturing drug compounds in the quantities necessary for approval by regulatory agencies, to supply the clinical trials for new drugs, and to demonstrate new manufacturing processes.

Voluntary Environmental Performance Programs

CordenPharma Colorado participates in a variety of federal, state, local, and industry-wide initiatives that set challenging pollution prevention standards. The following are the pollution prevention programs in which CordenPharma Colorado currently participates:

City of Boulder Pollution Prevention Program

CordenPharma Colorado has been a voluntary participant in the City of Boulder's Pollution Prevention Program since its inception. Participation in the Pollution Prevention Program began with the development of a "Pollution Prevention Master Plan and Statement of Commitments" and the setting of specific pollution reduction goals. CordenPharma Colorado tracks the success of its environmental initiatives as a founding participant in the Pollution Prevention Program through this annual report to the City of Boulder, now titled "Environmental Programs Status Report."

Colorado Environmental Leadership Recognition

The State of Colorado's Environmental Leadership certification recognizes companies that voluntarily perform above and beyond existing mandated environmental regulations. Environmental Leaders like CordenPharma Colorado must have a comprehensive and operational environmental management system and a pollution prevention plan that commits the company to a program of continuous environmental improvement. In its letter announcing the Environmental Leadership certification, the Colorado Department of Public Health and Environment thanked CordenPharma Colorado for the "effort and dedication" it brings to environmental issues. Under the Environmental Leadership program, CordenPharma Colorado has participated in statewide pollution prevention workshops and mentoring programs. Since 2003, CordenPharma Colorado has held the highest environmental honor that the State of Colorado bestows, the title of "Gold Level" Environmental Leader.

ISO 14001 Certification

CordenPharma Colorado obtained certification under the ISO 14001 standard in 2006 and has maintained the certification since that time. CordenPharma Colorado earned and maintains its ISO 14001 certification through a comprehensive independent audit of the company's environmental, health, safety, and security management system.

Colorado Industrial Energy Challenge

In 2010, CordenPharma Colorado became a Charter Member of the Colorado Industrial Energy Challenge (CIEC) program. CIEC is a voluntary program sponsored by the Colorado Energy Office (CEO) and the U.S. Department of Energy (DOE). The program challenges industrial firms to set energy efficiency goals and to demonstrate progress towards achieving their goals. CordenPharma Colorado was awarded an "Excellence in Energy Efficiency" award in 2012, and again in 2017, for its energy reduction efforts.

Volunteer Work with Boulder County Parks and Open Space

CordenPharma Colorado has been supporting Boulder County Open Space (BCOS) since 2009. Each year, CordenPharma Colorado employees, along with their friends and families, volunteer to spend a day or two working to maintain and improve various open spaces. Employees have built fences, repaired trails, collected native seeds, fixed bridges, restored burned slash pile areas, removed infected trees, and worked on whatever else might be needed.

Environmental Compliance or Regulatory Status Changes

There was no change in CordenPharma Colorado's compliance or regulatory status in 2020.

Pollution Prevention Goals and Objectives

CordenPharma Colorado is committed to pursuing pollution prevention goals associated with our energy reduction, process waste minimization, and other pollution prevention efforts. This section details the progress CordenPharma Colorado made in 2020 towards these goal categories, including specific program achievements and plans for further action in 2021 and 2022.

Energy Reduction Goals

Due to recent increases in energy demand driven by facility improvements and growth of the business, energy reduction has been a challenge. From 2019 to 2020, the company decreased onsite energy consumption by 2 percent. However, energy consumption at CordenPharma Colorado has decreased 16 percent since 2005 when the company's original energy goals were set.

CordenPharma Colorado continues to identify, evaluate, and implement energy reduction measures. A number of initiatives have been completed over the last ten years that were highly effective. The following recent objectives are underway to continue to support energy reduction:

Objective 1a: Implement a new standard for lighting in office and manufacturing buildings, where LED lights will be used in new installations. This will result in lower energy consumption.

Achievement: CordenPharma Colorado has implemented the new lighting standard and over the last several years has installed many LED lights for specific applications to collect data on performance and functionality. In 2019, in the office areas, the T-8 lighting system replacement program progressed. A keystone Smart Drive LED system is being utilized that allows direct replacement into ballasted systems. Assuming 25 percent utilization, this saves 20 kilowatt-hour per year per bulb. This allows the changeover to continue with minimal disruption to the office areas. In 2019, 1129 units were purchased, which annualized saves approximately 23,000 KWH of electricity per year.

