and POTWs must incorporate state water quality standards where necessary. Once these revised pharmaceutical effluent guidelines and standards are in place, regulatory burdens on the states and local POTWs in developing pollutant control requirements that heretofore have not been addressed for this industry, particularly for volatile organic pollutants and other wastewater discharge characteristics, will be reduced. For example, the Agency is aware that certain POTWs have expended considerable resources for outside contractors (e.g., engineering consultants) to secure technical support in developing the basis for local limits or other special requirements, for POTW maintenance and equipment replacement, and for special treatment systems. These requirements were needed to prevent pollutant pass through, interference, or sludge contamination attributable to pharmaceutical facility discharges.

In compliance with E.O. 12875, EPA has involved state and local governments in the process of developing this rule. Since the inception of the project in 1986, there have been periodic meetings with the industry and its trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), to discuss progress on the rulemaking. The Agency also has met with the Natural Resources Defense Council (NRDC) to discuss progress on this rulemaking. Because most of the facilities affected by this proposal are indirect dischargers, the Agency conducted an outreach survey to a limited number of POTWs substantially affected by one or more pharmaceutical manufacturing facilities to solicit their input on the need for this proposed rule and pertinent technical issues. The Agency has worked with the Food and Drug Administration (FDA) to explore pollution prevention opportunities to the maximum extent feasible. As described previously in this preamble, EPA shared with FDA information and data gathered from the industry in responses to EPA's detailed Section 308 questionnaire. This was done to assist FDA in evaluating the environmental impacts of revised drug manufacturing processes (as described in "supplement" applications) and of new drug manufacturing processes. These reviews will ensure that opportunities for solvent use minimization/elimination and waterbased manufacturing processes (e.g., water-based tablet coating) are considered and adopted within the constraints of maintaining the efficacy

of both existing and new pharmaceutical products.

The Agency also held a public meeting on May 23, 1994. EPA representatives of the Office of Water and the Office of Air and Radiation outlined the underlying technical basis and options being considered for this proposal, the efforts to coordinate the future air rule and this proposed water rule, and took comments and questions from the audience. The Agency also consulted with representatives of selected POTWs regarding underlying technical aspects of this proposal.

The Agency will continue this process of consulting with state, local, and other affected parties after proposal in order to further minimize the potential for unfunded mandates that may result from this rule.

G. Paperwork Reduction Act

The proposed effluent guidelines and standards for the pharmaceutical manufacturing industry contain no information collection activities beyond those required for the NPDES permit program and the general pretreatment program. Therefore, an information collection request (ICR) has not been submitted to the Office of Management and Budget (OMB) for review and approval under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

OMB has approved the existing information collection requirements associated with NPDES discharge permit applications and the general pretreatment program under the provisions of the Paperwork Reduction Act.

The collection of information required for NPDES discharge permit applications has an estimated reporting burden averaging 12 hours per response and an estimated annual recordkeeping burden averaging two hours per respondent. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

XIV. Solicitation of Data and Comments

A. Introduction and General Solicitation

EPA invites and encourages public participation in this rulemaking. The Agency asks that comments address any perceived deficiencies in the record of this proposal and that suggested revisions or corrections be supported by data.

The Agency invites all parties to coordinate their data collection activities with EPA to facilitate mutually beneficial and cost-effective data submissions. EPA is interested in participating in study plans, data collection and documentation. Please refer to the "For Further Information" section at the beginning of this preamble for technical contacts at EPA.

When responding to these comment solicitations, please identify for each comment or data submission the comment solicitation number or numbers that the comment or data submission addresses. Commenters should also submit an electronic version on diskette if possible.

B. Specific Data and Comment Solicitations

EPA has solicited comments and data on many individual topics throughout this preamble. The Agency incorporates each of these solicitations here, and reiterates its interest in receiving data and comments on the issues addressed by those solicitations. EPA particularly requests comments and data on the following issues:

1.0 General

1.1 Comments on Options and Technologies Evaluated

The Agency solicits comments on all of the technologies and technology options identified in today's proposal.

1.2 Comments on Options/ Technologies Selected for Proposal

The Agency solicits comments on the options and technologies and compliance monitoring points selected for proposal today, and the technical, policy, and legal bases expressed by EPA in support of such selections.

1.3 Comments on Proposed Effluent Limitations and Standards

The Agency solicits comments on the effluent limitations and standards proposed today.

1.4 Comments on the Methodology Used to Develop Steam Stripper- and Steam Stripper With Distillation-Based Limitations and Standards

The Agency solicits comment regarding its methodology for developing the proposed limitations and standards based on available steam stripper and steam stripper/distillation performance data.

2.0 Adequacy of the 308 Questionnaire Database

The Agency has collected a significant amount of technical and economic data from pharmaceutical manufacturing facilities. Nonetheless, the Agency is open to suggestions regarding any additional data collections that may be