

**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 BOD<sub>5</sub> 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](mailto: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.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

#### *C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. Please submit with your comments any references cited in your comments. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments; however, late comments may be considered if time permits. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in section I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD-ROM you submit, and in any

cover letter accompanying the disk or CD-ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select "Information Sources," "Dockets," and "EPA Dockets." Once in the system, select "search," and then key in Docket ID No. OW-2003-0007. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by electronic mail (e-mail) to [OW-Docket@epa.gov](mailto:OW-Docket@epa.gov), Attention Docket ID No. OW-2003-0007. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD-ROM.* You may submit comments on a disk or CD-ROM that you mail to the mailing address identified in section 1.C.2. These electronic submissions will be accepted in Word Perfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send an original and three (3) copies of your comments to the Water Docket, Environmental Protection Agency, Mail Code 4101T, 1200 Pennsylvania Ave., NW., Washington,

DC 20460, Attention Docket ID No. OW-2003-0007.

#### 3. *By Hand Delivery or Courier.*

Deliver your comments to: Water Docket, EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OW-2003-0007. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.B.1.

#### *D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send information identified as CBI by mail only to the following address: Office of Science and Technology, Mail Code 4303T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention: Frank Hund, Docket ID No. OW-2003-0007.

You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD-ROM, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD-ROM, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

## **II. Discussion of Direct Final Rulemaking**

In the "Rules and Regulations" section of today's **Federal Register**, EPA is promulgating these revisions as a direct final rule without prior proposal because we view them as noncontroversial revisions and anticipate no adverse comment. We have explained our reasons for these revisions in the preamble to the direct final rule. If we receive no adverse comment, we will not take further

action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule or portions thereof, and the direct final rule or portions thereof will not take effect. We will address all public comments in a subsequent final rule based on this action. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

### **III. Related Acts of Congress, Executive Orders, and Agency Initiatives**

For the various statutes and Executive Orders that require findings for rulemaking, EPA incorporates the findings from the direct final rule into this companion proposal for the purpose of providing public notice and opportunity for comment.

### **List of Subjects in 40 CFR Part 439**

Environmental protection, Drugs, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: February 28, 2003.

**Christine Todd Whitman,**  
*Administrator.*

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