

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 439**

[FRL-5165-2]

RIN 2060-AC49

Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Pharmaceutical Manufacturing Category**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: This proposed rule would limit the discharge of pollutants into waters of the United States and the introduction of pollutants into publicly owned treatment works by existing and new facilities that manufacture pharmaceuticals. The proposed rule establishes limitations on pollutants, but does not specify the technology to be employed to achieve compliance. The Agency intends that this proposed rule will have a common technology basis with a rule yet to be proposed to control air emissions to allow coordinated and cost effective compliance planning by the industry.

This proposed rule would annually reduce priority pollutant discharges from this industry by an estimated 15.7 million pounds and total pollutant discharges by 139 million pounds at an estimated annual cost of \$80 million (1994 \$). The benefits include reductions in both carcinogenic and non-carcinogenic risk, ecological and recreational benefits due to improved water quality, and benefits to publicly owned treatment works such as improved worker health and safety.

As a result of consultation with stakeholders, the preamble solicits comments and data not only on issues raised by EPA, but also on those issues raised by State and local governments who will be implementing these regulations and by industry representatives who will be affected by them.

DATES: Comments on the proposed rule must be received by July 31, 1995 at the address noted below. EPA will conduct a public hearing on the effluent pretreatment standards included in the proposed rule. EPA will publish in the **Federal Register** an announcement of the public hearing.

ADDRESSES: Send written comments on this proposal in triplicate and in electronic form if possible to Mr. David Hoadley, Engineering and Analysis Division (4303), U.S. EPA, 401 M Street

SW., Washington, DC 20460. The public record supporting the proposed effluent limitations guidelines and standards is in the Water Docket located in the basement of the EPA Headquarters building, Room L102, 401 M Street SW., Washington, DC 20460, telephone number (202) 260-3027. EPA regulations at 40 CFR part 2 provide that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT:

Background documents supporting the proposed regulations are described in the "Background Documents" section below. Contact the Office of Water Resource Center, RC-4100, at the U.S. EPA, Washington, DC address shown above, telephone (202) 260-7786, for the voice mail publication request line. For additional information on the engineering aspects of the regulation, contact Dr. Frank H. Hund, Engineering and Analysis Division (4303), U.S. EPA, 401 M Street SW., Washington, DC 20460, at (202) 260-7182. For additional information on the economic and statistical aspects of the regulation, contact Mr. Neil Patel at the address above at (202) 260-5405. For additional engineering information on the preliminary air emissions control aspects of this rule, contact Mr. Randy McDonald, Office of Air Quality Planning and Standards (MD-13), Research Triangle Park, NC 27711, at (919) 541-5402.

SUPPLEMENTARY INFORMATION:**Overview**

The preamble describes the definitions, acronyms, and abbreviations used in this notice; the background documents that support these proposed regulations; the legal authority of this rule; a summary of the proposal; background information; and the technical and economic methodologies used by the Agency to develop these proposed regulations. This preamble also solicits comment and data on all aspects of this rulemaking, including on specific areas of interest.

Confidential Business Information

EPA notes that many documents in the record supporting this proposed rule have been claimed as confidential business information and, therefore, are not included in the record that is available to the public in the Water Docket. To support the rulemaking, EPA is presenting certain information in aggregated form or is masking plant identities to preserve confidentiality claims. Further, the Agency has withheld from disclosure some data not

claimed as confidential business information because release of this information could indirectly reveal information claimed to be confidential.

Plant-specific data that have been claimed as confidential business information are available to the company that submitted the information. To ensure that all CBI is protected in accordance with EPA regulations, any requests for company-specific data should be submitted on that company's letterhead and signed by a responsible official authorized to receive such data. The request must list the specific data requested and include the following statement, "I certify that EPA is authorized to transfer confidential business information submitted by my company, and that I am authorized to receive it." Organization of this document:

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