EQR Data Dictionary

Appendix D. Time Zone

| Time Zone | Definition |
|---|---|
| AD | *Atlantic Daylight* |
| AP | *Atlantic Prevailing* |
| AS | *Atlantic Standard* |
| CD | *Central Daylight* |
| CP | *Central Prevailing* |
| CS | *Central Standard* |
| ED | *Eastern Daylight* |
| EP | *Eastern Prevailing* |
| ES | *Eastern Standard* |
| MD | *Mountain Daylight* |
| MP | *Mountain Prevailing* |
| MS | *Mountain Standard* |
| NA | *Not Applicable* |
| PD | *Pacific Daylight* |
| PP | *Pacific Prevailing* |
| PS | *Pacific Standard* |
| UT | *Universal Time* |

EQR Data Dictionary

Appendix E. Units

| Units | Definition |
|---|---|
| KV | *Kilovolt* |
| KVA | *Kilovolt Amperes* |
| KVR | *Kilovar* |
| KW | *Kilowatt* |
| KWH | *Kilowatt Hour* |
| KW-DAY | *Kilowatt Day* |
| KW-MO | *Kilowatt Month* |
| KW-WK | *Kilowatt Week* |
| KW-YR | *Kilowatt Year* |
| MVAR-YR | *Megavar Year* |
| MW | *Megawatt* |
| MWH | *Megawatt Hour* |
| MW-DAY | *Megawatt Day* |
| MW-MO | *Megawatt Month* |
| MW-WK | *Megawatt Week* |
| MW-YR | *Megawatt Year* |
| RKVA | *Reactive Kilovolt Amperes* |
| FLAT RATE | *Flat Rate* |

EQR Data Dictionary

Appendix F. Rate Units

| Rate Units | Definition |
|---|---|
| $/KV | *dollars per kilovolt* |
| $/KVA | *dollars per kilovolt amperes* |
| $/KVR | *dollars per kilovar* |
| $/KW | *dollars per kilowatt* |
| $/KWH | *dollars per kilowatt hour* |
| $/KW-DAY | *dollars per kilowatt day* |
| $/KW-MO | *dollars per kilowatt month* |
| $/KW-WK | *dollars per kilowatt week* |
| $/KW-YR | *dollars per kilowatt year* |
| $/MW | *dollars per megawatt* |
| $/MWH | *dollars per megawatt hour* |
| $/MW-DAY | *dollars per megawatt day* |
| $/MW-MO | *dollars per megawatt month* |
| $/MW-WK | *dollars per megawatt week* |
| $/MW-YR | *dollars per megawatt year* |
| $/MVAR-YR | *dollars per megavar year* |
| $/RKVA | *dollars per reactive kilovar amperes* |
| CENTS | *cents* |
| CENTS/KVR | *cents per kilovolt amperes* |
| CENTS/KWH | *cents per kilowatt hour* |
| FLAT RATE | *rate not specified in any other units* |

EQR Data Dictionary

Appendix G. Index Price Publisher

| Index PricePublisher Abbreviation | Index Price Publisher |
|---|---|
| AM | *Argus Media* |
| EIG | *Energy Intelligence Group, Inc.* |
| IP | *Intelligence Press* |
| P | *Platts* |
| B | *Bloomberg* |
| Pdx | *Powerdex* |
| SNL | *SNL Energy* |

## EQR Data Dictionary
## ID Data

Appendix H. Exchange/Broker Services

| Exchange/Brokerage Service | Definition |
|---|---|
| BROKER | *A broker was used to consummate or effectuate the transaction.* |
| ICE | *Intercontinental Exchange* |
| NODAL | *Nodal Exchange* |
| NYMEX | *New York Mercantile Exchange* |

[FR Doc. 2014–07121 Filed 4–3–14; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 1

**[Docket No. FDA–2002–N–0153 (Formerly Docket No. 2002N–0277)]**

**RIN 0910–AG73**

## Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final regulation that adopts, without change, the interim final rule (IFR) entitled ''Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements.'' This final rule affirms the IFR's change to FDA's records access as required by the FDA Food Safety Modernization Act (FSMA). Prior to the passage of FSMA, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) provided the Secretary (by delegation FDA) with access to records relating to food that

FDA reasonably believes to be adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The FSMA amendment expands FDA's former records access authority beyond records relating to the specific suspect article of food to include records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner. In addition, the FSMA amendment permits FDA to access records relating to articles of food for which FDA believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. This final rule does not make any changes to the regulatory requirements established by the IFR. The final regulation also responds to comments submitted in response to the request for comments in the IFR.

**DATES:** This final rule is effective April 4, 2014.

**FOR FURTHER INFORMATION CONTACT:** William A. Correll, Jr., Office of Compliance, Center for Food Safety and Applied Nutrition (HFS–607), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1611.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Each year about 48 million people (1 in 6 Americans) get sick from foodborne diseases, 128,000 are hospitalized, and 3,000 die, according to 2011 data from the Centers for Disease Control and Prevention (*http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html*). This is a significant public health burden that is largely preventable.

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities to help it achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to better ensure the safety of imported foods and directs FDA to build an integrated national food safety system in partnership with State and local authorities.

