

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 890 be amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 890.5290 is amended by revising paragraph (c) to read as follows:

§ 890.5290 Shortwave diathermy.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [date 90 days after date of publication of the final rule in the **Federal Register**], for any shortwave diathermy for all other uses (as described in paragraph (b)(1) of this section) that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date of publication of the final rule in the **Federal Register**], been found to be substantially equivalent to any shortwave diathermy for all other uses (as described in paragraph (b)(1) of this section) that was in commercial distribution before May 28, 1976. Any other shortwave diathermy for all other uses (as described in paragraph (b)(1) of this section) shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: June 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-16487 Filed 7-5-12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 50 and 51**

[EPA-HQ-OAR-2011-0887; FRL-9696-1]

RIN 2060-AN40

Draft Guidance To Implement Requirements for the Treatment of Air Quality Monitoring Data Influenced by Exceptional Events

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and public comment period.

SUMMARY: Notice is hereby given that the EPA has posted its draft non-binding guidance titled, *Draft Guidance to Implement Requirements for the Treatment of Air Quality Monitoring Data Influenced by Exceptional Events* and associated attachments, on the agency's Internet Web site. The EPA invites public comments on this guidance document and plans to issue an updated version of the guidance after reviewing timely submitted comments. The EPA intends to hold a conference call to provide interested stakeholders with an overview of the Exceptional Events draft guidance.

DATES: Comments must be received on or before September 4, 2012. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the comment period.

ADDRESSES: *Access to the draft guidance:* Please see the EPA's Web site at <http://www.epa.gov/ttn/analysis/exevents.htm> for additional details on the draft non-binding guidance titled, *Draft Guidance to Implement Requirements for the Treatment of Air Quality Monitoring Data Influenced by Exceptional Events* and associated attachments and the conference call for interested stakeholders.

Comments: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2011-0887, by one of the following methods:

- *http://www.regulations.gov.* Follow the online instructions for submitting comments. Attention Docket ID No. EPA-HQ-OAR-2011-0887.

- *Email:* a-and-r-docket@epa.gov. Attention Docket ID No. EPA-HQ-OAR-2011-0887.

- *Fax:* (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2011-0887.

- *Mail:* Air Docket, Attention Docket ID No. EPA-HQ-OAR-2011-0887, U.S. Environmental Protection Agency, Mail Code: 6102T, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Please include a total of two copies.

- *Hand Delivery:* EPA Docket Center, 1301 Constitution Avenue NW., Room 3334, Washington, DC, Attention Docket ID No. EPA-HQ-OAR-2011-0887. Such deliveries are only accepted during the Docket Center's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OAR-2011-0887. The EPA's policy is that all comments received will be included in the public docket without change and

may be made available online at www.regulations.gov, 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 www.regulations.gov or email. The www.regulations.gov Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through www.regulations.gov, your email 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, the 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 the EPA is unable to read your comment and cannot contact you for clarification due to technical difficulties, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>. For additional instructions on submitting comments, go to Section II of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket. All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., 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 www.regulations.gov or in hard copy at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Avenue 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.

FOR FURTHER INFORMATION CONTACT: Beth W. Palma, U.S. EPA, Office of Air

Quality Planning and Standards, Air Quality Policy Division, Mail Code C539-04, Research Triangle Park, NC 27711, telephone (919) 541-5432, email at palma.elizabeth@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Instructions for Submitting Public Comments

What should I consider as I prepare my comments for the EPA?

1. *Submitting CBI.* Do not submit this information to the EPA through www.regulations.gov or email. 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 the 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. Send or deliver information identified as CBI only to the following address: Roberto Morales, U.S. EPA, Office of Air Quality Planning and Standards, Mail Code C404-02, Research Triangle Park, NC 27711, telephone (919) 541-0880, email at morales.roberto@epa.gov, Attention Docket ID No. EPA-HQ-OAR-2011-0887.

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

- Identify this notice 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 in the guidance.
- 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.

II. Background

The purpose of this document is to solicit public comments on the EPA's recently posted draft non-binding guidance on the implementation of the March 22, 2007, Exceptional Events Rule (72 FR at 13560). These documents are available online at <http://www.epa.gov/ttn/analysis/exevents.htm> or within the associated docket, EPA-HQ-OAR-2011-0887.

