3/20/97 **FACT SHEET**

PROPOSED AIR TOXICS RULE FOR PHARMACEUTICAL PRODUCTION

TODAY'S ACTION...

- Under authority of the Clean Air Act Amendments of 1990, the Environmental Protection Agency (EPA) is today proposing a regulation to reduce emissions of toxic air pollutants from the manufacture of pharmaceutical products, such as prescription and over-the-counter drugs.

- EPA worked in partnership with major stakeholders, including representatives from industry and State and Territorial Air Pollution Program Administrators/Association of Local Air Pollution Control Officials (STAPPA/ALAPCO), in developing the proposal.

WHAT ARE THE HEALTH AND ENVIRONMENTAL BENEFITS?

- EPA's proposed rule would reduce emissions of a number of air toxics, including methylene chloride, methanol, toluene, and hydrogen chloride. Air toxics are those pollutants that are known or suspected of causing cancer or other serious health effects.

- EPA's proposal would reduce emissions of air toxics by approximately 24,000 tons annually, representing a 65 percent reduction from current levels.

- Today’s action demonstrates EPA’s commitment to making pollution prevention an integral part of regulatory actions whenever possible. EPA’s proposal provides facilities with an alternative, pollution prevention-based standard as an option for complying with the rule’s requirements. The pollution prevention-based option would require a reduction in the use of solvents (which are also toxic air pollutants) during the manufacturing process.

BACKGROUND

- Under the Clean Air Act Amendments of 1990, EPA is required to regulate emissions of 188 listed toxic air pollutants. On July 16, 1992, EPA published a list of source categories that emit one or more of these air toxics. For listed categories of "major" sources (those that emit 10 tons/year or more of a listed pollutant or 25 tons/year or more of a combination of pollutants), the Clean Air Act requires EPA

to develop standards that require the application of stringent air pollution controls, known as maximum achievable control technology (MACT).

- EPA's published list of industry groups (known as "source categories") to be regulated includes major sources that manufacture pharmaceutical products.

WHAT DOES EPA'S PROPOSED RULE REQUIRE?

- The pharmaceutical manufacturing process consists mainly of chemical production operations used to produce drugs and medication. These operations include chemical synthesis (deriving a drug’s active ingredient)and chemical formulation (producing a drug in its final form.) EPA's proposal would set an emissions limit or control efficiency requirements for the following emissions points at affected sources or facilities: storage tanks, process vents, equipment leaks, wastewater collection and treatment systems, and cooling towers.

- The monitoring, recordkeeping and reporting requirements outlined in the proposed rule are similar to those required for other EPA air toxics regulations.

HOW DOES EPA’S PROPOSAL PROVIDE FLEXIBILITY TO INDUSTRY?

- Today’s action would provide industry with the option of complying with the regulation through an alternative, pollution prevention-based standard. The alternative standard would require reductions in the amounts of solvents (also toxic air pollutants)used during the manufacturing process. It would allow facilities to focus on improving processes by reducing solvent loss and incorporating solvent recovery and reuse techniques.

- EPA's proposed rule also contains a market-based provision, "emissions averaging," that would allow facilities flexibility to choose certain emissions points to control in order to achieve the required emissions reductions in the most cost-effective manner possible. The proposal would allow facilities to use emissions averaging among process vents and storage tanks. In some situations, facilities may find it more cost-effective to overcontrol these emissions points and undercontrol others, so that the overall result would be greater emissions reductions at lesser control costs. The proposed rule spells out how facilities would be able to use emissions averaging.

WHO WOULD BE AFFECTED BY EPA'S PROPOSED RULE?

- There are about 100 pharmaceutical manufacturing facilities nationwide that would be affected by the proposed rule. Many of these facilities have already installed stringent air pollution controls.

HOW MUCH WOULD THE PROPOSED RULE COST?

- The capital cost of the proposal for all affected facilities is estimated to be about $183 million.

- The total annual cost of the proposal is estimated to be about $73 million for existing and new facilities.

- EPA expects that the actual compliance cost impacts of the standard would be less than projected because of the potential to use common control devices; upgrade existing control devices; use other less expensive control technologies; implement pollution prevention technologies; and employ emissions averaging.

- The price of pharmaceutical products for consumers is projected to increase by about one percent.

FOR FURTHER INFORMATION...

- Anyone with a computer and a modem can download the proposed rule from the Clean Air Act Amendments bulletin board (under "Recently Signed Rules") on EPA's Technology Transfer Network (TTN) by calling (919) 541-5742. For further information about how to access the bulletin board, call (919) 541-5384. You can also access the TTN directly through the World Wide Web at http://ttnwww.rtpnc.epa.gov. For further information about the proposal, contact Randy McDonald of EPA's Office of Air Quality Planning and Standards at (919) 541-5402.

- EPA's Office of Air and Radiation's homepage on the internet contains a wide range of information on the air toxics program, as well as many other air pollution programs and issues. The Office of Air and Radiation's home page address is: HTTP://WWW.EPA.GOV/OAR/