In 2020, a plan was developed to accelerate the lighting conversion of both the office and production areas. This led to a capital project investment approval of \$150K in 2021 above the normal light replacement funding, in addition to other capital projects with funding for lighting upgrades, as well as additional capital planned for future years. These lighting investments will target the entire plant-site and will ensure that both Corden Pharma goals of lighting improvements and industrial campus requirements are met on schedule.

Process Waste Minimization Goals

CordenPharma Colorado strives to reduce the solvent waste and air emissions its pharmaceutical manufacturing processes generate. The company achieves these goals by modifying manufacturing processes to reduce the need for production material, recycling materials for re-use, controlling air emissions, and many other process waste minimization efforts. Over the years, CordenPharma Colorado has successfully reduced the process waste from many manufacturing steps. The following specific objectives were identified to further advance these efforts in 2020 and 2021.

Objective 2a: Evaluate three solvent waste streams in a specific manufacturing process for on-site recycle. Heptane, MTBE, and ethyl acetate, which are used in a manufacturing process, will be evaluated for recycling feasibility and implemented if possible.

Achievement: Laboratory studies and engineering evaluations were completed, and ethyl acetate was identified as a likely viable solvent recycle operation for this process. Unfortunately the specific product demand was reduced, and this effort is no longer being pursued. However if the demand returns, demonstration of this recycling will be completed.

Objective 2b: Reduce solvent usage in one process manufacturing step by increasing the ratio of product to solvent during process purification.

Achievement: Complete. Implemented in April 2021. The process is now saving approximately 650 liters of solvent per kilogram of product produced. This represents 28 percent less solvent being used for the purification step. As much as 2.6 million liters of waste solvent will be avoided throughout the remainder of 2021 due to this process improvement.

Objective 2c: Evaluate two solvent waste streams in a specific manufacturing process for on-site or off-site recycle. DMF and acetonitrile, which are used in the manufacturing process, will be evaluated for recycling feasibility during the scale-up of this process.

Achievement: Engineering evaluations have been completed, as well as initial evaluation of off-site recycling. Acetonitrile recovery will be demonstrated in the plant in a future production campaign. DMF will require more development work to determine viability. Additionally, physical piping improvements are planned to logistically support more off-site recycle.

Objective 2d: Evaluate one process wastewater stream for treatment in the CordenPharma Colorado onsite wastewater treatment plant instead of being shipped offsite for incineration.

Achievement: Utilizing a new wastewater treatment pilot system, treatability studies were completed in 2019. Unfortunately, onsite wastewater treatment does not appear to be feasible for this stream. Instead, an offsite byproduct recovery program has been identified, and CordenPharma Colorado is scheduled to begin shipping the byproduct stream later in 2021.

Objective 2e: Evaluate one process manufacturing step for a reduction in acetonitrile usage. If viable, the target will be a 50 percent reduction in acetonitrile usage in this step of the process.

Objective 2f: Reduce solvent waste from a process manufacturing step by directly re-using it as a byproduct in a secondary market.

Achievement: Complete. Physical changes were made to the manufacturing plant piping to allow for segregation and shipment of this byproduct stream, which began shipping in April 2021. In the first month, over 90,000 gallons of byproduct were shipped offsite for a beneficial re-use.

Objective 2g: Evaluate the feasibility to recycle and reuse waste solvent from one process manufacturing step into a different step of the same process. The project has the potential to reuse over 200,000 liters of solvent per month, eliminating that volume of solvent waste.

Objective 2h: Evaluate two process waste streams containing iodide for use as a byproduct for recovery into a secondary market.

Achievement: In 2021, an outlet for this stream was identified, allowing for offsite reuse. This effort is expected to reduce waste by over 40,000 kilograms in 2021.

Objective 2i: Reduce the volume of waste generated by two manufacturing process steps by expanding the streams treated in the onsite wastewater treatment plant.

Achievement: Complete. One process change was implemented in 2020, and another in May of 2021, reducing the volume of hazardous waste generated by these two manufacturing process steps.

Objective 2j: Modify a process manufacturing step in a way that dries a wet silica, both reducing the total weight of the waste stream and also making it non-hazardous.

Achievement: Complete. This change was implemented in 2021, and now 200 kilograms per batch of hazardous waste is avoided.

Other Pollution Prevention Activities

In addition to the projects and plans mentioned above, all CordenPharma Colorado process teams continue to identify and evaluate pollution prevention opportunities in their areas of expertise. The Pollution Prevention Team supports and tracks all pollution prevention efforts at CordenPharma Colorado, with a focus on reducing energy consumption and solvent usage and increasing solvent recovery in production processes.