The draft guidance consists of an overview document, titled *Draft Guidance to Implement Requirements for the Treatment of Air Quality Monitoring Data Influenced by Exceptional Events* and its attachments: Attachment 1, *Draft Exceptional Events Rule Frequently Asked Questions*; Attachment 2, *Draft Guidance on the Preparation of Demonstrations in Support of Requests to Exclude Ambient Air Quality Data Affected by High Winds under the Exceptional Events Rule* (High Winds Guidance Document); and Attachment 3, *Request for Comments on the Draft Guidance Documents on the Implementation of the Exceptional Events Rule*. Together, these documents clarify key provisions and respond to questions and issues that have arisen since the EPA promulgated the *Treatment of Data Influenced by Exceptional Events; Final Rule* (72 FR at 13560), known as the Exceptional Events Rule (EER), pursuant to the 2005 amendment of Clean Air Act (CAA) Section 319.

The EPA provided previous versions of these draft guidance documents to state, local, and tribal agencies, and to other parties as requested, in May of 2011 to solicit preliminary comments. The EPA has prepared the document *Responses to Significant First-Round Comments on the Draft Guidance Documents on the Implementation of the Exceptional Events Rule* (the Response to Comments document), to track these preliminary comments and the EPA's responses.

During this preliminary review period, the EPA received numerous comments, some of which the EPA has incorporated into the revised draft guidance documents. For example, the EPA has added an optional prospective controls analysis process and revised the discussion of the optional High Wind Action Plan; both of these are voluntary analyses that can facilitate agreement between states/local agencies/tribes and the EPA as to what measures constitute "reasonable" controls in advance of an actual event.

Once the plans have gone through a notice and comment process at the state/local/tribal level and the EPA has approved these plans, the EPA generally anticipates that they will be effective for three years. Both of these approaches are described in more detail in the revised, draft High Winds Guidance document. The EPA solicits feedback on the anticipated use and functionality of these plans. Initial commenter feedback also asked the EPA to identify timelines for steps in the exceptional event submittal and review process. In the draft guidance documents, the EPA identifies suggested review and response timeframes, and indicates willingness to work with agencies on these timeframes to the extent the mandatory timing of the EPA regulatory actions allows.

The EPA has also begun applying the principles in the draft guidance documents as we receive exceptional event submittal packages. For example, the EPA's Region 9 office worked with agencies in Arizona to incorporate approaches presented in the draft guidance documents into a consolidated exceptional events demonstration package that addresses numerous exceedances of the PM₁₀ standard. The EPA hopes that, once finalized, much of the information included in this streamlined exceptional events demonstration submittal could be transferable and serve as a model for future events for both Arizona and other areas experiencing high wind dust events.

While the EPA incorporated some comments into the revised draft guidance documents, the EPA did not incorporate all aspects of commenter feedback. For example, multiple commenters suggested that Exceptional Events Rule revisions are the appropriate mechanism to implement some of the approaches described in the guidance documents. The EPA maintains that guidance documents do not change, increase, or decrease rule requirements; they assist by providing information and illustrations for better understanding of and compliance with the rule. The EPA is deferring a decision on whether to revise the Exceptional Events Rule.

Initial feedback on the draft guidance documents also raised the following questions on which the EPA is specifically seeking comment:

- The EPA has developed draft exceptional event implementation guidance with the goal of establishing clear expectations to enable affected agencies to better manage resources as they prepare the documentation required under the EER. These draft

guidance documents identify mechanisms (e.g., demonstration prioritization, review time lines, High Wind Action Plans) to streamline the demonstration development, submittal, and review process. The EPA seeks comment regarding other specific, broadly applicable, streamlining mechanisms that the EPA could incorporate into the exceptional event implementation process.

- The EPA has modified the exceptional events Web site at <http://www.epa.gov/ttn/analysis/exevents.htm> to include additional links to tools, such as the DataFed Web site, that submitting agencies may use in the development of their demonstration submittals. The EPA has also posted exceptional event demonstrations that have already been reviewed and acted upon by the EPA. The EPA solicits feedback regarding other web-based information, links, tools, or methodologies that we can similarly post on our Web site.

