

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[OAR-2004-0023; FRL-7911-4]

RIN 2060-AM52

National Emission Standards for Pharmaceuticals Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; amendments.

SUMMARY: On September 21, 1998, EPA promulgated national emission standards for pharmaceuticals production (40 CFR part 63, subpart GGG). This action proposes to amend the national emission standards for pharmaceuticals production to include provisions for planned routine maintenance of wastewater tanks and alternative monitoring for condensers and scrubbers. The proposed amendments also reference general standards for containers.

In the Rules and Regulations section of this **Federal Register**, we are taking direct final action on the proposed amendments because we view the amendments as noncontroversial and anticipate no adverse comments. We have explained our reasons for the amendments in the preamble to the direct final rule. If we receive no adverse comments, we will take no further action on the proposed amendments. If we receive adverse comments, we will withdraw those provisions on which we received adverse comments. We will publish a timely withdrawal in the **Federal Register** indicating which provisions will become effective and which provisions are being withdrawn. If part or all of the direct final rule in the Rules and Regulations section of today's **Federal Register** is withdrawn, all comments pertaining to those provisions will be addressed in a subsequent final rule based on the proposed amendments. We will not institute a second comment period on the subsequent final action. Any parties interested in commenting must do so at this time.

DATES: *Comments.* Written comments must be received on or before June 13, 2005, unless a hearing is requested by May 23, 2005. If a hearing is requested,

written comments must be received on or before June 27, 2005.

Public Hearing. If anyone contacts the EPA requesting to speak at a public hearing, a public hearing will be held on May 27, 2005.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR-2004-0023, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- Agency Web site: <http://www.epa.gov/edocket>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- E-mail: air-and-r-docket@epa.gov.
- Fax: (202) 566-1741.
- Mail: EPA Docket Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a duplicate copy, if possible.

• Hand Delivery: Air and Radiation Docket, Environmental Protection Agency, 1301 Constitution Avenue, NW, Room B-108, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

We request that a separate copy also be sent to the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**).

Instructions: Direct your comments to Docket ID No. OAR-2004-0023. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.epa.gov/edocket>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the federal regulations.gov Web sites are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through

EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102).

Docket: All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The 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 Air Docket is (202) 566-1742.

Public Hearing. If a public hearing is held, it will be held at 10 a.m. at the EPA's Environmental Research Center Auditorium, Research Triangle Park, North Carolina or at an alternate site nearby.

FOR FURTHER INFORMATION CONTACT: Mr. Randy McDonald, Organic Chemicals Group, Emission Standards Division (C504-04), Office of Air Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5402, electronic mail address mcdonald.randy@epa.gov.

SUPPLEMENTARY INFORMATION: *Regulated Entities.* The regulated category and entities affected by this action include:

Category	NAICS codes	SIC codes	Examples of regulated entities
Industry	325411 and 325412	2833 and 2834	• Producers of finished dosage forms of drugs (e.g., tablets, capsules, and solutions), active ingredients, or precursors.

Category	NAICS codes	SIC codes	Examples of regulated entities
	Typically 325199	Typically 2869	<ul style="list-style-type: none"> Producers of material whose primary use is as an active ingredient of precursor.

This table is not intended to be exhaustive, but rather provides a guide for readers likely to be interested in the revisions to the regulation affected by this action. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should carefully examine all of the applicability criteria in 40 CFR 63.1250. If you have questions regarding the applicability of the amendments to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

What should I consider as I prepare my comments for EPA? Submitting CBI. Do not submit this information to EPA through EDOCKET, regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

Tips for Preparing Your Comments. When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

- Make sure to submit your comments by the comment period deadline identified.

Public Hearing. Persons interested in presenting oral testimony or inquiring as to whether a hearing is to be held should contact Mr. Randy McDonald, Organic Chemicals Group, Emission Standards Division (Mail Code C504-04), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5402, electronic mail address mcdonald.randy@epa.gov, at least 2 days in advance of the potential date of the public hearing. Persons interested in attending the public hearing must also call Mr. Randy McDonald to verify the time, date, and location of the hearing. The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning these proposed emission standards.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of today's proposal will also be available through the WWW. Following the Administrator's signature, a copy of this action will be posted on EPA's Technology Transfer Network (TTN) policy and guidance page for newly proposed or promulgated rules at <http://www.epa.gov/ttn/oarpg>. The TTN at EPA's Web site provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541-5384.

Direct Final Rule. A direct final rule identical to the proposal is published in the Rules and Regulations section of today's **Federal Register**. If we receive any adverse comment pertaining to the amendments in the proposal, we will publish a timely notice in the **Federal Register** informing the public that the amendments are being withdrawn due to adverse comment. We will address all public comments concerning the withdrawn amendments in a subsequent final rule. If no relevant adverse comments are received, no further action will be taken on the proposal, and the direct final rule will become effective as provided in that action.

The regulatory text for the proposal is identical to that for the direct final rule published in the Rules and Regulations section of today's **Federal Register**. For further supplementary information, the detailed rationale for the proposal and

the regulatory revisions, see the direct final rule published in a separate part of this **Federal Register**.

Statutory and Executive Order Reviews

For a complete discussion of all of the administrative requirements applicable to this action, see the direct final rule in the Rules and Regulations section of today's **Federal Register**.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's proposed amendments on small entities, a small entity is defined as: (1) A small business having up to 500 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed amendments on small entities, EPA has certified that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a proposed rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact, since the primary purpose of the regulatory flexibility analysis is to identify and address regulatory alternatives "which minimize any significant economic impact of the proposed rule on small entities" (5 U.S.C. 603 and 604). Thus, any agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden or otherwise has a positive economic effect on all of the small entities subject to the rule. The proposed amendments grant greater flexibility to small entities

subject to the final rule that may result in a more efficient use of resources for them and, therefore, impose no additional regulatory costs or requirements on owners or operators of affected sources. The EPA continues to be interested in the potential impacts of the proposed rule on small entities and

welcomes comments on issues related to such impacts.

List of Subjects in 40 CFR Part 63

Environmental protection,
Administrative practice and procedure,
Air pollution control, Hazardous
substances, Intergovernmental relations,

Reporting and recordkeeping requirements.

Dated: May 6, 2005.

Stephen L. Johnson,
Administrator.

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