During the sampling program, EPA gathered analytical data to characterize the wastewater from five direct dischargers and eight indirect dischargers. Treatment system performance data were gathered from three advanced biological treatment systems and two biological pretreatment systems. Treatment unit performance data documenting the performance of five steam stripping columns were also gathered. The performance of one resin adsorption column and one cyanide destruction unit was also documented.

a. Bench-, Pilot-, and Full-Scale Studies. Between October and December 1991, EPA conducted bench-scale and pilot-scale tests to study: (1) Air stripping technology (with ammonia capture) for ammonia removal from pharmaceutical plant final effluent; and (2) steam stripping technology for removal of volatile organic pollutants from pharmaceutical plant process wastewaters.

EPA conducted the air stripping and steam stripping pilot studies at a pharmaceutical manufacturing facility with fermentation, chemical synthesis, formulation, and research operations. The objective of the air stripping study was to examine the feasibility of obtaining at least 90 percent ammonia removal using air stripping technology. A portion of the total facility effluent was used as the feed to the pilot-scale air stripping study.

The objectives of the steam stripping study were to demonstrate the achievement of the lowest practical concentrations of volatile organic pollutants in the treated effluent, using the available bench- and pilot-scale steam stripping test equipment, and to collect sufficient data to document these concentrations using the available bench- and pilot-scale data. On-site pilot-scale testing was conducted for two of the three streams. EPA elected not to run pilot-scale tests on one of the streams because the stream flow from that process area was insufficient for pilot-scale testing during the study time period. Performance data for this third process wastewater stream were collected using bench-scale equipment.

In September 1993, EPA conducted an on-site treatment performance study using a pharmaceutical manufacturing facility's existing distillation column that treated wastewaters containing methanol. The objective of the study was to achieve the lowest practical concentrations of methanol (within the operating constraints of the facility) in the treated effluent and to collect sufficient data to document these concentrations. All of the studies are

discussed in more detail in sections 5 and 8 of the TDD.

B. Air Emission Data

In July 1993, pursuant to section 114 of the Clean Air Act, EPA distributed questionnaires seeking data on air emissions to 396 pharmaceutical manufacturing facilities. The scope of the survey included all manufacturing operations that were covered by the SIC Code Nos. 2833, 2834, and 2836 and that also emitted hazardous air pollutants. Research facilities were not included. The questionnaire requested production data, process flow diagrams, emissions data, emission control technology data, and information on source reduction measures. EPA will use this data and information in developing standards to be promulgated under the Clean Air Act for the pharmaceutical manufacturing industry. EPA will compare these data and information, to the extent it is appropriate, to the data and information collected under the Clean Water Act to ensure that the best and most consistent data are used in both rulemaking efforts. See Section X below.

IX. Development of Effluent Limitations Guidelines and Standards

A. Industry Subcategorization

1. Introduction

In developing today's proposed rule, EPA considered whether different effluent limitations and standards were appropriate for different groups of plants or subcategories within the pharmaceutical manufacturing industry. Factors considered included: processes employed, effluent characteristics, costs, age of equipment and facilities, size, location, engineering aspects of the application of various types of control techniques, process changes, and nonwater quality environmental impacts. In determining which subcategories were appropriate for this proposed rule, EPA, using recently available data, evaluated the scheme for establishing subcategories regulated under the current effluent limitations guidelines and standards applicable to this industry.

2. Current Subcategorization

The current subcategorization of this industry dates back to 1976 and was developed using data from the mid-1970s. The current subcategories are as follows:

Subpart A Fermentation

Subpart B Biological and Natural Extraction

Subpart C Chemical Synthesis

Subpart D Mixing/Compounding/

Formulating

Subpart E Pharmaceutical Research

3. Rationale for Maintaining the Current Subcategorization

Prior to finalizing the 1983 regulation, the Agency evaluated the original subcategorization scheme developed for the 1976 interim final regulations. This evaluation is discussed in section 4 of the 1983 technical development document and in the preamble to the final regulation at 48 FR 49808 (October 27, 1983). The Agency concluded at that time that the original subcategorization scheme based on manufacturing process type was the most appropriate one for the Pharmaceutical Manufacturing Point Source Category. In determining whether this scheme is appropriate for the rule being proposed today, the Agency evaluated the wastewater and production data obtained from the detailed questionnaire responses as well as plant sampling data in light of the current scheme. The Agency compared the wastewater flow and pollutant characteristics data (influent and effluent BOD₅, TSS, and COD) obtained from the 1990 detailed questionnaire responses with the data presented in Section 4 of the 1983 TDD. EPA concluded that the similarities and data trends reported for both subcategory A and C and subcategory B and D facilities were identical to those reported in 1983 for analogous data. Consequently, the Agency concluded that the current subcategorization scheme continues to be appropriate for today's proposed rule. As was the case with the 1983 final regulation, the limitations and standards being proposed today for subcategory A are identical to those proposed for subcategory C and those limitations and standards being proposed for subcategory B are identical to those being proposed for subcategory D. The Agency invites comments regarding this regulatory scheme. The subcategorization analysis is discussed in more detail in section 4 of the TDD for this rulemaking. See Section XIV, solicitation number 4.0.

4. Subcategory Regulation Not Revised

EPA is not proposing new or revised effluent limitations and standards for the Pharmaceutical Research Subcategory (Subcategory E). Rather, research activities falling within this subcategory will continue to be subject to the BPT regulations established for that subcategory in the 1983 regulations for this industry. The 1983 regulations did not establish BCT, BAT, NSPS, PSES, or PSNS effluent limitations and standards for the research subcategory, and today's proposed revisions to 40