2020 Summary Tables

2020 Production at CordenPharma Colorado

In 2020, as measured by mass, CordenPharma Colorado increased the production of bulk pharmaceuticals and pharmaceutical intermediates by 8 percent from 2019. At the same time, the company's raw materials usage also increased by 112 percent. The environmental figures below reflect the result of both CordenPharma Colorado's production changes as well as the company's implementation of pollution prevention measures.

Recycling of Raw Materials – Onsite Recycling

The table below compares process requirements and recycling volumes for chemicals that were recycled onsite. The "process requirement" represents the amount of each material needed during the year. The "amount recycled" reflects the reuse of a compound in a process, rather than disposing of it. The "percentage recycled" is the percentage of the process requirement that was met using recycled material instead of virgin material.

Chemical ¹	Usage (lbs)	Amount Recycled (lbs)	Percentage Recycled
Methanol	1,565,000	236,000	15%

¹ Offsite recycling is not included in this list. See table below, "Bulk Liquid Sent Offsite- Waste and Recycling"

Water Usage

The following table details water use at CordenPharma Colorado.

Type of Usage	2016 (gallons)	2017 (gallons)	2018 (gallons)	2019 (gallons)	2020 (gallons)
Process	19,019,464	20,893,779	17,414,096	20,613,118	20,378,551
Commercial	1,655,609	1,838,633	1,930,145	2,433,331	3,028,291
Cooling	7,853,316	8,230,401	10,221,153	11,042,487	11,100,029
Irrigation	1,459,250	1,587,350	1,513,788	1,751,800	1,773,700
Total	29,987,639	32,550,163	31,079,183	35,840,736	36,280,571

Wastewater Pretreatment Plant Discharge

CordenPharma Colorado sends aqueous wastes from production activities through its onsite pretreatment facility. Wastewater leaving the system is discharged to the City of Boulder treatment facility. The following table lists the major components of the wastewater that CordenPharma Colorado discharges to the City of Boulder treatment facility.

	Discharge (in Pounds unless otherwise indicated)					
	1995 (Baseline)	2016	2017	2018	2019	2020
Volume, gal	21,035,000	7,378,314	8,752,348	9,720,383	11,107,944	12,554,033
Total Organic Content (TOC)	115,000	3,673	3,878	6,504	5,990	6,247
Chromium	31	1.3	1.0	1.1	1.0	1.2
Copper	4.3	16.6	10.4	11.2	11.5	9.5
Lead	2.8	3.1	3.6	0.0	0.0	1.3
Nickel	4.1	1.8	2.6	2.9	2.8	3.1
Zinc	73	55.6	40.0	51.7	42.1	45.5

Bulk Liquid Sent Offsite - Waste Disposal and Recycling

The following values represent the amount of material CordenPharma Colorado sent offsite in bulk quantities for recycling, energy recovery, or incineration. Due to an increase in production, a change in production mix, and the different solvents required for each product, from 2019 to 2020, the total bulk liquid sent offsite increased by 97 percent, and bulk liquid sent offsite per unit of product produced increased by 82 percent. However, the percentage sent offsite for the beneficial purposes of recycling or energy recovery improved from 92 percent to 97 percent.

