c. Priority pollutants. The priority pollutants selected for control include cyanide, phenol and various solvents used by the industry. EPA estimates that direct and indirect discharging facilities discharge 0.5 and 1.8 million pounds per year, respectively, of the 10 priority pollutants addressed in this proposal. EPA is proposing to promulgate BPT, BAT, NSPS, PSES, and PSNS for some or all of these pollutants in subcategories A, B, C, and D.

d. Nonconventional pollutants. Nonconventional pollutants include ammonia, COD (Chemical Oxygen Demand), and various volatile and semivolatile organic compounds that are used for the most part as solvents by the industry. EPA estimates that 0.8 and 0.5 million pounds per year of ammonia and 32 and 78 million pounds per year of COD are discharged by direct and indirect discharging facilities, respectively. With respect to COD, EPA is proposing to revise existing BPT limitations and promulgate new BAT limitations and NSPS for subcategories A, B, C, and/or D. With respect to ammonia, EPA is proposing to promulgate BAT, NSPS, PSES, and PSNS for subcategories A and/or C. EPA has determined that ammonia is not a pollutant of concern in wastewaters of facilities with subcategory B and/or D operations and hence does not propose limits for ammonia for those subcategories. See Section 5 of the TDD. See Section XIV, solicitation numbers 20.0 and 23.0. For PSES, EPA is coproposing a finding of no pass-through for 33 priority and nonconventional pollutants.

2. Pollutants Not Regulated

EPA is not proposing effluent limitations or standards for 85 priority and nonconventional pollutants identified as potentially present in pharmaceutical wastewaters. In Section 6 of the TDD, EPA describes for each pollutant or group of pollutants the reasons each is excluded from this proposal. EPA bases its decision to exclude these pollutants or groups of pollutants on one or more of the following reasons:

(1) The pollutant or group of pollutants is deemed not present in pharmaceutical wastewaters, because it was not detected in the effluent with the use of analytical methods promulgated pursuant to section 304(h) of the Clean Water Act or with other state-of-the-art methods;

(2) The pollutant or group of pollutants is present only in trace amounts and is neither causing nor likely to cause toxic effects in humans or aquatic life; (3) The pollutant or group of pollutants is detected in the effluent from only one or a small number of sources;

(4) The pollutant or group of pollutants is effectively controlled by the technologies used as a basis for limitations on other pollutants, including those limitations and standards proposed today; or

(5) Insufficient data are available to establish effluent limitations or standards for that pollutant or group of pollutants.

In addition, EPA proposes to control phenol discharged by direct dischargers (through BAT and NSPS) but not by indirect dischargers (through PSES and PSNS) because pass-through has not been demonstrated for phenol. See the discussion on the analysis of pollutant pass-through in Section IX.E.5.a. of this preamble. EPA also is proposing to exclude two nonconventional pollutants from control by PSES and PSNS regulations (acetonitrile and polyethylene glycol 600) because passthrough has not be demonstrated for these pollutants. In addition, as noted in Section C above, EPA is proposing two alternative pass-through for PSES for 33 priority and nonconventional pollutants. Under one of the proposed alternatives, EPA proposes to exclude 33 pollutants because EPA has some doubt as to whether these pollutants pass through. Under the other coproposal, EPA proposes PSES for those pollutants based on a determination that they do pass through according to the data presently available to EPA.

D. Available Technologies

1. Pollution Prevention Technologies Considered

EPA requested pollution prevention and process information regarding organic solvent use from pharmaceutical manufacturing facilities in its 1990 questionnaire. The responses indicate that while plants can make some process changes that would result in some source reduction, the opportunities to minimize or eliminate solvent use by changes in existing processes are limited, especially for facilities with subcategory A and/or C operations. Fermentation (A) and chemical synthesis (C) processes often involve complicated procedures which utilize solvents according to an exact recipe. In most cases, any change in the specific process or the amount of solvent used may result in a significant reduction in the yield of product obtained. Nonetheless, some Subcategory D (Mixing/Compounding/ Formulating) facilities have utilized

aqueous-based solvents instead of organic solvents to coat tablets, thereby eliminating solvent use for that operation. This approach is generally not applicable to all tablet coating operations because most coating materials are not soluble in aqueous solvents.

Pharmaceutical plants sometimes cite an administrative, as well as a technical, impediment to pollution prevention. That is, once a pharmaceutical company gains approval from the Food and Drug Administration (FDA) to manufacture a pharmaceutically active ingredient or drug via a specific procedure, it may not deviate significantly from the approved procedure without additional FDA approval. Thus, if a company wishes to alter significantly an approved manufacturing procedure for any reason, including pollution prevention, it must submit a "supplement" application to FDA, which must be approved before the company can use the altered procedure.

EPA understands that FDA historically needs to take a long period of time to process these requests for approval. However, since the enactment of the "Prescription Drug User Fee Act of 1992," 21 U.S.C. 379 et seq., Pub. L. 102-571, Oct. 29, 1992, the FDA has committed to using the revenues generated under that Act to expedite the prescription drug review and approval process, which include decisions on manufacturing supplements relating to pollution prevention-oriented process changes. EPA understands that the FDA hopes to eliminate its backlog of overdue manufacturing supplements by the end of Fiscal Year 1995 and to achieve, by Fiscal Year 1997, its goal of reviewing and acting upon every complete manufacturing supplement within six months of submission. EPA believes that such expeditious processing of supplements will eliminate impediments that presently discourage pharmaceutical plants from making process changes necessary to achieve source reductions.

In addition to evaluating opportunities for source reduction, EPA also examined potential treatment technologies to determine whether any might promote recovery, recycling, and reuse of chemicals in process wastewater generated by pharmaceutical manufacturing operations, such as solvents. After evaluating the various technologies available to treat solventladen wastewaters, EPA concluded that in-plant technologies such as steam stripping and steam stripping with distillation offered the best opportunity for recovery of solvents from wastewater. As discussed in greater