

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 439****[FRL-7462-7]****Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category; Proposed Rule****AGENCY:** Environmental Protection Agency.**ACTION:** Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing 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, 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: Comments must be received by May 12, 2003. Comments postmarked after this date may not be considered.

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, U.S. 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 §§ 439.10, 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.

Certain types of information will not be placed in the EPA Dockets. Information claimed as confidential business information (CBI) and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.