VI. SUMMARY OF APPLICABLE FEDERAL STATUTES AND REGULATIONS

This section discusses the Federal regulations that may apply to this sector. The purpose of this section is to highlight and briefly describe the applicable Federal requirements, and to provide citations for more detailed information. The three following sections are included:

Section VI.A contains a general overview of major statutes
Section VI.B contains a list of regulations specific to this industry
Section VI.C contains a list of pending and proposed regulations
Section VI.D contains a general overview of other federal statutes applicable to the industry
Section VI.E. contains a general overview of state regulations affecting the industry.

The descriptions within Section VI are intended solely for general information. Depending upon the nature or scope of the activities at a particular facility, these summaries may or may not necessarily describe all applicable environmental requirements. Moreover, they do not constitute formal interpretations or clarifications of the statutes and regulations. For further information readers should consult the Code of Federal Regulations and state or local regulatory agencies. EPA Hotline contacts are also provided for each major statute.

VI.A. General Description of Major Statutes

Resource Conservation And Recovery Act (RCRA)

RCRA of 1976, which amended the Solid Waste Disposal Act, addresses solid (Subtitle D) and hazardous (Subtitle C) waste management activities. The Hazardous and Solid Waste Amendments (HSWA) of 1984 strengthened RCRA's waste management provisions and added Subtitle I, which governs underground storage tanks (USTs).

Regulations promulgated pursuant to Subtitle C of RCRA (40 CFR Parts 260-299) establish a "cradle-to-grave" system governing hazardous waste from the point of generation to disposal. RCRA hazardous wastes include the specific materials listed in the regulations (commercial chemical products, designated with the code "P" or "U"; hazardous wastes from specific industries/sources, designated with the code "K"; or hazardous wastes from non-specific sources, designated with the code "F") or materials which exhibit a hazardous waste characteristic (ignitability, corrosivity, reactivity, or toxicity and designated with the code "D").

Regulated entities that generate hazardous waste are subject to waste accumulation, manifesting, and record keeping standards. Facilities must

obtain a permit either from EPA or from a State agency which EPA has authorized to implement the permitting program if they store hazardous wastes for more than 90 days before treatment or disposal. Facilities may treat hazardous waste stored in less-than-ninety-day tanks or containers without a permit. Subtitle C permits contain general facility standards such as contingency plans, emergency procedures, record keeping and reporting requirements, financial assurance mechanisms, and unit-specific standards. RCRA also contains provisions (40 CFR Part 264 Subpart S and §264.10) for conducting corrective actions which govern the cleanup of releases of hazardous waste or constituents from solid waste management units at RCRA-regulated facilities.

Although RCRA is a Federal statute, many States implement the RCRA program. Currently, EPA has delegated its authority to implement various provisions of RCRA to 47 of the 50 States and to two U.S. territories. Delegation has not been given to Alaska, Hawaii, or Iowa.

Most RCRA requirements are not industry specific but apply to any company that generates, transports, treats, stores, or disposes of hazardous waste. Here are some important RCRA regulatory requirements:

Identification of Solid and Hazardous Wastes (40 CFR Part 261) lays out the procedure every generator should follow to determine whether the material in question created is considered a hazardous waste, solid waste, or is exempted from regulation.

Standards for Generators of Hazardous Waste (40 CFR Part 262) establishes the responsibilities of hazardous waste generators including obtaining an EPA ID number, preparing a manifest, ensuring proper packaging and labeling, meeting standards for waste accumulation units, and record keeping and reporting requirements. Generators can accumulate hazardous waste for up to 90 days (or 180 days depending on the amount of waste generated) without obtaining a permit.

Land Disposal Restrictions (LDRs) (40 CFR Part 268) are regulations prohibiting the disposal of hazardous waste on land without prior treatment. Under the LDRs program, materials must meet LDR treatment standards prior to placement in a RCRA land disposal unit (landfill, land treatment unit, waste pile, or surface impoundment). Generators of waste subject to the LDRs must provide notification of such to the designated TSD facility to ensure proper treatment prior to disposal.

Used Oil Management Standards (40 CFR Part 279) impose

management requirements affecting the storage, transportation, burning, processing, and re-refining of the used oil. For parties that merely generate used oil, regulations establish storage standards. For a party considered a used oil processor, re-refiner, burner, or marketer (one who generates and sells off-specification used oil), additional tracking and paperwork requirements must be satisfied.

RCRA contains unit-specific standards for all units used to store, treat, or dispose of hazardous waste, including **Tanks and Containers**. Tanks and containers used to store hazardous waste with a high volatile organic concentration must meet emission standards under RCRA. Regulations (40 CFR Part 264-265, Subpart CC) require generators to test the waste to determine the concentration of the waste, to satisfy tank and container emissions standards, and to inspect and monitor regulated units. These regulations apply to all facilities that store such waste, including large quantity generators accumulating waste prior to shipment off-site.

Underground Storage Tanks (USTs) containing petroleum and hazardous substances are regulated under Subtitle I of RCRA. Subtitle I regulations (40 CFR Part 280) contain tank design and release detection requirements, as well as financial responsibility and corrective action standards for USTs. The UST program also includes upgrade requirements for existing tanks that must be met by December 22, 1998.

Boilers and Industrial Furnaces (BIFs) that use or burn fuel containing hazardous waste must comply with strict design and operating standards. BIF regulations (40 CFR Part 266, Subpart H) address unit design, provide performance standards, require emissions monitoring, and restrict the type of waste that may be burned.

EPA's RCRA/Superfund/UST Hotline, at (800) 424-9346, responds to questions and distributes guidance regarding all RCRA regulations. The RCRA Hotline operates weekdays from 9:00 a.m. to 6:00 p.m., ET, excluding Federal holidays.

Comprehensive Environmental Response, Compensation, And Liability Act (CERCLA)

CERCLA, a 1980 law commonly known as Superfund, authorizes EPA to respond to releases, or threatened releases, of hazardous substances that may endanger public health, welfare, or the environment. CERCLA also enables EPA to force parties responsible for environmental contamination to clean it up or to reimburse the Superfund for response costs incurred by EPA. The Superfund Amendments and Reauthorization Act (SARA) of 1986 revised

various sections of CERCLA, extended the taxing authority for Superfund, and created a free-standing law, SARA Title III, also known as the Emergency Planning and Community Right-to-Know Act (EPCRA).

The CERCLA **hazardous substance release reporting regulations** (40 CFR Part 302) direct the person in charge of a facility to report to the National Response Center (NRC) any environmental release of a hazardous substance which equals or exceeds a reportable quantity. Reportable quantities are defined and listed in 40 CFR §302.4. A release report may trigger a response by EPA, or by one or more Federal or State emergency response authorities.

EPA implements **hazardous substance responses** according to procedures outlined in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (40 CFR Part 300). The NCP includes provisions for permanent cleanups, known as remedial actions, and other cleanups referred to as "removals." EPA generally takes remedial actions only at sites on the National Priorities List (NPL), which currently includes approximately 1300 sites. Both EPA and states can act at other sites; however, EPA provides responsible parties the opportunity to conduct removal and remedial actions and encourages community involvement throughout the Superfund response process.

EPA's RCRA/Superfund and EPCRA Hotline, at (800) 424-9346, answers questions and references guidance pertaining to the Superfund program. The CERCLA Hotline operates weekdays from 9:00 a.m. to 6:00 p.m., ET, excluding Federal holidays.

Emergency Planning And Community Right-To-Know Act (EPCRA)

The Superfund Amendments and Reauthorization Act (SARA) of 1986 created EPCRA, also known as SARA Title III, a statute designed to improve community access to information about chemical hazards and to facilitate the development of chemical emergency response plans by State and local governments. EPCRA required the establishment of State emergency response commissions (SERCs), responsible for coordinating certain emergency response activities and for appointing local emergency planning committees (LEPCs).

EPCRA and the EPCRA regulations (40 CFR Parts 350-372) establish four types of reporting obligations for facilities which store or manage specified chemicals:

EPCRA §302 requires facilities to notify the SERC and LEPC of the presence of any "extremely hazardous substance" (the list of such substances is in 40 CFR Part 355, Appendices A and B) if it has such

substance in excess of the substance's threshold planning quantity, and directs the facility to appoint an emergency response coordinator.

EPCRA §304 requires the facility to notify the SERC and the LEPC in the event of a release equaling or exceeding the reportable quantity of a CERCLA hazardous substance or an EPCRA extremely hazardous substance.

EPCRA §311 and §312 require a facility at which a hazardous chemical, as defined by the Occupational Safety and Health Act, is present in an amount exceeding a specified threshold to submit to the SERC, LEPC and local fire department material safety data sheets (MSDSs) or lists of MSDS's and hazardous chemical inventory forms (also known as Tier I and II forms). This information helps the local government respond in the event of a spill or release of the chemical.

EPCRA §313 requires manufacturing facilities included in SIC codes 20 through 39, which have ten or more employees, and which manufacture, process, or use specified chemicals in amounts greater than threshold quantities, to submit an annual toxic chemical release report. This report, commonly known as the Form R, covers releases and transfers of toxic chemicals to various facilities and environmental media, and allows EPA to compile the national Toxic Release Inventory (TRI) database.

All information submitted pursuant to EPCRA regulations is publicly accessible, unless protected by a trade secret claim.

EPA's RCRA, Superfund and EPCRA Hotline, at (800) 424-9346, answers questions and distributes guidance regarding the emergency planning and community right-to-know regulations. The EPCRA Hotline operates weekdays from 9:00 a.m. to 6:00 p.m., ET, excluding Federal holidays.

Clean Water Act (CWA)

The primary objective of the Federal Water Pollution Control Act, commonly referred to as the CWA, is to restore and maintain the chemical, physical, and biological integrity of the nation's surface waters. Pollutants regulated under the CWA include "priority" pollutants and various toxic pollutants; "conventional" pollutants, such as biochemical oxygen demand (BOD), total suspended solids (TSS), fecal coliform, oil and grease, and pH; and "non-conventional" pollutants which are pollutants not identified as either conventional or priority.

The CWA regulates both direct and indirect discharges. The **National**

Pollutant Discharge Elimination System (NPDES) program (CWA §402) controls direct discharges into navigable waters. Direct discharges or "point source" discharges are from sources such as pipes and sewers. NPDES permits, issued by either EPA or an authorized State (EPA has authorized 42 States to administer the NPDES program), contain industry-specific, technology-based and/or water quality-based limits, and establish pollutant monitoring requirements. A facility that intends to discharge into the nation's waters must obtain a permit prior to initiating its discharge. A permit applicant must provide quantitative analytical data identifying the types of pollutants present in the facility's effluent. The permit will then set forth the conditions and effluent limitations under which a facility may make a discharge.

A NPDES permit may also include discharge limits based on Federal or State water quality criteria or standards that were designed to protect designated uses of surface waters, such as supporting aquatic life or recreation. These standards, unlike the technological standards, generally do not take into account technological feasibility or costs. Water quality criteria and standards vary from state to state, and site to site, depending on the use classification of the receiving body of water. Most states follow EPA guidelines, which propose aquatic life and human health criteria for many of the 126 priority pollutants.

Storm Water Discharges

In 1987 the CWA was amended to require EPA to establish a program to address storm water discharges. In response, EPA promulgated the NPDES storm water permit application regulations. These regulations require that facilities with the following storm water discharges apply for an NPDES permit: (1) a discharge associated with industrial activity; (2) a discharge from a large or medium municipal storm sewer system; or (3) a discharge which EPA or the State determines to contribute to a violation of a water quality standard or is a significant contributor of pollutants to waters of the United States.