- In the draft exceptional events guidance documents, the EPA defines the high wind threshold as the minimum threshold wind speed capable of overwhelming reasonable controls on anthropogenic sources (i.e., capable of causing significant dust emissions from controlled sources) or causing emissions from natural undisturbed areas. The EPA further notes that this area-specific threshold, along with the submitter's analysis of implemented reasonable controls and other factors, helps inform the analysis of the "not reasonably controllable or preventable" criterion. The EPA intends to allow air agencies to use wind data from a multitude of sources in the development of high wind thresholds. The EPA has identified several sources of local wind speed data including the National Weather Service, the National Climate Center, and local air monitoring stations. In addition, air agencies may use models such as Fifth Generation Pennsylvania State University/National Center for Atmospheric Research Mesoscale Mode (MM5), Weather Research and Forecasting Model (WRF) and North American Mesoscale Model (NAM), to develop local wind speed data. The EPA solicits feedback on additional available sources of wind data and their applicability in informing local high wind analyses.

- As previously mentioned, demonstrations for high wind dust events necessarily include wind speed analyses. Generally, the EPA will accept that high winds could be the cause of a high 24-hour average PM₁₀ or PM_{2.5} concentration if there was at least one full hour in which the hourly average wind speed was above area-specific

high wind threshold. Potential issues arise when determining the hourly average wind speed if wind speeds are not recorded at specified intervals throughout each hour. While some sources of wind speed data use hourly averages, other data sources employ 1–5 minute ("short-period") averages. When the available wind speed data consist of only the wind speed during a fixed short period of each hour (e.g., the first or last 5 minutes of each hour) or the wind speed during the variable short period when wind speed was at its maximum during the hour, the EPA will generally accept that the hourly average wind speed was above the threshold if the reported short-period wind speed was above the threshold. Where wind speed is recorded at specified intervals throughout each hour, agencies should use all recorded data to calculate the hourly average wind speed.

AERMINUTE, a preprocessor to AERMOD that takes short-period wind speed observations and calculates an hourly average wind, can assist in this calculation. AERMINUTE data, or other sub-hourly data with a resolution equal or greater than 5 minutes, can be fed into AERMET, the AERMOD meteorological processor, to get a user-friendly output. The EPA solicits additional feedback and tools to convert 1–5 minute wind speed data to hourly averages.

- Within the EPA's Air Quality System (AQS), monitoring agencies can use two types of data validation, or data qualifier, codes: the *Request Exclusion* flags (*R*) and the *Informational Only* flags (*I*). Agencies should use the *I* series flags when identifying informational data and the *R* series flags to identify data points for which the agency intends to request an exceptional event exclusion and the EPA's concurrence. Given that the EPA can act/concur only on *R* flags, some agencies have questioned the utility of *I* flags. Do AQS users find *I* flags in AQS useful? If so, how do users employ these flags?

- In response to comments received and in an effort to streamline the development of high wind demonstrations, the EPA has added an optional "Prospective Controls Analysis" process by which states, local agencies, and tribes can voluntarily provide information on attainment status, identify natural and anthropogenic windblown dust sources and emissions, provide the status of SIP submittals (if applicable), and identify the wind speed up to which the collective windblown dust controls are expected to be effective. This optional analysis can facilitate agreement between states/local agencies/tribes and

the EPA as to what constitutes "reasonable" controls in advance of an actual event. The EPA has also added an optional "High Wind Action Plan" that states/local agencies/tribes can use to document current in-place controls, document controls on new sources that need reasonable controls for future events, and/or document current and/or planned mitigation measures. Both of these approaches are described in more detail in the revised draft High Winds Guidance document. The EPA anticipates that air agencies would submit the prospective controls analysis in advance of or with a demonstration package and similarly expects that air agencies would submit the High Wind Action Plan following the EPA's initial review of a demonstration package. The EPA recognizes that the information contained in the prospective controls analysis and the High Wind Action Plan is likely to overlap. The EPA solicits feedback on the anticipated use and functionality of these plans.

