APPENDIX A TO PART 439—TABLES

AUTHORITY: 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

SOURCE: 48 FR 49821, Oct. 27, 1983, unless otherwise noted.

GENERAL

§ 439.0 Applicability.

(a) This part applies to process wastewater discharges resulting from the research and manufacture of pharmaceutical products, which are generally, but not exclusively, reported under SIC 2833, SIC 2834 and SIC 2836 (1987 Standard Industrial Classification Manual).

(b) Although not reported under SIC 2833, SIC 2834 and SIC 2836, discharges from the manufacture of other pharmaceutical products to which this part applies include (but are not limited to):

(1) Products manufactured by one or more of the four types of manufacturing processes described in subcategories A, B, C or D of this part, and considered by the Food and Drug Administration to be pharmaceutical active ingredients;

(2) Multiple end-use products (e.g., components of formulations, chemical intermediates, or final products) derived from pharmaceutical manufacturing operations and intended for use primarily in pharmaceutical applications;

(3) Pharmaceutical products and intermediates not subject to other categorical limitations and standards, provided the manufacturing processes generate process wastewaters that are similar to those derived from the manufacture of pharmaceutical products elsewhere (an example of such a product is citric acid);

(4) Cosmetic preparations that are reported under SIC 2844 and contain pharmaceutical active ingredients, or active ingredients that are intended for the treatment of a skin condition. (These preparations do not include products such as lipsticks or perfumes that serve to enhance appearance, or provide a pleasing odor, but do not enhance skin care. Also excluded are deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

(c) The provisions of this part do not apply to wastewater discharges resulting from the manufacture of the following products, or as a result of providing one or more of the following services:

(1) Surgical and medical instruments and apparatus reported under SIC 3841;

(2) Orthopedic, prosthetic, and surgical appliances and supplies reported under SIC 3842;

(3) Dental equipment and supplies reported under SIC 3843;

(4) Medical laboratory services reported under SIC 8071;

(5) Dental laboratory services reported under SIC 8072;

(6) Outpatient care facility services reported under SIC 8081;

(7) Health and allied services reported under SIC 8091, and not classified elsewhere;

(8) Diagnostic devices other than those reported under SIC 3841;

(9) Animal feed products that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(10) Food and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(11) Pharmaceutical products and intermediates subject to the provisions of 40 CFR part 414, provided their manufacture results in less than 50 percent of the total flow of process wastewater that is regulated by 40 CFR part 414 at the facility.

[63 FR 50424, Sept. 21, 1998]

§ 439.1 General definitions.

As used in this part:

(a) The general definitions, abbreviations and methods of analysis in 40 CFR part 401 shall apply.

(b) *Bench-scale operation* means the laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

(c) *Cyanide (T)* means the parameter total cyanide.

(d) *In-plant monitoring point* means a location within a plant, where an individual process effluent can be exclusively monitored before it is diluted or mixed with other process wastewaters en route to the end-of-pipe.

(e) *Maximum daily* means the highest allowable discharge of wastewater pollutants during a calendar day or any 24 hour period that reasonably represents a calendar day for purposes of sampling.

(f) *Maximum monthly average* means the highest allowable average of daily discharges of wastewater pollutants over a calendar month, and is calculated as the sum of all daily values measured during a calendar month divided by the number of daily values measured during that month.

(g) *mg/L* means milligrams per liter or parts per million (ppm)

(h) *Minimum level* means the level at which an analytical system gives recognizable signals and an acceptable calibration point.

(i) *Nitrification capability* means the capability of a POTW treatment system to oxidize ammonia or ammonium salts initially to nitrites (via *Nitrosomonas* bacteria) and subsequently to nitrates (via *Nitrobacter* bacteria). Criteria for determining the nitrification capability of a POTW treatment system are: bioassays confirming the presence of nitrifying bacteria; and analyses of the nitrogen balance demonstrating a reduction in the concentration of ammonia or ammonium salts and an increase in the concentrations of nitrites and nitrates.

(j) *Non-detect (ND)* means a concentration value below the minimum level that can be reliably measured by the analytical method.

(k) *Pilot-scale operation* means processing equipment being operated at an intermediate stage between laboratory-scale and full-scale operation for the purpose of developing a new product or manufacturing process.

(l) *POTW* means publicly owned treatment works (40 CFR 403.3).

(m) *Process wastewater*, as defined at 40 CFR 122.2 and for the purposes of this part, does not include the following:

(1) Trimethyl silanol, any active anti-microbial materials, process wastewater from imperfect fermentation batches, and process area spills. Discharges containing such materials are not subject to the limitations and standards of this part.

(2) Non-contact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other non-process water generated on site. Discharges of such waters and wastewaters are not subject to the limitations and standards of this part.

(n) *Non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor ''toxic'' pollutants (40 CFR 401.15).

(o) *Surrogate pollutant* means a regulated parameter that, for the purpose of compliance monitoring, is allowed to serve as a surrogate for a group of specific regulated parameters. Plants would be allowed to monitor for a surrogate pollutant(s), when the other parameters for which it stands are receiving the same degree of treatment as the surrogate pollutant(s) and all of the parameters discharged are in the same treatability class(es) as their respective surrogate pollutant(s). Treatability classes have been identified in appendix A of this part for both steam stripping and biological treatment technologies, which are the respective technology bases for PSES/PSNS and BAT/NSPS limitations controlling the discharge of regulated organic parameters.

(p) *Xylenes* means a combination of the three isomers: o-xylene, m-xylene, and p-xylene.

[63 FR 50425, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999, as amended at 68 FR 12270, Mar. 13, 2003]

§ 439.2 General monitoring requirements.

(a) Permit compliance monitoring is required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as