The term "storm water discharge associated with industrial activity" means a storm water discharge from one of 11 categories of industrial activity defined at 40 CFR 122.26. Six of the categories are defined by SIC codes while the other five are identified through narrative descriptions of the regulated industrial activity. If the primary SIC code of the facility is one of those identified in the regulations, the facility is subject to the storm water permit application requirements. If any activity at a facility is covered by one of the five narrative categories, storm water discharges from those areas where the activities occur are subject to storm water discharge permit application requirements.

Those facilities/activities that are subject to storm water discharge permit application requirements are identified below. To determine whether a particular facility falls within one of these categories, the regulation should be consulted.

Category i: Facilities subject to storm water effluent guidelines, new source performance standards, or toxic pollutant effluent standards.

Category ii: Facilities classified as SIC 24-lumber and wood products (except wood kitchen cabinets); SIC 26-paper and allied products (except paperboard containers and products); SIC 28-chemicals and allied products (except drugs and paints); SIC 291-petroleum refining; and SIC 311-leather tanning and finishing, 32 (except 323)-stone, clay, glass, and concrete, 33-primary metals, 3441-fabricated structural metal, and 373-ship and boat building and repairing.

Category iii: Facilities classified as SIC 10-metal mining; SIC 12-coal mining; SIC 13-oil and gas extraction; and SIC 14-nonmetallic mineral mining.

Category iv: Hazardous waste treatment, storage, or disposal facilities.

Category v: Landfills, land application sites, and open dumps that receive or have received industrial wastes.

Category vi: Facilities classified as SIC 5015-used motor vehicle parts; and SIC 5093-automotive scrap and waste material recycling facilities.

Category vii: Steam electric power generating facilities.

Category viii: Facilities classified as SIC 40-railroad transportation; SIC 41-local passenger transportation; SIC 42-trucking and warehousing (except public warehousing and storage); SIC 43-U.S. Postal Service; SIC 44-water transportation; SIC 45-transportation by air; and SIC 5171-petroleum bulk storage stations and terminals.

Category ix: Sewage treatment works.

Category x: Construction activities except operations that result in the disturbance of less than five acres of total land area.

Category xi: Facilities classified as SIC 20-food and kindred products; SIC 21-tobacco products; SIC 22-textile mill products; SIC 23-apparel related products; SIC 2434-wood kitchen cabinets manufacturing; SIC 25-furniture and fixtures; SIC 265-paperboard containers and boxes; SIC 267-converted paper and paperboard products; SIC 27-printing, publishing, and allied industries; SIC 283-drugs; SIC 285-paints, varnishes, lacquer, enamels, and allied products; SIC 30-rubber and plastics; SIC 31-leather and leather products (except leather and tanning and finishing); SIC 323-glass products; SIC 34-fabricated metal products (except fabricated structural metal); SIC 35-industrial and commercial machinery and computer equipment; SIC 36-electronic and other electrical equipment and components; SIC 37-transportation equipment (except ship and boat building and repairing); SIC 38-measuring, analyzing, and controlling instruments; SIC 39-miscellaneous manufacturing industries; and SIC 4221-4225-public warehousing and storage.

Pretreatment Program

Another type of discharge that is regulated by the CWA is one that goes to a publicly-owned treatment works (POTWs). The national **pretreatment program** (CWA §307(b)) controls the indirect discharge of pollutants to POTWs by "industrial users." Facilities regulated under §307(b) must meet certain pretreatment standards. The goal of the pretreatment program is to protect municipal wastewater treatment plants from damage that may occur when hazardous, toxic, or other wastes are discharged into a sewer system and to protect the quality of sludge generated by these plants. Discharges to a POTW are regulated primarily by the POTW itself, rather than the State or EPA.

EPA has developed technology-based standards for industrial users of POTWs. Different standards apply to existing and new sources within each category. "Categorical" pretreatment standards applicable to an industry on a nationwide basis are developed by EPA. In addition, another kind of pretreatment standard, "local limits," are developed by the POTW in order to assist the POTW in achieving the effluent limitations in its NPDES permit.

Regardless of whether a State is authorized to implement either the NPDES or the pretreatment program, if it develops its own program, it may enforce requirements more stringent than Federal standards.

Spill Prevention, Control and Countermeasure Plans

The 1990 Oil Pollution Act requires that facilities that could reasonably be

expected to discharge oil in harmful quantities prepare and implement more rigorous Spill Prevention Control and Countermeasure (SPCC) Plan required under the CWA (40 CFR §112.7). There are also criminal and civil penalties for deliberate or negligent spills of oil. Regulations covering response to oil discharges and contingency plans (40 CFR Part 300), and Facility Response Plans to oil discharges (40 CFR §112.20) and for PCB transformers and PCB-containing items were revised and finalized in 1995.

EPA's Office of Water, at (202) 260-5700, will direct callers with questions about the CWA to the appropriate EPA office. EPA also maintains a bibliographic database of Office of Water publications which can be accessed through the Ground Water and Drinking Water resource center, at (202) 260-7786.

Safe Drinking Water Act (SDWA)

The SDWA mandates that EPA establish regulations to protect human health from contaminants in drinking water. The law authorizes EPA to develop national drinking water standards and to create a joint Federal-State system to ensure compliance with these standards. The SDWA also directs EPA to protect underground sources of drinking water through the control of underground injection of liquid wastes.

EPA has developed primary and secondary drinking water standards under its SDWA authority. EPA and authorized states enforce the primary drinking water standards, which are, contaminant-specific concentration limits that apply to certain public drinking water supplies. Primary drinking water standards consist of maximum contaminant level goals (MCLGs), which are non-enforceable health-based goals, and maximum contaminant levels (MCLs), which are enforceable limits set as close to MCLGs as possible, considering cost and feasibility of attainment.

The SDWA **Underground Injection Control** (UIC) program (40 CFR Parts 144-148) is a permit program which protects underground sources of drinking water by regulating five classes of injection wells. UIC permits include design, operating, inspection, and monitoring requirements. Wells used to inject hazardous wastes must also comply with RCRA corrective action standards in order to have RCRA permit by rule status, and must meet applicable RCRA land disposal restrictions standards. The UIC permit program is primarily state-enforced, since EPA has authorized all but a few states to administer the program.

The SDWA also provides for a Federally-implemented Sole Source Aquifer program, which prohibits Federal funds from being expended on projects that may contaminate the sole or principal source of drinking water for a given

area, and for a State-implemented Wellhead Protection program, designed to protect drinking water wells and drinking water recharge areas.

EPA's Safe Drinking Water Hotline, at (800) 426-4791, answers questions and distributes guidance pertaining to SDWA standards. The Hotline operates from 9:00 a.m. through 5:30 p.m., ET, excluding Federal holidays.

Toxic Substances Control Act (TSCA)

TSCA granted EPA authority to create a regulatory framework to collect data on chemicals in order to evaluate, assess, mitigate, and control risks which may be posed by their manufacture, processing, and use. TSCA provides a variety of control methods to prevent chemicals from posing unreasonable risk.

TSCA standards may apply at any point during a chemical's life cycle. Under TSCA §5, EPA has established an inventory of chemical substances. If a chemical is not already on the inventory, and has not been excluded by TSCA, a premanufacture notice (PMN) must be submitted to EPA prior to manufacture or import. The PMN must identify the chemical and provide available information on health and environmental effects. If available data are not sufficient to evaluate the chemicals effects, EPA can impose restrictions pending the development of information on its health and environmental effects. EPA can also restrict significant new uses of chemicals based upon factors such as the projected volume and use of the chemical.

Under TSCA §6, EPA can ban the manufacture or distribution in commerce, limit the use, require labeling, or place other restrictions on chemicals that pose unreasonable risks. Among the chemicals EPA regulates under §6 authority are asbestos, chlorofluorocarbons (CFCs), and polychlorinated biphenyls (PCBs).

EPA's TSCA Assistance Information Service, at (202) 554-1404, answers questions and distributes guidance pertaining to Toxic Substances Control Act standards. The Service operates from 8:30 a.m. through 4:30 p.m., ET, excluding Federal holidays.

Clean Air Act (CAA)

The CAA and its amendments, including the Clean Air Act Amendments (CAAA) of 1990, are designed to "protect and enhance the nation's air resources so as to promote the public health and welfare and the productive capacity of the population." The CAA consists of six sections, known as Titles, which direct EPA to establish national standards for ambient air quality and for EPA and the States to implement, maintain, and enforce these

standards through a variety of mechanisms. Under the CAAA, many facilities will be required to obtain permits for the first time. State and local governments oversee, manage, and enforce many of the requirements of the CAAA. CAA regulations appear at 40 CFR Parts 50-99.

Pursuant to Title I of the CAA, EPA has established national ambient air quality standards (NAAQSs) to limit levels of "criteria pollutants," including carbon monoxide, lead, nitrogen dioxide, particulate matter, volatile organic compounds (VOCs), ozone, and sulfur dioxide. Geographic areas that meet NAAQSs for a given pollutant are classified as attainment areas; those that do not meet NAAQSs are classified as non-attainment areas. Under §110 of the CAA, each State must develop a State Implementation Plan (SIP) to identify sources of air pollution and to determine what reductions are required to meet Federal air quality standards. Revised NAAQSs for particulates and ozone were proposed in 1996 and may go into effect as early as late 1997.

Title I also authorizes EPA to establish New Source Performance Standards (NSPSs), which are nationally uniform emission standards for new stationary sources falling within particular industrial categories. NSPSs are based on the pollution control technology available to that category of industrial source.

Under Title I, EPA establishes and enforces National Emission Standards for Hazardous Air Pollutants (NESHAPs), nationally uniform standards oriented towards controlling particular hazardous air pollutants (HAPs). Title I, section 112(c) of the CAA further directed EPA to develop a list of sources that emit any of 189 HAPs, and to develop regulations for these categories of sources. To date, EPA has listed 174 categories and developed a schedule for the establishment of emission standards. The emission standards will be developed for both new and existing sources based on "maximum achievable control technology (MACT)." The MACT is defined as the control technology achieving the maximum degree of reduction in the emission of the HAPs, taking into account cost and other factors.

Title II of the CAA pertains to mobile sources, such as cars, trucks, buses, and planes. Reformulated gasoline, automobile pollution control devices, and vapor recovery nozzles on gas pumps are a few of the mechanisms EPA uses to regulate mobile air emission sources.

Title IV of the CAA establishes a sulfur dioxide emissions program designed to reduce the formation of acid rain. Reduction of sulfur dioxide releases will be obtained by granting to certain sources limited emissions allowances, which, beginning in 1995, will be set below previous levels of sulfur dioxide releases.

Title V of the CAA of 1990 created a permit program for all "major sources"

(and certain other sources) regulated under the CAA. One purpose of the operating permit is to include in a single document all air emissions requirements that apply to a given facility. States are developing the permit programs in accordance with guidance and regulations from EPA. Once a State program is approved by EPA, permits will be issued and monitored by that State.

Title VI of the CAA is intended to protect stratospheric ozone by phasing out the manufacture of ozone-depleting chemicals and restrict their use and distribution. Production of Class I substances, including 15 kinds of chlorofluorocarbons (CFCs) and chloroform, were phased out (except for essential uses) in 1996.

EPA's Clean Air Technology Center, at (919) 541-0800, provides general assistance and information on CAA standards. The Stratospheric Ozone Information Hotline, at (800) 296-1996, provides general information about regulations promulgated under Title VI of the CAA, and EPA's EPCRA Hotline, at (800) 535-0202, answers questions about accidental release prevention under CAA §112(r). In addition, the Clean Air Technology Center's website includes recent CAA rules, EPA guidance documents, and updates of EPA activities (www.epa.gov/ttn then select Directory and then CATC).