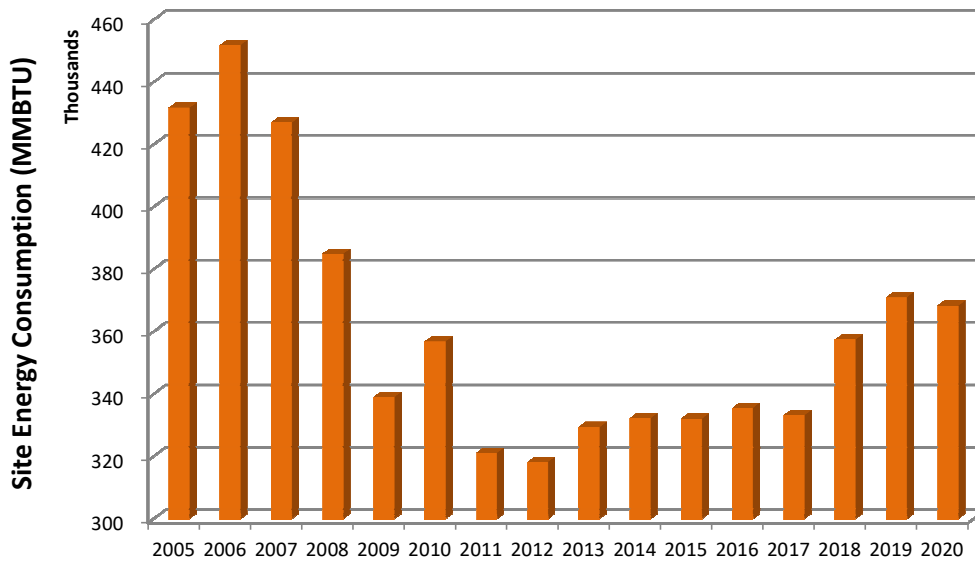
Description	2016	2017	2018	2019	2020
Total bulk liquid sent offsite (kg)	1,704,338	2,587,731	3,401,666	4,768,507	9,401,938
% Change from previous year	-27%	+52%	+31%	+40%	+97%
% Sent offsite for recycling	0%	1%	0%	0.4%	0%
% Sent offsite for energy recovery	71%	53%	72%	92%	97%

Energy Consumption

The following table presents the standard energy metrics of natural gas and electricity consumption at CordenPharma Colorado. From 2019 to 2020, natural gas usage decreased and electricity increased slightly.

Energy Type	2016	2017	2018	2019	2020
Natural Gas (therms)	1,135,760	1,083,400	1,180,350	1,350,160	1,283,270
Electricity (KWH)	22,469,916	22,484,035	23,735,366	23,596,124	23,997,928

Combined Onsite Energy Use (Electricity & Natural Gas)



NOTE: Electricity unit conversions made using Colorado Industrial Energy Challenge methodology, accounting for typical coal plant thermal efficiency.

Air Emissions

The following table displays CordenPharma Colorado's air emissions, divided into Toxic Release Inventory (TRI) compounds, Hazardous Air Pollutants (HAPs), and Volatile Organic Compounds (VOCs). From 2019 to 2020, overall VOC emissions increased by 35 percent and HAP emissions increased by 25 percent. An overall increase in production and differences in products manufactured resulted in the increase.

	1989 (Baseline)	2016	2017	2018	2019	2020
Acetone ³	242,500	3,200	3,700	5,200	4,130	640
Acetonitrile ^{1,2}	--	2,100	2,700	5,100	8,800	9,400
Dimethylformamide ^{1,2}	--	150	190	280	1,120	2,100
1,4-Dioxane ^{1,2}	--	260	250	620	570	2
Hexane ^{1,2}	36,600	1,400	950	100	1,450	470
Hydrochloric acid ¹	4,000	190	160	160	390	350
Methanol ^{1,2}	109,600	4,900	4,790	6,000	6,420	6,600
Methyl chloride ^{1,2}	6,700	--	--	--	--	--
n-Methyl-2-pyrrolidinone ²	--	7	3	40	5	5
Methyl Tert-Butyl Ether ^{1,2}	--	680	1060	1,750	3,420	7,000
Methylene chloride ¹	103,300	1,230	850	1,270	1,240	2,100
Pyridine ²	--	3	0	1	--	--
Toluene ^{1,2}	284,400	240	220	730	640	1,300
Triethylamine ^{1,2}	--	19	20	30	30	1
Total TRI air emissions (tons)	375	5	6	8	12	14
% change from previous year	--	-55%	+20%	+33%	+50%	17%
% change from 1989	--	-99%	-98%	-98%	-97%	-96%

Total HAP emissions (tons)	293	6	6	8	12	15
% change from previous year	--	-45%	0%	+33%	+50%	+25%
% change from 1989	--	-98%	-98%	-97%	-96%	-95%

Total VOC emissions (tons)	490	8	10	16	20	27
% change from previous year	--	-38%	+25%	+60%	+25%	+35%
% change from 1989	--	-98%	-98%	-97%	-96%	-94%

¹ These chemicals are also classified as HAPs and are included in the HAP total above.

² These chemicals are also classified as VOCs and are included in the VOC total above.

