

subcategory and subject to BAT and BCT limitations, where appropriate, set on a case-by-case basis using best professional judgment (BPJ).

Pharmaceutical manufacturers use many different raw materials and manufacturing processes to create a wide range of products. These products include medicinal and feed grades of all organic chemicals having therapeutic value, whether obtained by chemical synthesis, fermentation, extraction from naturally occurring plant or animal substances, or by refining a technical grade product.

The pharmaceutical products, processes and activities covered by this proposal include:

a. Biological products covered by the U.S. Department of Commerce, Bureau of the Census Standard Industrial Classification (SIC) Code No. 2836, with the exception of diagnostic substances. (Products covered by SIC Code No. 2836 were formerly covered under the 1977 SIC Code No. 2831.)

b. Medicinal chemicals and botanical products covered by SIC Code No. 2833;

c. Pharmaceutical products covered by SIC Code No. 2834;

d. All fermentation, biological and natural extraction, chemical synthesis and formulation products considered to be pharmaceutically active ingredients by the Food and Drug Administration that are not covered by SIC Code Nos. 2833, 2834, and 2836;

e. Multiple end-use products derived from pharmaceutical manufacturing operations (e.g., components of formulations, intermediates, or final products, provided that the primary use of the product is intended for pharmaceutical purposes);

f. Products not covered by SIC Code Nos. 2833, 2834, and 2836 if they are manufactured by a pharmaceutical manufacturer by processes that generate wastewaters that in turn closely correspond to those of pharmaceutical products;

g. Cosmetic preparations covered by SIC Code No. 2844 that function as a skin treatment. (This group of preparations does not include products such as lipsticks or perfumes that serve to enhance appearance or to provide a pleasing odor, but do not provide skin care. In general, this also excludes deodorants, manicure preparations, and shaving preparations that do not function primarily as a skin treatment.); and

h. Pharmaceutical research that includes biological, microbiological, and chemical research, product development, clinical and pilot-scale activities. (This does not include farms that breed, raise, and/or hold animals

for research at another site. This also does not include ordinary feedlot or farm operations utilizing feed that contains pharmaceutically active ingredients.) Pilot-scale and product development operations conducted at research facilities would be subject to the specific manufacturing subcategory limitations and standards corresponding to the subcategory wastewater that the research facility's wastewater resembles. For example, a pilot chemical synthesis operation that generates wastewater that is similar to wastewater generated by chemical synthesis manufacturing would be subject to the subcategory C limitations and standards.

A number of products and/or activities such as surgical and medical manufacturing and medical laboratory activity are not part of the pharmaceutical manufacturing category. A descriptive listing of the products and activities that are specifically excluded from the pharmaceuticals manufacturing category may be found in section 2 of the TDD.

V. Background

A. Clean Water Act

1. Statutory Requirements of Regulations

The objective of the Clean Water Act (CWA) is to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters". Section 101(a) of the CWA. To assist in achieving this objective, EPA issues effluent limitations guidelines, pretreatment standards, and new source performance standards for industrial dischargers. These guidelines and standards are summarized below:

a. *Best Practicable Control Technology Currently Available (BPT)*—section 304(b)(1) of the CWA. BPT effluent limitations guidelines apply to all discharges from existing direct dischargers. BPT guidelines are based on the average of the best performance achieved by plants in a category or subcategory utilizing currently available technology. In establishing BPT, EPA considers the cost of achieving effluent reductions in relation to the effluent reduction benefits, the age of equipment and facilities, the processes employed, process changes required, engineering aspects of the control technologies, non-water quality environmental impacts (including energy requirements), and other factors as the EPA Administrator deems appropriate. Section 304(b)(1)(B) of the CWA. Where existing performance is uniformly inadequate within a category or subcategory, BPT may be transferred from a different subcategory or category.

b. *Best Conventional Pollutant Control Technology (BCT)*—section 304(b)(4) of the CWA. The 1977 amendments to the CWA established BCT as an additional level of control for discharges of conventional pollutants from existing industrial point sources. Section 304(a)(4) designates the following as conventional pollutants: biochemical oxygen demanding pollutants (measured as BOD₅), total suspended solids (TSS), fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as an additional conventional pollutant on July 30, 1979 (44 FR 44501). See 40 CFR 401.16. In addition to other factors specified in section 304(b)(4)(B), the CWA requires that BCT limitations be established in light of a two part "cost-reasonableness" test. EPA issued a methodology for the development of BCT limitations on July 9, 1986 (51 FR 24974).

c. *Best Available Technology Economically Achievable (BAT)*—section 304(b)(2) of the CWA. In general, BAT effluent limitations guidelines represent the best economically achievable performance of plants in the industrial subcategory or category, based on available technology. The CWA establishes BAT as a principal means of controlling the direct discharge of toxic and nonconventional pollutants to waters of the United States. The factors considered in assessing BAT include the age of equipment and facilities involved, the process employed, potential process changes, and non-water quality environmental impacts, including energy requirements. The Agency retains considerable discretion in assigning the weight to be accorded these factors. As with BPT, where existing performance is uniformly inadequate within a category or subcategory, BAT may be transferred from a different category or subcategory. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

d. *New Source Performance Standards (NSPS)*—section 306 of the CWA. NSPS are based on the best available demonstrated treatment technology. New plants have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS should represent the most stringent controls attainable through the application of the best available control technology for all pollutants (i.e., conventional, nonconventional, and toxic pollutants). In establishing NSPS,