VI.B. Industry Specific Requirements

The pharmaceutical industry is affected by several major federal environmental statutes. In addition, the industry is subject to numerous laws and regulations from state and local governments designed to protect and improve the nation's health, safety, and environment. A summary of the major federal regulations affecting the pharmaceutical industry follows.

Clean Air Act (CAA)

The original CAA authorized EPA to set limits on pharmaceutical plant emissions. Some of these new source performance standards (NSPS) apply to pharmaceutical manufacturers including those for flares (40 CFR Part 60 Subpart A), and storage of volatile organic liquids (40 CFR Part 60 Subpart Kb). The Clean Air Act Amendments of 1990 set control standards by industrial sources for 41 pollutants to be met by 1995 and for 148 other pollutants to be reached by 2003. Under the air toxics provisions of the CAAA, more sources are covered including small businesses. The Hazardous Organic National Emissions Standard for Hazardous Air Pollutants, also known as HON, covers hundreds of chemicals and thousands of process units. The pharmaceutical industry is affected by standards for equipment leaks (40 CFR Part 63 Subpart H), equipment leaks from pharmaceutical processes using carbon tetrachloride or methylene chloride (40 CFR Part 63 Subpart I), and standards for emissions from halogenated solvent cleaning (40 CFR Part 63 Subpart T). The HON also includes innovative provisions such as emissions trading, that offer industry flexibility in complying with the rule's emissions goals.

Specific industries are regulated under other National Emission Standards for Hazardous Air Pollutants (NESHAP). These standards are being developed for the pharmaceutical industry (see Section VI. C). Title V of the CAA introduces a new permit system that will require all major sources to obtain operating permits to cover all applicable control requirements. States were required to develop and implement the program in 1993 and the first permits were issued in 1994. In December 1994, Schering-Plough Pharmaceutical's facility in Kenilworth, New Jersey, was the first in the nation to receive a facility-wide permit under this Title V program.

Clean Water Act (CWA)

The Clean Water Act, first passed in 1972 and amended in 1977 and 1987, gives EPA the authority to regulate effluents from sewage treatment works, chemical plants, and other industrial sources into waters. The act sets "best available" technology standards for treatment of wastes for both direct and indirect (to a Publicly Owned Treatment Works (POTW)) discharges. In 1983, EPA proposed effluent guidelines for the pharmaceutical

manufacturing point source category. These guidelines are currently undergoing revisions (see Section VI. C). The implementation of the guidelines is left to the states who issue National Pollutant Discharge Elimination System (NPDES) permits for each facility.

The pharmaceutical manufacturing effluent guidelines for point source category (40 CFR Part 439) is divided into process specific effluent guidelines as follows:

Fermentation - 40 CFR Part 439 Subpart A,
Natural product extraction - 40 CFR Part 439 Subpart B,
Chemical synthesis - 40 CFR Part 439 Subpart C,
Mixing, compounding, formulation - 40 CFR Part 439 Subpart D, and
Research - 40 CFR Part 439 Subpart E.

Each Subpart consists of effluent limitations representing the amount of effluent reduction possible by using either best practicable control technologies (BPT), best conventional pollution technologies (BCT), or best available technologies (BAT). BPTs are used for discharges from existing point sources to control conventional and non-conventional pollutants as well as some priority pollutants. BCTs are used for discharges from point sources to control conventional pollutants. Finally, BATs are used to control priority pollutants and non-conventional pollutants when directly discharged into the nation's waters. Standards are provided for cyanide, biologic oxygen demand (BOD), chemical oxygen demand (COD), total suspended solids (TSS) and pH. Guidelines for BCT and BAT for the research category, new source performance standards (NSPS), and pre-treatment standards for new and existing sources, are being revised and are in the final rule stage (see Section VI. C).

The Storm Water Rule (40 CFR §122.26) requires pharmaceutical facilities discharging storm water associated with industrial activities (40 CFR §122.26 (b)(14)(xi)) to apply for storm water permits.

Safe Drinking Water Act Underground Injection Control Program

The federal Underground Injection Control (UIC) program was established under the provisions of the SDWA of 1974. This federal program prescribes minimum requirements for effective state UIC programs. Since ground water is a major source of drinking water in the United States, the UIC program requirements were designed to prevent contamination of Underground Sources of Drinking Water (USDW) resulting from the operation of injection wells. A USDW is defined as an "aquifer or its portion which supplies any public water system or contains a sufficient quantity of ground water to supply a public water system, or contains less than 10,000 milligrams per liter total dissolved solids and is not an exempted aquifer."

Since the passage of the Safe Drinking Water Act, state and federal regulatory agencies have modified existing programs or developed new strategies to protect ground water by establishing regulations to control the permitting, construction, operation, monitoring, and closure of injection wells. In Michigan, where all five of the pharmaceutical industry's injection wells are located, the state has not sought authority to implement the federal UIC program but does regulate use of injection wells through state law. The EPA is the responsible regulatory agency for implementing the UIC program in the state.

The five wells used by the pharmaceutical companies in Michigan are termed hazardous Class I injection wells since they inject hazardous waste into formations below the USDW. The process of selecting a site for a Class I disposal well involves evaluating many conditions with the most important being the determination that the underground formations possess the natural ability to contain and isolate the injected waste. A detailed study is conducted to determine the suitability of the underground formation for disposal. The receiving formation must be far below any usable ground waters and be separated from them by confining layers of rock, which prevent fluid migration into the ground water. The injection zone in the receiving formation must be of sufficient size and have sufficient pore space to accept and maintain the injected wastes.

Class I injection wells are regulated in 40 CFR Part 146, Subpart G. Subpart G requires facilities with injection wells to submit operating reports and to submit plans for testing and monitoring the wastes, hydrogeologic conditions, condition of the well materials, mechanical integrity of the well, and ambient conditions in adjacent aquifers. Subpart G also sets criteria for siting Class I hazardous waste injection wells, construction requirements, corrective action procedures, operating requirements, and closure plans.

Resource Conservation and Recovery Act (RCRA)

The Resource Conservation and Recovery Act (RCRA) was enacted in 1976 to address problems related to hazardous and solid waste management. RCRA gives EPA the authority to establish a list of solid and hazardous wastes and to establish standards and regulations for the treatment, storage, and disposal of these wastes. Regulations in Subtitle C of RCRA address the identification, generation, transportation, treatment, storage, and disposal of hazardous wastes. These regulations are found in 40 CFR Part 124 and CFR Parts 260-279. Under RCRA, persons who generate waste must determine whether the waste is defined as solid waste or hazardous waste. Solid wastes are considered hazardous wastes if they are listed by EPA as hazardous or if they exhibit characteristics of a hazardous waste: toxicity, ignitability, corrosivity, or reactivity.

Products, intermediates, and off-specification products potentially generated at pharmaceutical facilities that are considered hazardous wastes are listed in 40 CFR Part 261.33(f). Some of the handling and treatment requirements for RCRA hazardous waste generators are covered under 40 CFR Part 262 and include the following: determining what constitutes a RCRA hazardous waste (Subpart A); manifesting (Subpart B); packaging, labeling, and accumulation time limits (Subpart C); and record keeping and reporting (Subpart D).

Many pharmaceutical facilities store some hazardous wastes at the facility for more than 90 days, and are therefore, a storage facility under RCRA. Storage facilities are required to have a RCRA treatment, storage, and disposal facility (TSDF) permit (40 CFR Part 262.34). Some pharmaceutical facilities are considered TSDF facilities and are subject to the following regulations covered under 40 CFR Part 264: contingency plans and emergency procedures (40 CFR Part 264 Subpart D); manifesting, record keeping, and reporting (40 CFR Part 264 Subpart E); use and management of containers (40 CFR Part 264 Subpart I); tank systems (40 CFR Part 264 Subpart J); surface impoundments (40 CFR Part 264 Subpart K); land treatment (40 CFR Part 264 Subpart M); corrective action of hazardous waste releases (40 CFR Part 264 Subpart S); air emissions standards for process vents of processes that process or generate hazardous wastes (40 CFR Part 264 Subpart AA); emissions standards for leaks in hazardous waste handling equipment (40 CFR Part 264 Subpart BB); and emissions standards for containers, tanks, and surface impoundments that contain hazardous wastes (40 CFR Part 264 Subpart CC).

A number of RCRA wastes have been prohibited from land disposal unless treated to meet specific standards under the RCRA Land Disposal Restriction (LDR) program. The wastes covered by the RCRA LDRs are listed in 40 CFR Part 268 Subpart C and include a number of wastes commonly generated at pharmaceutical facilities. Standards for the treatment and storage of restricted wastes are described in Subparts D and E, respectively.

Many pharmaceutical manufacturing facilities are also subject to the underground storage tank (UST) program (40 CFR Part 280). The UST regulations apply to facilities that store either petroleum products or hazardous substances (except hazardous waste) identified under the Comprehensive Environmental Response, Compensation, and Liability Act. UST regulations address design standards, leak detection, operating practices, response to releases, financial responsibility for releases, and closure standards.

Comprehensive Environmental Response Compensation and Liability Act (CERCLA)

The Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA) and the Superfund Amendments and Reauthorization Act of 1986 (SARA) provide the basic legal framework for the federal "Superfund" program to clean up abandoned hazardous waste sites (40 CFR Part 305). The 1986 SARA legislation extended these taxes for five years and adopted a new broad-based corporate environmental tax, applicable to the allied chemicals (SIC 28) industry, which includes the pharmaceuticals industry. In 1990, Congress passed a simple reauthorization that did not substantially change the law but extended the program authority until 1994 and the taxing authority until the end of 1995. A comprehensive reauthorization was considered in 1994, but not passed. Since the expiration of the taxing authority on December 31, 1995, taxes for Superfund have been temporarily suspended. The taxes can only be reinstated by reauthorization of Superfund or an omnibus reconciliation act which could specifically reauthorize taxing authority. The allied chemical industry pays about $300 million a year in Superfund chemical feedstock taxes. Superfund's liability standard is such that Potentially Responsible Parties (PRPs) may pay the entire cost of clean-up at sites, even though they may be responsible for only a fraction of the waste.

Title III of the 1986 SARA amendments (also known as Emergency Response and Community Right-to-Know Act, EPCRA) requires all manufacturing facilities, including pharmaceutical facilities, to report annual information to the public about stored toxic substances as well as release of these substances into the environment (42 U.S.C. 9601). This is known as the Toxic Release Inventory (TRI). EPCRA also establishes requirements for federal, state, and local governments regarding emergency planning. In 1994, over 300 more chemicals were added to the list of chemicals for which reporting is required.

Toxic Substances Control Act (TSCA)

The pharmaceutical industry is specifically excluded from some of the requirements of TSCA. Any drugs manufactured, processed, and distributed in commerce are excluded by definition from the Inventory Reporting Regulations (40 CFR Part 710.4(c)) and the Pre-Manufacturing Notice requirements (40 CFR 720.30(a)) of TSCA.

VI.C. Pending and Proposed Regulatory Requirements

Clean Air Act (CAA)

Under the Clean Air Act, National Emissions Standards for Hazardous Air Pollutants (NESHAPS) are being developed for the pharmaceutical manufacturing industry.