Specifically, the EPA requests that commenters identify: (1) Specific elements in the prospective controls analysis and High Wind Action Plan that are useful, (2) whether these concepts should be combined or kept separate and (3) whether the flexibility to implement needed dust controls provided by the High Wind Action Plan as a voluntary alternative to the traditional regulatory nonattainment designation process is helpful.

- In Table 3 of the revised draft High Winds Guidance document, the EPA identifies example technical analyses that air agencies should consider when preparing their high wind dust event controls analysis to demonstrate the not reasonably controllable or preventable criterion. The EPA solicits comment on the identified analyses and any additional technical analyses that air agencies could use to demonstrate that the wind exceeded an identified high wind threshold and that the exceedance was caused by emissions that were not reasonably controllable.

- The EPA acknowledges that certain extreme exceptional event cases may require more limited demonstration packages. Whether a particular event should be considered "extreme" for this purpose depends on the type and severity of the event, pollutant concentration, spatial extent, temporal extent, and proximity of the event to the violating monitor. Several meteorological phenomena that could be considered extreme events include hurricanes, tornadoes, haboobs, and catastrophic volcanic eruptions. The EPA addresses "extreme" high wind dust events in the draft Q&A document,

but solicits comment on whether and how specific events of various types should be considered to be "extreme."

With this document, the EPA is announcing the availability of revised draft guidance, along with examples of approved demonstrations on the EPA's Web site at <http://www.epa.gov/ttn/analysis/exevents.htm>. The EPA is providing the draft guidance to facilitate review of these materials by outside parties and to help ensure that the EPA's final guidance provides an efficient and effective process to make determinations regarding air quality data affected by events. The EPA notes that these draft guidance documents and the exceptional events Web site present examples to illustrate specific points. The example analyses and level of rigor are not necessarily required for all demonstrations.

After receiving timely submitted public comments on the draft guidance, the EPA plans to issue updated non-binding guidance. In addition, the EPA will continue to work closely with state, local, and tribal agencies to address issues arising during the development and submittal of exceptional event demonstration packages. The EPA is deferring a decision on whether to revise the Exceptional Events Rule.

The EPA invites public comment on all aspects of this draft guidance during the 60-day comment period. The draft guidance is not a regulation or any other kind of final action and does not establish binding requirements on the EPA or any state, local, or tribal agency or any emissions source. While the EPA has established a docket and is requesting public comment on the draft guidance, this procedure does not alter the nature or effect of the draft guidance and does not constitute a formal rulemaking process or require the EPA to respond to public comments in the updated guidance before the EPA or other agencies may use the guidance in reaching decisions making related exceptional event demonstration submittals. The EPA retains the discretion to revise its guidance, issue additional guidance, propose regulations as appropriate, and to use information submitted in public comments to inform future decisions. Because this draft guidance does not constitute a formal rulemaking action, the EPA is not required to respond to comments, but intends to consider significant comments in amending or updating the non-binding guidance. Following the 60-day comment period and review and incorporation of comments, the EPA expects to post the revised, final guidance documents at

<http://www.epa.gov/ttn/analysis/exevents.htm>.

Please refer to the **ADDRESSES** section above in this document for specific instructions on submitting comments.

III. Internet Web Site for Guidance Information

Interested parties can find the draft guidance titled, Draft Guidance Documents on the Implementation of the Exceptional Events Rule, on the Exceptional Events Web site for this rulemaking at <http://www.epa.gov/ttn/analysis/exevents.htm>. The Web site includes examples of reviewed exceptional event submissions, best practices components, and links to publicly available support information and tools that the public may find useful.

Dated: June 26, 2012.

Mary E. Henigin,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 2012-16308 Filed 7-5-12; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0441; FRL-9352-9]

Difenzoquat; Proposed Data Call-in Order for Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed order.

SUMMARY: This document proposes to require the submission of various data to support the continuation of the tolerances for the pesticide difenzoquat. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before September 4, 2012.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0441; FRL-9352-9, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Eric Miederhoff, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 347-8028; email address: miederhoff.eric@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to, those involved with:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through www.regulations.gov or email. 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