DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 312, 314, 320, 600, 601, and 606

[Docket No. 2000N–1484]

RIN 0910–AA97

Safety Reporting Requirements for Human Drug and Biological Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 14, 2003, the comment period for a proposed rule published in the **Federal Register** of March 14, 2003 (68 FR 12406). The proposed rule would amend the agency's pre- and postmarketing safety reporting regulations for human drug and biological products. The agency is taking this action in response to a request for more time to submit comments to FDA.

DATES: Submit written or electronic comments on the proposed rule by October 14, 2003.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *FDADockets@oc.fda.gov* or on the Internet at *http://accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm.*

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Audrey A. Thomas, Center for Drug Evaluation and Research (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5626.

For information concerning human biological products: Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6079.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 14, 2003 (68 FR 12406), FDA published a proposed rule that, if finalized, would amend its pre-and postmarketing safety reporting regulations for human drug and biological products to:

- Implement definitions and reporting formats and standards recommended by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and by the World Health Organization's Council for International Organizations of Medical Sciences;
- Codify the agency's expectations for timely acquisition, evaluation, and submission of relevant safety information for marketed drugs and licensed biological products;
- Require that certain information, such as domestic reports of medication errors, be submitted to the agency in an expedited manner; and
- Clarify certain requirements and make other minor revisions.

FDA also proposed to amend its postmarketing annual reporting regulations for human drug and licensed biological products by revising the content for these reports.

Interested persons were given until July 14, 2003, to submit written or electronic comments to the agency on the proposal. On May 7, 2003, FDA received a written request to allow an additional 90 days for interested persons to comment. FDA believes that an extension of 90 days to the comment period is appropriate, given the length and complexity of the proposed rule. Therefore, FDA is extending the comment period until October 14, 2003. This extension will provide the public with a total of 210 days to submit comments.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the proposal. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 11, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15341 Filed 6–17–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO 180–1180; FRL–7514–1]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve a revision to the Missouri State Implementation Plan (SIP) which pertains to the control of emissions from Perchloroethylene Dry Cleaning Installations in Kansas City and St. Louis areas, respectively. This revision will rescind two rules that have been superseded by the statewide Maximum Achievable Control Technology rule. There is no relaxation of controls by rescinding these rules. Approval of this revision will eliminate redundancy and conflicting requirements. In the final rules section of the **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment.

DATES: Comments on this proposed action must be received in writing by July 18, 2003.

ADDRESSES: Comments may be mailed to Amy Algoe-Eakin, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101, or E-mail her at *algoe-eakin.amy@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Amy Algoe-Eakin at (913) 551–7942.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final

rule which is located in the rules section of the **Federal Register**.

Dated: June 8, 2003.

James B. Gulliford,

Regional Administrator, Region 7.

[FR Doc. 03–15252 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW–FRL–7514–5]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule and request for comment.

SUMMARY: The Environmental Protection Agency (EPA, also the Agency or we in this preamble) is proposing to grant a petition submitted by the Southeastern Public Service Authority (SPSA) and Onyx Environmental Services (Onyx), to exclude (or delist) on a one-time basis certain solid wastes generated at the SPSA Power Plant in Portsmouth, Virginia, from the lists of hazardous waste. This waste is currently located at the SPSA Regional Landfill in Suffolk, Virginia.

The Agency has tentatively decided to grant the petition based on an evaluation of specific information provided by the petitioners. This tentative decision, if finalized, would conditionally exclude the petitioned waste from the requirements of the hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA).

The Agency is requesting comments on this proposed decision.

DATES: To make sure we consider your comments on this proposed exclusion, they must be postmarked by August 4, 2003. Comments received after the close of the comment period will be designated as late. EPA is not required to consider late comments.

Any person may request a hearing on this tentative decision to grant the petition by filing a request by July 3, 2003. The request must contain the information prescribed in 40 CFR 260.20(d).

ADDRESSES: Please send two copies of your comments to David M. Friedman, Technical Support Branch (3WC11), Waste and Chemicals Management Division, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103–2029.

Your request for a hearing should be addressed to James J. Burke, Director, Waste and Chemicals Management Division (3WC00), U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103–2029.

FOR FURTHER INFORMATION CONTACT: For technical information concerning this document, please contact David M. Friedman at the address above, at (215) 814–3395, or via e-mail at *friedman.davidm@epa.gov.*

SUPPLEMENTARY INFORMATION:

Docket

EPA has established an official docket for this action. The official docket consists of the petition submitted by SPSA/Onyx, the results of a risk assessment which evaluates the potential impact of the petitioned waste on human health and the environment, any public comments received, and other information related to this action. The official docket for this proposed rule is located at the offices of U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103–2029, and is available for you to view from 8:30 a.m. to 5:00 p.m., Monday through Friday, except on Federal holidays. Please call David M. Friedman at (215) 814–3395 for appointments. The public may copy material from the docket at $0.15 per page.

Outline

The information in this preamble is organized as follows:

I. Background

A. What Laws and Regulations Give EPA the Authority To Delist Waste?

EPA published amended lists of hazardous wastes from non-specific and specific sources on January 16, 1981, as part of its final and interim final regulations implementing Section 3001 of RCRA. These lists have been amended several times, and are found at 40 CFR 261.31 and 261.32.

We list these wastes as hazardous because: (1) they typically and frequently exhibit one or more of the characteristics of hazardous wastes identified in subpart C of 40 CFR part 261 (*i.e.*, ignitability, corrosivity, reactivity, and toxicity), or (2) they meet the criteria for listing contained in 40 CFR 261.11(a)(2) or (a)(3).

We also define residues from the treatment, storage, or disposal of listed hazardous wastes and mixtures containing listed hazardous wastes as hazardous wastes. (*See* 40 CFR 261.3(a)(2)(iv) and (c)(2)(i), referred to as the ''mixture'' and ''derived-from'' rules, respectively.)

Individual waste streams may vary, however, depending on raw materials, industrial processes, and other factors. Thus, while a waste that is described in these regulations generally is hazardous, a specific waste from an individual facility that would otherwise meet the listing description may not be.

For this reason, 40 CFR 260.20 and 260.22 provide an exclusion procedure which allows a person to demonstrate that a specific listed waste from a particular generating facility should not be regulated as a hazardous waste, and should, therefore, be delisted.

According to 40 CFR 260.22(a)(1), in order to have a waste excluded, a petitioner must first show that the waste generated at its facility does not meet any of the criteria for which the waste was listed. The criteria which we use to list wastes are found in 40 CFR 261.11. An explanation of how these criteria apply to a particular waste is contained in the background document for that listed waste.

In addition to the criteria that we considered when we originally listed the waste, we are also required by the provisions of 40 CFR 260.22(a)(2) to consider any other factors (including additional constituents), if there is a reasonable basis to believe that these factors could cause the waste to be hazardous.

In a delisting petition, the petitioner must demonstrate that the waste does not exhibit any of the hazardous waste characteristics defined in subpart C of 40 CFR part 261 (*i.e.*, ignitability, corrosivity, reactivity, and toxicity), and must present sufficient information for EPA to determine whether the waste contains any other constituents at hazardous levels.