Clean Water Act (CWA)

As part of the Clean Water Act revision process, the effluent guidelines for the pharmaceutical industry (40 CFR 439) are currently being revised and reviewed. A major part of the review considers the inclusion of limitations for toxic and non-conventional volatile organic pollutants. Additionally, the 1983 New Source Performance Standards (NSPS) for conventional pollutants will also be reevaluated.

VI.D. Other Federal Regulations Affecting the Pharmaceutical Industry

Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) is part of the Department of Health and Human Services. FDA has the statutory authority to regulate a wide range of products such as prescription and over-the-counter drugs, foods, biologics (e.g., blood plasma, vaccines), medical devices (e.g., needles, heart valves), veterinary drugs, cosmetics and consumer goods that emit radiation. This authority has been granted to FDA by Congress under various laws including the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

There are five Centers within FDA that deal with FDA-regulated articles: Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), Center for Devices and Radiological Health (CDRH), and Center for Food Safety and Applied Nutrition (CFSAN). The Centers review scientific information provided by persons wishing to place FDA-regulated articles into interstate commerce in order to determine whether regulatory requirements are met. FDA has offices throughout the U.S. where testing of FDA-regulated articles is performed and where investigators are based. Investigators go to U.S. and foreign manufacturing facilities and other types of facilities involved in FDA-regulated activities to verify that they are in compliance with FDA regulations.

FDA's general approach to regulating various articles is similar, however, due to the diverse nature of these products, there are regulatory requirements tailored to each type of FDA-regulated article. Below is a summary of information relating to the type of products regulated by CDER. Additional information on other FDA-regulated articles may be located in 21 CFR or by contacting FDA directly.

The manufacturing facilities that produce drugs for human use are regulated by CDER. The methods, facilities, and controls used for the manufacture, processing, and packing of a drug are reviewed by FDA to determine whether they are adequate to ensure and preserve the drug's identity, strength, quality and purity. These characteristics are critical to ensure the safety and efficacy of a drug for human use. CDER conducts a scientific review of manufacturing methods and process controls for the drug substance and drug product. Field investigators conduct on-site reviews to verify the accuracy of the information submitted to CDER and to determine facility compliance with FDA's Good Manufacturing Practices (GMPs).

FDA's review of a pharmaceutical facility does not include auditing compliance with regulations pertaining to the protection of the environment.

However, in accordance with the National Environmental Policy Act of 1969 (NEPA), which requires all Federal agencies to assess the environmental impacts of their actions, CDER has integrated the consideration of the environmental impacts of approving drug product applications into its regulatory process (21 CFR Part 25). When an environmental review under NEPA is required, the review focuses on the environmental impacts of consumer use and disposal of the drug and is based on information submitted by the manufacturers, or on a manufacturer's certification that an application falls within an established category of applications excluded from the requirement to submit information.

After the original approval from CDER, an applicant may wish or need to make changes in the method of manufacture, testing, etc. described in their application. An applicant is required to notify FDA about each change in each condition established in an approved application (e.g., ingredients, solvents, processes) beyond the variations already provided for in the application (21 CFR §314.70(a)). Depending on the type of change, the applicant notifies FDA about it in (1) a supplement requiring FDA approval before the change is made (§314.70(b)), (2) a supplement for changes that may be made before FDA approval (§314.70(c)), or (3) an annual report (§314.70(d)). Changes requiring FDA approval before they are made may include changes in the synthesis of the drug product or changes in solvents; the addition or deletion of an ingredient; and changes in the method of manufacture or in-process control of the drug product manufacturing process. The regulations specify the method of reporting certain changes. CDER also provides additional guidance on the method of reporting changes and documentation needed to support changes in guidance for industry (e.g., "Guidance for Industry, Immediate Release Solid Oral Dosage Forms, Scale-Up and Post Approval Changes: Chemistry Manufacturing and Controls, *In Vitro* Dissolution Testing and *In Vivo* Bioequivalence Documentation," November 1995).

The changes in a manufacturing process that a manufacturer may wish to undertake to prevent or reduce pollution would most likely be reported in a supplement requiring FDA approval before the change could be made (e.g., §§314.70(b)(1)(iv) and 314.70(b)(2)(v)). Changes such as these often require the manufacturer, before submitting the supplemental application to the FDA, to generate data that demonstrate the proposed change does not adversely affect the identity, strength, quality or purity of the drug. An applicant may ask FDA to expedite its review if a delay in making the change would impose an extraordinary hardship on the applicant (§314.70(b)). For changes relating to pollution prevention, "expedited review" is typically reserved for those changes mandated by the Federal, State or local environmental protection agencies, which must be accomplished within a specified time frame. The granting of an expedited review does not change the type of documentation that needs to be submitted to CDER to support the change.

Summary of FDA Regulations Applicable to the Pharmaceutical Industry

Statutory Authority

The Federal Food Drug and Cosmetic Act, principally Sections 201, 301, 501, 502, 503, 505, 506, 507, 512, 701, 704.

CDER Regulations

21 CFR Parts 300-499

Manufacturing Information Submittal

Manufacturing Information Submitted to CDER in Investigational New Drug Applications (INDs), New Drug Applications (NDAs), Antibiotic Applications, Abbreviated New Drug Applications (ANDAs), and Abbreviated Antibiotic Drug Applications (AADAs)

INDs: §312.23(a)(7)(i)

Other applications: §§314.50(d)(1)(i) and 314.50(d)(1)(ii)(a)

Reporting Changes in Manufacturing Methods and Controls to CDER

IND Information amendments: §312.31

Supplements and other changes to an approved application: §314.70

Good Manufacturing Practices (GMPs)

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, Part 210

Current Good Manufacturing Practice for Finished Pharmaceuticals: Part 211

VI.E. Other Statutes and Regulations Affecting the Pharmaceutical Industry

State Statutes and Regulations

Most states have long-established broad-based environmental regulatory programs. Many of these regulatory schemes were enacted to implement federal programs and have been granted local primacy by the USEPA. Generally, the state programs are allowed to be more restrictive than federal requirements and, in some cases, they are.

Some states with high concentrations of pharmaceutical manufacturing facilities, have their own regulations pertaining specifically to the industry. For example, both New York and New Jersey have Reasonably Achievable Control Technology (RACT) requirements for process specific volatile organic compound (VOC) emissions. Other states may have similar requirements under their own State Implementation Plans (SIPs).

International Standards

The U.S. Pharmaceutical industry is largely an international industry in which many companies have manufacturing facilities and sales and distribution operations in countries other than the U.S. In addition to U.S. federal statutes and regulations there are international laws, regulations, treaties, conventions and initiatives which are drivers of the environmental programs of pharmaceutical companies. The Basel Convention, ISO 14000 standards, the environmental requirements of NAFTA, and the evolving European Union Directives and Regulations are a few examples of important international environmental standards and programs which affect this industry.

Drug Enforcement Administration Regulations

Pharmaceutical manufacturing operations may also be regulated under the Controlled Substances Act. This Act regulates the manufacture, distribution, and dispensing of controlled substances and is enforced by the Drug Enforcement Administration (DEA). Examples of pharmaceutical products regulated under this Act include Demerol, Percodan, Ritalin, Valium, and Darvon. A list of controlled substances can be found in §1308 of 21 CFR.

The statute provides "closed" system for virtually every person who legitimately handles controlled substances, other than the ultimate user. As a means of controlling the distribution of regulated products, DEA sets quotas limiting the quantities which may be manufactured or produced to that amount which is necessary to meet the legitimate needs of the United States. The regulations set specific requirements for how such compounds are handled and stored at a manufacturing facility. In addition, when disposed of, these substances must be destroyed in the presence of DEA personnel in accordance with the regulations found in 21 CFR, Section 1307.21.

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VII. COMPLIANCE AND ENFORCEMENT HISTORY

Background

Until recently, EPA has focused much of its attention on measuring compliance with specific environmental statutes. This approach allows the Agency to track compliance with the Clean Air Act, the Resource Conservation and Recovery Act, the Clean Water Act, and other environmental statutes. Within the last several years, the Agency has begun to supplement single-media compliance indicators with facility-specific, multimedia indicators of compliance. In doing so, EPA is in a better position to track compliance with all statutes at the facility level, and within specific industrial sectors.

A major step in building the capacity to compile multimedia data for industrial sectors was the creation of EPA's Integrated Data for Enforcement Analysis (IDEA) system. IDEA has the capacity to "read into" the Agency's single-media databases, extract compliance records, and match the records to individual facilities. The IDEA system can match Air, Water, Waste, Toxics/Pesticides/EPCRA, TRI, and Enforcement Docket records for a given facility, and generate a list of historical permit, inspection, and enforcement activity. IDEA also has the capability to analyze data by geographic area and corporate holder. As the capacity to generate multimedia compliance data improves, EPA will make available more in-depth compliance and enforcement information. Additionally, sector-specific measures of success for compliance assistance efforts are under development.

Compliance and Enforcement Profile Description

Using inspection, violation, and enforcement data from the IDEA system, this section provides information regarding the historical compliance and enforcement activity of this sector. In order to mirror the facility universe reported in the Toxic Chemical Profile, the data reported within this section consists of records only from the TRI reporting universe. With this decision, the selection criteria are consistent across sectors with certain exceptions. For the sectors that do not normally report to the TRI program, data have been provided from EPA's Facility Indexing System (FINDS) which tracks facilities in all media databases. Please note, in this section, EPA does not attempt to define the actual number of facilities that fall within each sector. Instead, the section portrays the records of a subset of facilities within the sector that are well defined within EPA databases.

As a check on the relative size of the full sector universe, most notebooks contain an estimated number of facilities within the sector according to the Bureau of Census (See Section II). With sectors dominated by small businesses, such as metal finishers and printers, the reporting universe within

the EPA databases may be small in comparison to Census data. However, the group selected for inclusion in this data analysis section should be consistent with this sector's general makeup.

Following this introduction is a list defining each data column presented within this section. These values represent a retrospective summary of inspections and enforcement actions, and solely reflect EPA, State, and local compliance assurance activities that have been entered into EPA databases. To identify any changes in trends, the EPA ran two data queries, one for the five calendar years (April 1, 1992 to March 31, 1997) and the other for the most recent twelve-month period (April 1, 1996 to March 31, 1997). The five-year analysis gives an average level of activity for that period for comparison to the more recent activity.

Because most inspections focus on single-media requirements, the data queries presented in this section are taken from single media databases. These databases do not provide data on whether inspections are state/local or EPA-led. However, the table breaking down the universe of violations does give the reader a crude measurement of the EPA's and states' efforts within each media program. The presented data illustrate the variations across EPA Regions for certain sectors.[a] This variation may be attributable to state/local data entry variations, specific geographic concentrations, proximity to population centers, sensitive ecosystems, highly toxic chemicals used in production, or historical noncompliance. Hence, the exhibited data do not rank regional performance or necessarily reflect which regions may have the most compliance problems.

Compliance and Enforcement Data Definitions

General Definitions

Facility Indexing System (FINDS) -- this system assigns a common facility number to EPA single-media permit records. The FINDS identification number allows EPA to compile and review all permit, compliance, enforcement and pollutant release data for any given regulated facility.

