

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 439

[FRL-7462-8]

Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to amend certain provisions of the effluent guidelines for the Pharmaceutical Manufacturing Point Source Category, which were published on September 21, 1998 (63 FR 50424). First, EPA is clarifying the date on which a discharger subject to the New Source Performance Standards (NSPS) and the Pretreatment Standards for New Sources (PSNS) would be subject to effluent limitations and pretreatment

standards established in the 1998 regulation. Second, this rule re-establishes a minimum concentration for the maximum monthly average BOD₅ limitation that EPA inadvertently omitted from the Best Practicable Control Technology (BPT) requirements in two subcategories of the 1998 regulation. Next, the amendments correct an error in EPA's pass-through analysis prepared in support of the 1998 rule and, as a result, deletes methyl Cellosolve (2-methoxyethanol) from the pretreatment standards in two subcategories and from Appendix A, Table 2, "Surrogate Parameters for Indirect Dischargers." Finally, the Agency is making other non-substantive editorial and format changes such as removing redundancies, and adding definitions.

DATES: This rule is effective on June 11, 2003 without further notice, unless EPA receives adverse comment by May 12, 2003. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Please mail comments to the Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460 or submit them electronically to <http://www.epa.gov/edocket>. Send either to the Attention of Docket ID No. OW-2003-0007. See section I.C., of the **SUPPLEMENTARY INFORMATION** section for more information on submitting comments.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Hund, EPA Office of Water by phone at (202)566-1027 or by e-mail at hund.frank@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Regulated Entities

Entities potentially regulated by this action include facilities of the following types that discharge pollutants directly or indirectly to U.S. waters.

Category	Examples of regulated entities	SIC (NAICS) code
Industry	Facilities that generate process wastewater from the manufacture of pharmaceutical products and/or pharmaceutical intermediates by fermentation, extraction, chemical synthesis and/or mixing, compounding and formulating.	2833, R834, 2836 (2834-04, 2834-98).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definitions and applicability criteria in §§ 439.1, 439.10, 439.20, 439.30, 439.40 and 439.50 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

1. **Docket.** EPA has established an official public docket for this action under Docket ID No. OW-2003-0007. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. The official public docket is the collection of materials that is

available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426. For access to docket materials, please call ahead to schedule an appointment. Every user is entitled to copy 100 pages before incurring a charge. The Docket may charge 15 cents a page for each page over the 100-page limit.

2. **Electronic Access.** You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, "EPA Dockets." You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents

in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

II. Legal Authority

The U.S. Environmental Protection Agency is promulgating these regulations under the authority of 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

III. Overview of Effluent Limitations Guidelines and Standards

Congress adopted the Clean Water Act (CWA) to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (section 101(a), 33 U.S.C. 1251(a)). To achieve this goal, the CWA prohibits the discharge of pollutants into navigable waters except in compliance with the statute. The Clean Water Act confronts the problem of water pollution on a number of different fronts. Its primary reliance, however, is on establishing restrictions on the types and amounts of pollutants discharged from various industrial, commercial, and public sources of wastewater.