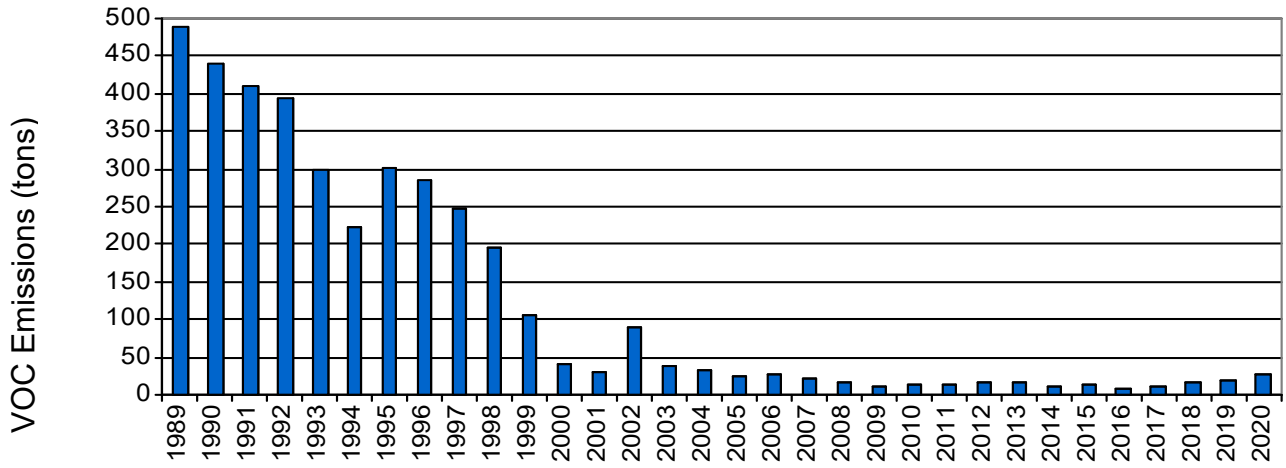
³ Acetone is no longer included in TRI. It is also no longer classified as a VOC. After 1996, it is not included in the VOC total.

⁴ Shaded blocks indicate that TRI reporting for that chemical was not required during that year. They are not included in the TRI emissions total.

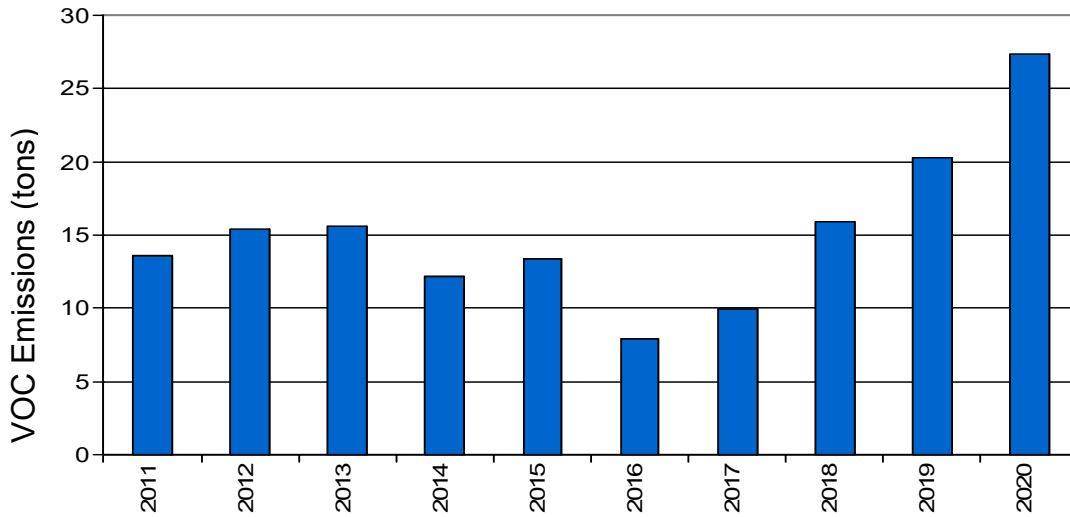
HAP = Hazardous Air Pollutant

VOC = Volatile Organic Compound

Volatile Organic Compounds (VOC) Air Emissions Trend, since 1989



Volatile Organic Compounds (VOC) Air Emissions Trend, Last 10 Years



General Waste Recycling

In 2020, CordenPharma Colorado recycled a considerable amount of general waste. The recycled metals volume presented here includes recycling of removed manufacturing equipment. In 2020, CordenPharma Colorado recycled about 54,500 pounds of office paper, shredded documentation, newspaper, cardboard, magazines, and phone books. These efforts helped CordenPharma Colorado save an estimated 464 trees from destruction.

Type of Material	Pounds Recycled
Paper and Cardboard	54,500
Metals	164,000
Plastic	1,600
Compost	~10,000