Integrated Data for Enforcement Analysis (IDEA) -- is a data integration system that can retrieve information from the major EPA program office databases. IDEA uses the FINDS identification number to link separate data records from EPA's databases. This allows retrieval of records from across

[a] EPA Regions include the following states: I (CT, MA, ME, RI, NH, VT); II (NJ, NY, PR, VI); III (DC, DE, MD, PA, VA, WV); IV (AL, FL, GA, KY, MS, NC, SC, TN); V (IL, IN, MI, MN, OH, WI); VI (AR, LA, NM, OK, TX); VII (IA, KS, MO, NE); VIII (CO, MT, ND, SD, UT, WY); IX (AZ, CA, HI, NV, Pacific Trust Territories); X (AK, ID, OR, WA).

media or statutes for any given facility, thus creating a "master list" of records for that facility. Some of the data systems accessible through IDEA are: AIRS (Air Facility Indexing and Retrieval System, Office of Air and Radiation), PCS (Permit Compliance System, Office of Water), RCRIS (Resource Conservation and Recovery Information System, Office of Solid Waste), NCDB (National Compliance Data Base, Office of Prevention, Pesticides, and Toxic Substances), CERCLIS (Comprehensive Environmental and Liability Information System, Superfund), and TRIS (Toxic Release Inventory System). IDEA also contains information from outside sources such as Dun and Bradstreet and the Occupational Safety and Health Administration (OSHA). Most data queries displayed in notebook sections IV and VII were conducted using IDEA.

Data Table Column Heading Definitions

Facilities in Search -- are based on the universe of TRI reporters within the listed SIC code range. For industries not covered under TRI reporting requirements (metal mining, nonmetallic mineral mining, electric power generation, ground transportation, water transportation, and dry cleaning), or industries in which only a very small fraction of facilities report to TRI (e.g., printing), the notebook uses the FINDS universe for executing data queries. The SIC code range selected for each search is defined by each notebook's selected SIC code coverage described in Section II.

Facilities Inspected --- indicates the level of EPA and state agency inspections for the facilities in this data search. These values show what percentage of the facility universe is inspected in a one-year or five-year period.

Number of Inspections -- measures the total number of inspections conducted in this sector. An inspection event is counted each time it is entered into a single media database.

Average Time Between Inspections -- provides an average length of time, expressed in months, between compliance inspections at a facility within the defined universe.

Facilities with One or More Enforcement Actions -- expresses the number of facilities that were the subject of at least one enforcement action within the defined time period. This category is broken down further into federal and state actions. Data are obtained for administrative, civil/judicial, and criminal enforcement actions. Administrative actions include Notices of Violation (NOVs). A facility with multiple enforcement actions is only counted once in this column, e.g., a facility with 3 enforcement actions counts as 1 facility.

Total Enforcement Actions -- describes the total number of enforcement actions identified for an industrial sector across all environmental statutes. A facility with multiple enforcement actions is counted multiple times, e.g., a facility with 3 enforcement actions counts as 3.

State Lead Actions -- shows what percentage of the total enforcement actions are taken by state and local environmental agencies. Varying levels of use by states of EPA data systems may limit the volume of actions recorded as state enforcement activity. Some states extensively report enforcement activities into EPA data systems, while other states may use their own data systems.

Federal Lead Actions -- shows what percentage of the total enforcement actions are taken by the United States Environmental Protection Agency. This value includes referrals from state agencies. Many of these actions result from coordinated or joint state/federal efforts.

Enforcement to Inspection Rate -- is a ratio of enforcement actions to inspections, and is presented for comparative purposes only. This ratio is a rough indicator of the relationship between inspections and enforcement. It relates the number of enforcement actions and the number of inspections that occurred within the one-year or five-year period. This ratio includes the inspections and enforcement actions reported under the Clean Water Act (CWA), the Clean Air Act (CAA) and the Resource Conservation and Recovery Act (RCRA). Inspections and actions from the TSCA/FIFRA/ EPCRA database are not factored into this ratio because most of the actions taken under these programs are not the result of facility inspections. Also, this ratio does not account for enforcement actions arising from non-inspection compliance monitoring activities (e.g., self-reported water discharges) that can result in enforcement action within the CAA, CWA, and RCRA.

Facilities with One or More Violations Identified -- indicates the percentage of inspected facilities having a violation identified in one of the following data categories: In Violation or Significant Violation Status (CAA); Reportable Noncompliance, Current Year Noncompliance, Significant Noncompliance (CWA); Noncompliance and Significant Noncompliance (FIFRA, TSCA, and EPCRA); Unresolved Violation and Unresolved High Priority Violation (RCRA). The values presented for this column reflect the extent of noncompliance within the measured time frame, but do not distinguish between the severity of the noncompliance. Violation status may be a precursor to an enforcement action, but does not necessarily indicate that an enforcement action will occur.

Media Breakdown of Enforcement Actions and Inspections -- four columns identify the proportion of total inspections and enforcement actions within EPA Air, Water, Waste, and FIFRA/TSCA/EPCRA databases. Each column is a percentage of either the "Total Inspections," or the "Total Actions" column.

VII.A. Pharmaceutical Industry Compliance History

Table 20 provides an overview of the reported compliance and enforcement data for the pharmaceutical industry over the past five years (April 1992 to April 1997). These data are also broken out by EPA Region thereby permitting geographical comparisons. A few points evident from the data are listed below.

- Region II has more than twice the number of pharmaceutical facilities than any other Region and more than half of all inspections nationally were carried out in this Region. The high rate of inspections in relation to the number of facilities is reflected in the Region's relatively low average time between inspections (6 months)

- Regions VI had only five pharmaceutical facilities (identified by the IDEA system) and a relatively high average time between inspections. However, in the past five years four enforcement actions were brought against facilities in the Region, giving it one of the highest enforcement to inspection rates.

- Region X had only one pharmaceutical facility identified by the IDEA system. In the past five years this facility was inspected twice and had two enforcement action brought against it.

Table 20: Five-Year Enforcement and Compliance Summary for the Pharmaceutical Industry									
A	B	C	D	E	F	G	H	I	J
Region	Facilities in Search	Facilities Inspected	Number of Inspections	Average Months Between Inspections	Facilities with 1 or More Enforcement Actions	Total Enforcement Actions	Percent State Lead Actions	Percent Federal Lead Actions	Enforcement to Inspection Rate
I	8	5	11	44	0	0	0%	0%	--
II	60	53	624	6	21	95	84%	16%	0.15
III	18	16	111	10	3	3	100%	0%	0.03
IV	24	17	227	6	4	12	83%	17%	0.05
V	22	16	143	9	4	5	60%	40%	0.03
VI	5	5	17	18	1	4	0%	100%	0.24
VII	12	8	37	19	1	1	100%	0%	0.03
VIII	6	5	22	16	0	0	0%	0%	--
IX	8	3	7	69	0	0	0%	0%	--
X	1	1	2	30	1	2	50%	50%	1.00
TOTAL	164	129	1,201	8	35	122	80%	20%	0.10

VII.B. Comparison of Enforcement Activity Between Selected Industries

Tables 21 and 22 allow the compliance history of the pharmaceutical industry to be compared with the other industries covered by the industry sector notebooks. Comparisons between Tables 21 and 22 permit the identification of trends in compliance and enforcement records of the industry by comparing data covering the last five years to that of the past year. Some points evident from the data are listed below.

- The pharmaceutical industry had one of the highest inspection rates as indicated by its relatively low average time between inspections (8 months) compared to other industries.

- Compared to other sectors, the pharmaceutical industry had a relatively high enforcement to inspection rate (0.07) and a relatively high percent of facilities inspected with violations (105 percent).

Tables 23 and 24 provide a more in-depth comparison between the pharmaceutical industry and other sectors by breaking out the compliance and enforcement data by environmental statute. As in Tables 21 and 22, the data cover the last five years (Table 23) and the previous year (Table 24) to facilitate the identification of recent trends. A few points evident from the data are listed below.

- Over the past five years, about 80 percent of the industry's inspections were for CAA and RCRA. Over the past year CAA and RCRA inspections accounted for almost 90 percent of inspections. This trend is primarily due to an increase in CAA inspections and a decrease in CWA and FIFRA/TSCA/EPCRA/Other inspections.

- The percentage of CAA enforcement actions increased from 49 percent over the past five years to 71 percent in the past year. At the same time the percentage of CWA enforcement actions decreased from 25 percent to 14 percent.

Table 21: Five-Year Enforcement and Compliance Summary for Selected Industries									
A	B	C	D	E	F	G	H	I	J
Industry Sector	**Facilities in Search**	**Facilities Inspected**	**Number of Inspections**	**Average Months Between Inspections**	**Facilities with 1 or More Enforcement Actions**	**Total Enforcement Actions**	**Percent State Lead Actions**	**Percent Federal Lead Actions**	**Enforcement to Inspection Rate**
Metal Mining	1,232	378	1,600	46	63	111	53%	47%	0.07
Coal Mining	3,256	741	3,748	52	88	132	89%	11%	0.04
Oil and Gas Extraction	4,676	1,902	6,071	46	149	309	79%	21%	0.05
Non-Metallic Mineral Mining	5,256	2,803	12,826	25	385	622	77%	23%	0.05
Textiles	355	267	1,465	15	53	83	90%	10%	0.06
Lumber and Wood	712	473	2,767	15	134	265	70%	30%	0.10
Furniture	499	386	2,379	13	65	91	81%	19%	0.04
Pulp and Paper	484	430	4,630	6	150	478	80%	20%	0.10
Printing	5,862	2,092	7,691	46	238	428	88%	12%	0.06
Inorganic Chemicals	441	286	3,087	9	89	235	74%	26%	0.08
Resins and Manmade Fibers	329	263	2,430	8	93	219	76%	24%	0.09
Pharmaceuticals	**164**	**129**	**1,201**	**8**	**35**	**122**	**80%**	**20%**	**0.10**
Organic Chemicals	425	355	4,294	6	153	468	65%	35%	0.11
Agricultural Chemicals	263	164	1,293	12	47	102	74%	26%	0.08
Petroleum Refining	156	148	3,081	3	124	763	68%	32%	0.25
Rubber and Plastic	1,818	981	4,383	25	178	276	82%	18%	0.06
Stone, Clay, Glass and Concrete	615	388	3,474	11	97	277	75%	25%	0.08
Iron and Steel	349	275	4,476	5	121	305	71%	29%	0.07
Metal Castings	669	424	2,535	16	113	191	71%	29%	0.08
Nonferrous Metals	203	161	1,640	7	68	174	78%	22%	0.11
Fabricated Metal Products	2,906	1,858	7,914	22	365	600	75%	25%	0.08
Electronics	1,250	863	4,500	17	150	251	80%	20%	0.06
Automobile Assembly	1,260	927	5,912	13	253	413	82%	18%	0.07
Shipbuilding and Repair	44	37	243	9	20	32	84%	16%	0.13
Ground Transportation	7,786	3,263	12,904	36	375	774	84%	16%	0.06
Water Transportation	514	192	816	38	36	70	61%	39%	0.09
Air Transportation	444	231	973	27	48	97	88%	12%	0.10
Fossil Fuel Electric Power	3,270	2,166	14,210	14	403	789	76%	24%	0.06

Table 22: One-Year Enforcement and Compliance Summary for Selected Industries

A	B	C	D	E		F		G	H
				Facilities with 1 or More Violations		Facilities with 1 or more Enforcement Actions			
Industry Sector	Facilities in Search	Facilities Inspected	Number of Inspections	Number	Percent*	Number	Percent*	Total Enforcement Actions	Enforcement to Inspection Rate
Metal Mining	1,232	142	211	102	72%	9	6%	10	0.05
Coal Mining	3,256	362	765	90	25%	20	6%	22	0.03
Oil and Gas Extraction	4,676	874	1,173	127	15%	26	3%	34	0.03
Non-Metallic Mineral Mining	5,256	1,481	2,451	384	26%	73	5%	91	0.04
Textiles	355	172	295	96	56%	10	6%	12	0.04
Lumber and Wood	712	279	507	192	69%	44	16%	52	0.10
Furniture	499	254	459	136	54%	9	4%	11	0.02
Pulp and Paper	484	317	788	248	78%	43	14%	74	0.09
Printing	5,862	892	1,363	577	65%	28	3%	53	0.04
Inorganic Chemicals	441	200	548	155	78%	19	10%	31	0.06
Resins and Manmade Fibers	329	173	419	152	88%	26	15%	36	0.09
Pharmaceuticals	**164**	**80**	**209**	**84**	**105%**	**8**	**10%**	**14**	**0.07**
Organic Chemicals	425	259	837	243	94%	42	16%	56	0.07
Agricultural Chemicals	263	105	206	102	97%	5	5%	11	0.05
Petroleum Refining	156	132	565	129	98%	58	44%	132	0.23
Rubber and Plastic	1,818	466	791	389	83%	33	7%	41	0.05
Stone, Clay, Glass and Concrete	615	255	678	151	59%	19	7%	27	0.04
Iron and Steel	349	197	866	174	88%	22	11%	34	0.04
Metal Castings	669	234	433	240	103%	24	10%	26	0.06
Nonferrous Metals	203	108	310	98	91%	17	16%	28	0.09
Fabricated Metal	2,906	849	1,377	796	94%	63	7%	83	0.06
Electronics	1,250	420	780	402	96%	27	6%	43	0.06
Automobile Assembly	1,260	507	1,058	431	85%	35	7%	47	0.04
Shipbuilding and Repair	44	22	51	19	86%	3	14%	4	0.08
Ground Transportation	7,786	1,585	2,499	681	43%	85	5%	103	0.04
Water Transportation	514	84	141	53	63%	10	12%	11	0.08
Air Transportation	444	96	151	69	72%	8	8%	12	0.08
Fossil Fuel Electric Power	3,270	1,318	2,430	804	61%	100	8%	135	0.06
Dry Cleaning	6,063	1,234	1,436	314	25%	12	1%	16	0.01

**Percentages in Columns E and F are based on the number of facilities inspected (Column C). Percentages can exceed 100% because violations and actions can occur without a facility inspection.*

Table 23: Five-Year Inspection and Enforcement Summary by Statute for Selected Industries

Industry Sector	Facilities Inspected	Total Inspections	Total Enforcement Actions	Clean Air Act		Clean Water Act		RCRA		FIFRA/TSCA/ EPCRA/Other	
				% of Total Inspections	% of Total Actions	% of Total Inspections	% of Total Actions	% of Total Inspections	% of Total Actions	% of Total Inspections	% of Total Actions
Metal Mining	378	1,600	111	39%	19%	52%	52%	8%	12%	1%	17%
Coal Mining	741	3,748	132	57%	64%	38%	28%	4%	8%	1%	1%
Oil and Gas Extraction	1,902	6,071	309	75%	65%	16%	14%	8%	18%	0%	3%
Non-Metallic Mineral Mining	2,803	12,826	622	83%	81%	14%	13%	3%	4%	0%	3%
Textiles	267	1,465	83	58%	54%	22%	25%	18%	14%	2%	6%
Lumber and Wood	473	2,767	265	49%	47%	6%	6%	44%	31%	1%	16%
Furniture	386	2,379	91	62%	42%	3%	0%	34%	43%	1%	14%
Pulp and Paper	430	4,630	478	51%	59%	32%	28%	15%	10%	2%	4%
Printing	2,092	7,691	428	60%	64%	5%	3%	35%	29%	1%	4%
Inorganic Chemicals	286	3,087	235	38%	44%	27%	21%	34%	30%	1%	5%
Resins and Manmade Fibers	263	2,430	219	35%	43%	23%	28%	38%	23%	4%	6%
Pharmaceuticals	**129**	**1,201**	**122**	**35%**	**49%**	**15%**	**25%**	**45%**	**20%**	**5%**	**5%**
Organic Chemicals	355	4,294	468	37%	42%	16%	25%	44%	28%	4%	6%
Agricultural Chemicals	164	1,293	102	43%	39%	24%	20%	28%	30%	5%	11%
Petroleum Refining	148	3,081	763	42%	59%	20%	13%	36%	21%	2%	7%
Rubber and Plastic	981	4,383	276	51%	44%	12%	11%	35%	34%	2%	11%
Stone, Clay, Glass and Concrete	388	3,474	277	56%	57%	13%	9%	31%	30%	1%	4%
Iron and Steel	275	4,476	305	45%	35%	26%	26%	28%	31%	1%	8%
Metal Castings	424	2,535	191	55%	44%	11%	10%	32%	31%	2%	14%
Nonferrous Metals	161	1,640	174	48%	43%	18%	17%	33%	31%	1%	10%
Fabricated Metal	1,858	7,914	600	40%	33%	12%	11%	45%	43%	2%	13%
Electronics	863	4,500	251	38%	32%	13%	11%	47%	50%	2%	7%
Automobile Assembly	927	5,912	413	47%	39%	8%	9%	43%	43%	2%	9%
Shipbuilding and Repair	37	243	32	39%	25%	14%	25%	42%	47%	5%	3%
Ground Transportation	3,263	12,904	774	59%	41%	12%	11%	29%	45%	1%	3%
Water Transportation	192	816	70	39%	29%	23%	34%	37%	33%	1%	4%
Air Transportation	231	973	97	25%	32%	27%	20%	48%	48%	0%	0%
Fossil Fuel Electric Power	2,166	14,210	789	57%	59%	32%	26%	11%	10%	1%	5%
Dry Cleaning	2,360	3,813	66	56%	23%	3%	6%	41%	71%	0%	0%

Table 24: One-Year Inspection and Enforcement Summary by Statute for Selected Industries												
Industry Sector	**Facilities Inspected**	**Total Inspections**	**Total Enforcement Actions**	**Clean Air Act**		**Clean Water Act**		**RCRA**		**FIFRA/TSCA/ EPCRA/Other**	
				% of Total Inspections	**% of Total Actions**	**% of Total Inspections**	**% of Total Actions**	**% of Total Inspections**	**% of Total Actions**	**% of Total Inspections**	**% of Total Actions**
Metal Mining	142	211	10	52%	0%	40%	40%	8%	30%	0%	30%
Coal Mining	362	765	22	56%	82%	40%	14%	4%	5%	0%	0%
Oil and Gas Extraction	874	1,173	34	82%	68%	10%	9%	9%	24%	0%	0%
Non-Metallic Mineral Mining	1,481	2,451	91	87%	89%	10%	9%	3%	2%	0%	0%
Textiles	172	295	12	66%	75%	17%	17%	17%	8%	0%	0%
Lumber and Wood	279	507	52	51%	30%	6%	5%	44%	25%	0%	40%
Furniture	254	459	11	66%	45%	2%	0%	32%	45%	0%	9%
Pulp and Paper	317	788	74	54%	73%	32%	19%	14%	7%	0%	1%
Printing	892	1,363	53	63%	77%	4%	0%	33%	23%	0%	0%
Inorganic Chemicals	200	548	31	35%	59%	26%	9%	39%	25%	0%	6%
Resins and Manmade Fibers	173	419	36	38%	51%	24%	38%	38%	5%	0%	5%
Pharmaceuticals	**80**	**209**	**14**	**43%**	**71%**	**11%**	**14%**	**45%**	**14%**	**0%**	**0%**
Organic Chemicals	259	837	56	40%	54%	13%	13%	47%	34%	0%	0%
Agricultural Chemicals	105	206	11	48%	55%	22%	0%	30%	36%	0%	9%
Petroleum Refining	132	565	132	49%	67%	17%	8%	34%	15%	0%	10%
Rubber and Plastic	466	791	41	55%	64%	10%	13%	35%	23%	0%	0%
Stone, Clay, Glass and Concrete	255	678	27	62%	63%	10%	7%	28%	30%	0%	0%
Iron and Steel	197	866	34	52%	47%	23%	29%	26%	24%	0%	0%
Metal Castings	234	433	26	60%	58%	10%	8%	30%	35%	0%	0%
Nonferrous Metals	108	310	28	44%	43%	15%	20%	41%	30%	0%	7%
Fabricated Metal	849	1,377	83	46%	41%	11%	2%	43%	57%	0%	0%
Electronics	420	780	43	44%	37%	14%	5%	43%	53%	0%	5%
Automobile Assembly	507	1,058	47	53%	47%	7%	6%	41%	47%	0%	0%
Shipbuilding and Repair	22	51	4	54%	0%	11%	50%	35%	50%	0%	0%
Ground Transportation	1,585	2,499	103	64%	46%	11%	10%	26%	44%	0%	1%
Water Transportation	84	141	11	38%	9%	24%	36%	38%	45%	0%	9%
Air Transportation	96	151	12	28%	33%	15%	42%	57%	25%	0%	0%
Fossil Fuel Electric Power	1,318	2,430	135	59%	73%	32%	21%	9%	5%	0%	0%
Dry Cleaning	1,234	1,436	16	69%	56%	1%	6%	30%	38%	0%	0%

VII.C. Review of Major Legal Actions

This section provides summary information about major cases that have affected this sector, and Supplementary Environmental Projects (SEPs). SEPs are compliance agreements that reduce a facility's stipulated penalty in return for an environmental project that exceeds the value of the reduction. Often, these projects fund pollution prevention activities that can significantly reduce the future pollutant loadings of a facility.

VII.C.1. Review of Major Cases

As indicated in EPA's *Enforcement Accomplishments Report, FY1995 and FY1996* publications, 5 significant enforcement actions were resolved between 1994 and 1996 for the pharmaceutical industry.

In the Matter of Ciba-Geigy, Inc.: On November 7, 1994, Region II issued an administrative consent order to Ciba-Geigy, Inc., assessing a penalty of $130,000 for violations of EPCRA at its Toms River, New Jersey, facility. The order was based upon an inspection of Ciba-Geigy's facility that resulted in a sixteen count complaint alleging that Ciba-Geigy failed to report that it used certain of the following: copper compounds; glycol ethers; chromium compounds; cobalt compounds; C.I. Disperse Yellow 3; diethanolamine and ethylene glycol during the calendar years 1988 through 1991.

Ciba-Geigy Superfund Site: On October 18, 1995, Region II issued an administrative order on consent under Sections 104, 107, and 122 of CERCLA to the Ciba-Geigy Corporation. The order requires Ciba-Geigy to perform, under EPA oversight, a feasibility study for Operable Unit Two to develop and evaluate remedial alternatives for approximately twenty-one potential source areas of groundwater contamination on the site. The estimated cost of the work that Ciba-Geigy will perform is $20 million. In addition, Ciba-Geigy will also pay all of EPA's unreimbursed past response costs, $797,000, plus all of EPA's future response costs, including oversight costs.

The site is on the National Priorities List and located in Toms River, Ocean County, New Jersey. Groundwater at the site is contaminated with organic and inorganic compounds, and emanates from surface and subsurface former disposal areas on the site. Pursuant to a settlement with EPA in 1994, Ciba-Geigy is currently remediating the groundwater contamination. EPA recently completed a baseline public health risk assessment or source area surface soils, as well as a remedial investigation to examine the nature and extent of the contamination in the source areas at the site. In performing the feasibility study for the source areas, Ciba-Geigy has agreed to adopt EPA's risk assessment and remedial investigation report.

Takeda Chemical Products USA, Inc. (NC): On August 31, 1995, Region IV entered into a consent agreement/consent order (CACO) resolving claims against Takeda Chemical Products USA, Inc., for violations of RCRA at its vitamin manufacturing plant in Wilmington, North Carolina. As part of a solvent extraction process, Takeda generated a by-product referred to as DAS-fuel, which Takeda intended to burn for energy recovery. Prior to receiving any permits to burn the DAS-fuel, Takeda generated DAS-fuel and stored it on-site for a period in excess of 90 days without a permit or interim status, and later shipped it off-site. EPA determined that the DAS-fuel (essentially spent toluene mixed with DAS water and polymers) was F005 hazardous waste. As a result, on September 24, 1994, Region IV issued a complaint for illegal storage of hazardous waste, failure to make a hazardous waste determination, and failure to manifest the DAS-fuel shipped off-site. The CACO requires Takeda to pay a civil penalty of $99,000, but allows Takeda to bring DAS-fuel back on-site for reprocessing, provided Takeda manages any waste it produces as a result as a hazardous waste.

Abbott Laboratories: A consent agreement and final order was signed in September 1995, concerning Abbott Laboratories Corporation's violations of RCRA standards applicable to the burning of hazardous waste in boilers and industrial furnaces (BIF) at its North Chicago, Illinois facility. Negotiations with Abbott Laboratories after issuance of the complaint in February 1994 resulted in a penalty of $182,654. Abbott also agreed to conduct a supplemental environmental project (SEP) that will allow Abbott to recover and recycle the methylene chloride produced in its manufacturing processes and will reduce fugitive methylene chloride emissions. The SEP involves three separate, albeit similar, operations, replacing "wet" vacuum pump systems with "dry" pumps and high efficiency condensers. The projected cost of the SEP is $480,000.

VII.C.2. Supplementary Environmental Projects (SEPs)

Supplemental environmental projects (SEPs) are enforcement options that require the non-compliant facility to complete specific projects. Information on SEP cases can be accessed via the internet at EPA's Enviroene website: http://es.inel.gov/sep.

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VIII. COMPLIANCE ACTIVITIES AND INITIATIVES

This section highlights the activities undertaken by this industry sector and public agencies to voluntarily improve the sector's environmental performance. These activities include those independently initiated by industrial trade associations. In this section, the notebook also contains a listing and description of national and regional trade associations.

VIII.A. Sector-related Programs and Activities

The Pharmaceutical Research and Manufacturers of America (PhRMA) and EPA are considering developing compliance and regulations guides, concerning the interactions of EPA and FDA regulations for the pharmaceutical industry.

VIII.B. EPA Voluntary Programs

33/50 Program

The 33/50 Program is a ground breaking program that has focused on reducing pollution from seventeen high-priority chemicals through voluntary partnerships with industry. The program's name stems from its goals: a 33% reduction in toxic releases and transfers by 1992, and a 50% reduction by 1995, against a baseline of 1.5 billion pounds of releases and transfers in 1988. The results have been impressive: 1,300 companies have joined the 33/50 Program (representing over 6,000 facilities) and have reached the national targets a year ahead of schedule. The 33% goal was reached in 1991, and the 50% goal -- a reduction of 745 million pounds of toxic wastes -- was reached in 1994. The 33/50 Program can provide case studies on many of the corporate accomplishments in reducing waste.

Table 25 lists those companies participating in the 33/50 program that reported the SIC codes 2833 and 2834 to TRI. Some of the companies shown also listed facilities that are not producing pharmaceuticals. The number of facilities within each company that are participating in the 33/50 program and that report pharmaceutical SIC codes is shown. Where available and quantifiable against 1988 releases and transfers, each company's 33/50 goals for 1995 and the actual total releases and transfers and percent reduction between 1988 and 1994 are presented. At the time of publication of this document (August 1997) 1995 33/50 Program TRI data were not available.

Table 20 shows that 34 companies comprised of 160 facilities reporting SIC 2833 and 2834 are participated in the 33/50 program. For those companies shown with more than one pharmaceutical manufacturing facility, all facilities may not be participating in 33/50. The 33/50 goals shown for

companies with multiple pharmaceutical facilities, however, are company-wide, potentially aggregating more than one facility and facilities not carrying out pharmaceutical operations. In addition to company-wide goals, individual facilities within a company may have their own 33/50 goals or may be specifically listed as not participating in the 33/50 program. Since the actual percent reductions shown in the last column apply to all of the companies' pharmaceutical manufacturing facilities and only pharmaceutical manufacturing facilities, direct comparisons to those company goals incorporating non-pharmaceutical facilities or excluding certain facilities may not be possible. For information on specific facilities participating in 33/50, contact David Sarokin (202-260-6907) at the 33/50 Program Office.

Table 25: Pharmaceutical Industry Participation in the 33/50 Program

Parent Company (Headquarters Location)	Company-Owned Pharmaceutical Facilities Reporting 33/50 Chemicals	Company-wide % Reduction Goal[1] (1988-1995)	1988 TRI Releases and Transfers of 33/50 Chemicals (pounds)	1994 TRI Releases and Transfers of 33/50 Chemicals (pounds)	Actual % Reduction for Pharmaceutical Facilities (1988 - 1994)
3M Minnesota Mining & Mfg.. Company - St. Paul, MN	2	70	885, 011	194, 850	78
Abbott Laboratories - North Chicago, IL	6	20	3, 017, 869	2, 869, 793	5.0
American Home Products Corporation - Madison ,NJ	19	50	1, 828, 970	930, 992	49
Anabolic Incorporated - Irvine, CA	1	75	39, 602	0	100
Baxter International Inc. - Deerfield, IL	8	80	921, 282	33, 312	96
Boehringer Ingelheim Corp. - Ridgefield, CT	2	50	198, 500	247, 166	-24.5
Bristol-Myers Squibb Co. - New York, NY	15	50	4, 876, 002	2, 305, 269	53
Burroughs Wellcome Co. - Durham, NC	2	26	469, 075	193, 171	59
Ciba-Geigy Company - Tarrytown, NY	14	50	2, 613, 266	1, 179, 471	55
Coating Place Incorporated - Verona, WI	1	***	149, 000	0	100
Dow Chemical Company - Midland, MI	1	50	115, 000	109, 100	5
Eastman Kodak Company - Rochester, NY	1	50	87, 350	15, 766	82
Eli Lilly and Company - Indianapolis, IN	7	50	5, 749, 879	1, 194, 760	79
Fisons Company - Rochester, NY	1	***	3, 395	2, 229	34
Ganes Chemicals Inc. - Carlstadt, NJ	2	***	67, 018	19, 586	71
Hoechst Celanese Company - Corpus Christi, TX	1	50	0	0	--
Hoffmann-La Roche Inc. - Nutley, NJ	5	62	2, 154, 667	1, 230, 361	43
Johnson & Johnson - New Brunswick, NJ	2	65	258, 090	234, 444	9
Mallinckrodt Group Inc. - Saint Louis, MO	1	50	0	500	--
Merck & Company Inc. - Whitehouse Station, NJ	7	50	5, 863, 293	927, 225	84

Table 25: Pharmaceutical Industry Participation in the 33/50 Program					
Monsanto Company - Saint Louis, MO	3	25	9, 200	3, 480	62
Par Pharmaceutical Inc. - Spring Valley, NY	1	***	194, 099	0	100
Perrigo Company - Allegan, MI	2	95	638, 235	0	100
Pfizer Incorporated - New York, NY	10	50	2, 492, 314	3, 250, 940	-30
Sandoz Corporation New York, NY	18	50	572, 915	100, 439	82
Schering-Plough Corp. - Madison, NJ	7	70	3, 181, 202	1, 867, 558	41
Smithkline Beecham Americas - Philadelphia, PA	6	81	2, 882, 573	35, 469	99
Solvay America Inc. - Houston, TX	1	*	0	36, 474	--
Syntex USA Incorporated - Palo Alto, CA	3	33	1, 093, 051	393, 493	64
Tishcon Corporation - Westbury, NY	2	**	3, 900	113, 000	-2797
United Organics Corp. - Williamston, NC	1	*	0	5, 950	--
Upjohn Company - Kalamazoo, MI	3	50	7, 128, 339	5, 654, 150	21
Upsher-Smith Laboratories Inc. - Minneapolis, MN	1	100	94, 000	320, 000	-240
Warner-Lambert Company - Morris Plains, NJ	4	40	197, 540	242, 638	-22
Total	160		47, 784, 637	23, 711, 586	50

Source: *US EPA 33/50 Program Office, 1996. 1995 33/50 TRI data was not available at time of publication.*

[1]Company-wide Reduction Goals aggregate all company-owned facilities which may include facilities not producing pharmaceuticals.

* = Reduction goal not quantifiable against 1988 TRI data.

** = Use reduction goal only.

*** = No numeric reduction goal.

Environmental Leadership Program

The Environmental Leadership Program (ELP) is a national initiative developed by EPA that focuses on improving environmental performance, encouraging voluntary compliance, and building working relationships with stakeholders. EPA initiated a one year pilot program in 1995 by selecting 12 projects at industrial facilities and federal installations that demonstrate the principles of the ELP program. These principles include: environmental management systems, multimedia compliance assurance, third-party verification of compliance, public measures of accountability, pollution

prevention, community involvement, and mentor programs. In return for participating, pilot participants received public recognition and were given a period of time to correct any violations discovered during these experimental projects.

EPA is making plans to launch its full-scale Environmental Leadership Program in 1997. The full-scale program will be facility-based with a 6-year participation cycle. Facilities that meet certain requirements will be eligible to participate, such as having a community outreach/employee involvement programs and an environmental management system (EMS) in place for 2 years. (Contact: http://es.inel.gov/elp or Debby Thomas, ELP Deputy Director, at 202-564-5041)

Project XL

Project XL was initiated in March 1995 as a part of President Clinton's *Reinventing Environmental Regulation* initiative. The projects seek to achieve cost effective environmental benefits by providing participants regulatory flexibility on the condition that they produce greater environmental benefits. EPA and program participants will negotiate and sign a Final Project Agreement, detailing specific environmental objectives that the regulated entity shall satisfy. EPA will provide regulatory flexibility as an incentive for the participants' superior environmental performance. Participants are encouraged to seek stakeholder support from local governments, businesses, and environmental groups. EPA hopes to implement fifty pilot projects in four categories, including industrial facilities, communities, and government facilities regulated by EPA. Applications are being accepted on a rolling basis.

In 1996, EPA accepted a proposal by Merck to deliver superior environmental protection while allowing flexible operation at its pharmaceutical manufacturing facility near Elkton, Virginia. Merck, along with its stakeholders, developed a simplified air permit for the facility that will cap total air emissions of criteria pollutants at less than recent actual levels and allow the facility to make changes and additions to its manufacturing processes as soon as they are needed without prior approval. The upfront environmental benefit which will enable Merck to operate flexibly under the emissions cap will come from converting the coal burning powerhouse to natural gas. This conversion will reduce the site's actual air emissions by over 900 tons per year of criteria pollutants, and 50 tons per year of hazardous air pollutants.

Under the proposal, EPA and the Virginia Department of Environmental Quality (VADEQ) will adopt the Prevention of Significant Deterioration (PSD) permit through different mechanisms under their respective jurisdictions. EPA plans to promulgate a site-specific rule making in order

to make adjustments to current applicable regulations to allow for the flexible operation of the permit. The Virginia State Air Pollution Control Board will promulgate a variance to make the PSD permit legally enforceable under state laws. These proposed actions and the draft permit were subject to public comment and it is expected that the permit will be issued to Merck during 1997.

For additional information regarding XL projects, including application procedures and criteria, see the May 23, 1995 Federal Register Notice. (Contact: Fax-on-Demand Hotline 202-260-8590, Web: http://www.epa.gov/ProjectXL, or Christopher Knopes at EPA's Office of Policy, Planning and Evaluation 202-260-9298)

Climate Wise Program

Climate Wise is helping US industries turn energy efficiency and pollution prevention into a corporate asset. Supported by the technical assistance, financing information and public recognition that Climate Wise offers, participating companies are developing and launching comprehensive industrial energy efficiency and pollution prevention action plans that save money and protect the environment. The nearly 300 Climate Wise companies expect to save more than $300 million and reduce greenhouse gas emissions by 18 million metric tons of carbon dioxide equivalent by the year 2000. Some of the actions companies are undertaking to achieve these results include: process improvements, boiler and steam system optimization, air compressor system improvements, fuel switching, and waste heat recovery measures including cogeneration. Created as part of the President's Climate Change Action Plan, Climate Wise is jointly operated by the Department of Energy and EPA. Under the Plan many other programs were also launched or upgraded including Green Lights, WasteWi$e and DoE's Motor Challenge Program. Climate Wise provides an umbrella for these programs which encourage company participation by providing information on the range of partnership opportunities available. (Contact: Pamela Herman, EPA, 202-260-4407 or Jan Vernet, DoE, 202-586-4755)

Energy Star Buildings Program

EPA's ENERGY STAR Buildings Program is a voluntary, profit-based program designed to improve the energy-efficiency in commercial and industrial buildings. Expanding the successful Green Lights Program, ENERGY STAR Buildings was launched in 1995. This program relies on a 5-stage strategy designed to maximize energy savings thereby lowering energy bills, improving occupant comfort, and preventing pollution -- all at the same time. If implemented in every commercial and industrial building in the United States, ENERGY STAR Buildings could cut the nation's energy bill by up to $25 billion and prevent up to 35% of carbon dioxide emissions. (This is

equivalent to taking 60 million cars of the road). ENERGY STAR Buildings participants include corporations; small and medium sized businesses; local, federal and state governments; non-profit groups; schools; universities; and health care facilities. EPA provides technical and non-technical support including software, workshops, manuals, communication tools, and an information hotline. EPA's Office of Air and Radiation manages the operation of the ENERGY STAR Buildings Program. (Contact: Green Light/Energy Star Hotline at 1-888-STAR-YES or Maria Tikoff Vargas, EPA Program Director at 202-233-9178 or visit the ENERGY STAR Buildings Program website at http://www.epa.gov/appdstar/buildings/)

Green Lights Program

EPA's Green Lights program was initiated in 1991 and has the goal of preventing pollution by encouraging U.S. institutions to use energy-efficient lighting technologies. The program saves money for businesses and organizations and creates a cleaner environment by reducing pollutants released into the atmosphere. The program has over 2,345 participants which include major corporations, small and medium sized businesses, federal, state and local governments, non-profit groups, schools, universities, and health care facilities. Each participant is required to survey their facilities and upgrade lighting wherever it is profitable. As of March 1997, participants had lowered their electric bills by $289 million annually. EPA provides technical assistance to the participants through a decision support software package, workshops and manuals, and an information hotline. EPA's Office of Air and Radiation is responsible for operating the Green Lights Program. (Contact: Green Light/Energy Star Hotline at 1-888-STARYES or Maria Tikoff Vargar, EPA Program Director, at 202-233-9178 the)

WasteWi$e Program

The WasteWi$e Program was started in 1994 by EPA's Office of Solid Waste and Emergency Response. The program is aimed at reducing municipal solid wastes by promoting waste prevention, recycling collection and the manufacturing and purchase of recycled products. As of 1997, the program had about 500 companies as members, one third of whom are Fortune 1000 corporations. Members agree to identify and implement actions to reduce their solid wastes setting waste reduction goals and providing EPA with yearly progress reports. To member companies, EPA, in turn, provides technical assistance, publications, networking opportunities, and national and regional recognition. (Contact: WasteWi$e Hotline at 1-800-372-9473 or Joanne Oxley, EPA Program Manager, 703-308-0199)

NICE[3]

The U.S. Department of Energy is administering a grant program called The National Industrial Competitiveness through Energy, Environment, and Economics (NICE[3]). By providing grants of up to 45 percent of the total project cost, the program encourages industry to reduce industrial waste at its source and become more energy-efficient and cost-competitive through waste minimization efforts. Grants are used by industry to design, test, and demonstrate new processes and/or equipment with the potential to reduce pollution and increase energy efficiency. The program is open to all industries; however, priority is given to proposals from participants in the forest products, chemicals, petroleum refining, steel, aluminum, metal casting and glass manufacturing sectors. (Contact: http//www.oit.doe.gov/access/nice3, Chris Sifri, DOE, 303-275-4723 or Eric Hass, DOE, 303-275-4728)

Design for the Environment (DfE)

DfE is working with several industries to identify cost-effective pollution prevention strategies that reduce risks to workers and the environment. DfE helps businesses compare and evaluate the performance, cost, pollution prevention benefits, and human health and environmental risks associated with existing and alternative technologies. The goal of these projects is to encourage businesses to consider and use cleaner products, processes, and technologies. For more information about the DfE Program, call (202) 260-1678. To obtain copies of DfE materials or for general information about DfE, contact EPA's Pollution Prevention Information Clearinghouse at (202) 260-1023 or visit the DfE Website at http://es.inel.gov/dfe.

VIII.C. Trade Association/Industry Sponsored Activity

VIII.C.1. Environmental Programs

The Pharmaceuticals Research and Manufacturers of America (PhRMA) coordinates the research-based pharmaceutical industry's response to industry-specific environmental issues, such as the pharmaceutical MACT. PhRMA works through an environmental committee, a series of subcommittees responsible for regulatory areas such as water and air, and ad hoc work groups to address narrowly-focused issues.

The research-based pharmaceutical industry also relies on other broad-based trade associations for issues that affect the larger business community. Several of the PhRMA members are also members of the Chemical Manufacturers Association (CMA) and therefore are part of CMA's Responsible Care® Initiative.

In addition, many pharmaceutical companies have been implementing their own environmental programs and initiatives to reduce the environmental impacts of their products and manufacturing processes. These programs are both company-wide and at the facility level. More information on such programs can be obtained by contacting individual companies and facilities.

VIII.C.2. Summary of Trade Associations

Pharmaceutical Research and Manufacturers of America (PhRMA)
1100 15th Street, NW
Washington, D.C. 20035
Phone: (202) 835-3400
Fax: (202) 835-3414

Budget:$20,000,000
Staff: 80
Members: 40 companies
Affiliates: 30 companies

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a non-profit organization which was established in 1958. Its main function is to assist research-based pharmaceutical companies in discovery, development, and marketing of new drugs for humans. Comprised of most of the largest pharmaceutical companies in the United States, PhRMA members are primarily engaged in research and development of new medicines. To be a member of PhRMA, a company must be heavily involved in research and development (R&D) and must also manufacture and market finished dosage-form drugs under their own brand name. PhRMA member companies invest nearly $19 billion a year in discovering and developing new drugs. Additionally, PhRMA members account for approximately 90% of total pharmaceutical sales in the United States.

Generic Pharmaceutical Industry Association
1620 I Street, NW
Washington, D.C. 20006-4005
Phone: (202) 833-9070
Fax: (202) 833-9612

Budget: $1-2,000,000
Staff: 6
Members: 46 companies

The Generic Pharmaceutical Industry Association (GPIA) is a primary trade association for manufacturers and distributors of generic drugs. Its main publication is “GPIA News”.

National Pharmaceutical Alliance (NPA)
421 King Street, Suite 222,
Alexandria, VA 22314
Phone: (703) 836-8816
Fax: (703) 549-4749

Budget: $250-500,000
Members: 165 companies

The National Pharmaceutical Alliance (NPA) is an organization which represents the interests of small pharmaceutical companies and allied industries. Members of NPA develop bioequivalent versions of major branded products, create products of alternative combinations, strengths, and/or dosage forms, and market products which are not produced by larger companies and which would not be available to the public

otherwise. NPA assists in meeting these goals for its member companies. NPA also publishes a bi-monthly journal called "NPA & News, Washington Report."

American Pharmaceutical Association
(APhA)
2215 Constitution Ave. NW
Washington, DC 20037
Phone: (202) 628-4410 Budget: $12,000,000
Fax: (202) 783-2351 Members: 44,000

The American Pharmaceutical Association (APhA) is a professional society that includes pharmacists in all practice settings, educators, students, researchers, editors and publishers of pharmaceutical literature, pharmaceutical chemists and scientists, and food and drug officials. APhA promotes quality health care and comprehensive pharmaceutical care through the appropriate use of pharmacy services. APhA works to: represent the interests of the profession before governmental bodies; interprets and disseminates information on developments in health care; and assure quality pharmacy services and patient care. APhA fosters professional education and training of pharmacists; supports the Academy of Pharmaceutical Research and Science, the Academy of Pharmacy Practice and Management, and the Academy of Students of Pharmacy. APhA also publishes a quarterly newsletter, *Academy Reporter*, and monthly journals including, *American Pharmacy* (*Journal of the American Pharmaceutical Association*) and *Journal of Pharmaceutical Sciences*.

United States Pharmacopeial
Convention (USP)
12601 Twinbrook Pky.
Rockville, MD 20852
Phone: (301) 881-0666 Budget: $20,000,000
Fax: (301) 816-8247 Members: 395

The United States Pharmacopeial Convention (USP) is a recognized authority in medicine, pharmacy, and allied sciences. USP revises and publishes legally recognized compendia of drug standards including the *National Formulary*.

National Association of Pharmaceutical Manufacturers (NAPM)
320 Old Country Road - Suite 205
Garden City, NY 11530
Phone: (516) 741-3699
Fax: (516) 741-3696

Nonprescription Drug Manufacturers Association
1150 Connecticut Avenue, NW
Washington, DC 20036
Phone: (202) 429-9260
Fax: (202) 223-6835

National Wholesale Druggist's Association
1821 Michael Faraday Drive
Suite 400
Reston, VA 22090
Phone: (703) 787-0000 ext. 240
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IX. CONTACTS/ACKNOWLEDGMENTS/REFERENCES

For further information on selected topics within the pharmaceutical industry a list of publications and contacts are provided below:

Contacts[a]

Name	Organization	Telephone	Subject
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Randy McDonald	EPA/OA	(919)541-5402	Regulatory Requirements (CAA)
Umesh Dholakia	EPA Region II	(212) 637-4023	Regulatory Requirements (CAA)
Nancy Sager	FDA- Center for Drug Evaluation and Research	(301) 594-5629	Information on Human Drugs
Daniel Kearns	FDA - Center for Biologics Evaluation and Research	(301) 827-3031	Information on Biologics
Charles E. Eirkson, III	FDA - Center for Veterinary Medicine	(301) 594-1683	Information on Veterinary Medicine
Mervin Parker	FDA - Center for Devices and Radiological Health	(301) 594-2186	Information on medical devices and radiological health
Buzz L. Hoffman	FDA - Center for Food Safety and Applied Nutrition	(202) 418-3005	Information on foods
Tom White	PhRMA	(202) 835-3546	Environmental Affairs

CAA: Clean Air Act
CWA: Clean Water Act
OECA: Office of Enforcement and Compliance Assurance
OA: Office of Air
OW: Office of Water
FDA: Food and Drug Administration
PhRMA: Pharmaceutical Research and Manufacturers of America

[a] Many of the contacts listed above have provided valuable background information and comments during development of this document. EPA appreciates this support and acknowledges that the individuals listed do not necessarily endorse all statements made within this notebook.

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