Section 101 of FSMA amended section 414(a) of the FD&C Act (21 U.S.C. 350c(a)). Section 414 was added to the FD&C Act by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188). Prior to the passage of FSMA, section 414(a) of the FD&C Act provided the Secretary (by delegation FDA) with access to records relating to food that FDA reasonably believes to be adulterated and presents a threat of serious adverse health consequences or death to humans or animals. As amended by FSMA, section 414(a)(1) of the FD&C Act expands FDA's access to records beyond records relating to the specific suspect article of food to include records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner. In addition, FDA can now, under section 414(a)(2) of the FD&C Act, access records if FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. Section 414(a)(1) and (2) of the FD&C Act both provide that, at the request of an officer or employee duly designated by FDA, ''each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article [(the suspect food)] shall . . . permit such officer or employee . . . at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and any other article of food that [FDA] reasonably believes is likely to be affected in a similar manner. . .'' The designated officer or employee shall have access to such records upon presentation of the appropriate credentials and a written notice to such person. FDA shall have access to the records that are needed to assist FDA in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals under section 414(a)(1) or whether there is a reasonable probability that use or exposure to the food will cause serious adverse health consequences or death to humans or animals under section 414(a)(2).

The Bioterrorism Act also amended section 704(a)(1)(B) of the FD&C Act (21 U.S.C. 374(a)(1)(B)) to include a cross-reference to section 414 of the FD&C Act. Section 101 of FSMA amends this section by updating the cross-reference to refer to the amended version of section 414(a). The amendments made by section 101 of FSMA to the FD&C Act were effective upon enactment of the law (January 4, 2011).

On February 23, 2012, FDA issued an IFR (77 FR 10658) that implemented section 101 of FSMA by amending the relevant requirements in FDA's regulation on the establishment, maintenance, and availability of records and also contained a request for comments. The IFR became effective on March 1, 2012. This final rule adopts, without making any changes, the regulatory requirements established in the IFR.

To the extent that 5 U.S.C. 553 applies to this action, the Agency's implementation of this action with immediate effective date comes within the good cause exception in 5 U.S.C. 553(d)(3) (21 CFR 10.40(c)(4)(ii)). As this final rule imposes no new regulatory requirements, a delayed effective date is unnecessary.

## II. Comments on the IFR

FDA received two responsive comments to the IFR. After considering these comments, the Agency is not making any changes to the regulatory language included in the IFR. Relevant portions of the responsive comments are summarized and responded to in this document. The Agency did not consider nonresponsive comments in developing this final rule. To make it easier to identify comments and FDA's responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before FDA's response. Each comment is numbered to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance.

(Comment 1) Comments requested that the Agency clarify the meaning of the new records access authority in section 414(a) of the FD&C Act, and in particular, the phrases ''reasonably believes is likely to be affected in a similar manner'' and ''reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death.''

(Response) As stated in the IFR (77 FR 10658 at 10659), decisions regarding whether FDA ''reasonably believes [a food] is likely to be affected in a similar manner'' to cause serious adverse health consequences or death to humans or

animals and whether there is a ''reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death'' will be made on a case-by-case basis because such decisions are fact-specific. The Agency will consider the individual facts in each particular situation to inform its decisions. Because such decisions are fact-specific, FDA has not, therefore, amended the regulation to provide additional explanation of the records access authority.

(Comment 2) FDA received a comment asking that we address all costs, such as large costs (e.g., updating a records system), small costs (e.g., copying records), and cumulative costs (e.g., reassigning personnel from their normal activities in order to respond to a records access request from FDA), associated with providing FDA access to records, as these costs can be debilitating to small businesses.

(Response) FDA does not expect firms to incur any large costs associated with this rule because, as stated in the IFR, this rule only affects FDA's records access and does not impose any new record maintenance requirements. Further, this rule only affects FDA's access to already existing records and as such, it neither requires firms to change or upgrade their current records management systems or procedures, nor does it require firms to make new records.

Also, as stated in the economic impact analysis of the IFR, to the extent that FDA requests access to more records than it was previously allowed to access under similar circumstances, businesses may incur additional retrieval costs per record (77 FR 10658 at 10661). Retrieval costs would include the time and opportunity costs of reassigning personnel from normal activities to retrieve, copy, or print records and can also include the costs of copying or printing equipment. However, the costs of retrieving one or more additional record from any number of records or the opportunity costs of reassigning personnel from regular duties to retrieve additional records in response to a records access request are considered part of a firm's private costs for planning for a records access request. These costs are determined by a firm's business plan. This business plan will vary by firm as each firm has its own policy on preparing for and responding to FDA records requests. Any potential changes to the business plan that a firm may make as a result of this rule are driven by internal firm decisions and thus, are not factored into the overall cost of the rule.

Consequently, any potential costs to businesses from this rule in general and in terms of retrieving more records than under the final regulation on the establishment, maintenance, and availability of records, published in 2004 (69 FR 71562; December 9, 2004) are still expected to be small.

## III. Executive Order 12866 and Executive Order 13563: Cost Benefit Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. OMB has determined that this is a significant regulatory action as defined by the Executive Orders.

The Regulatory Flexibility Act requires Agencies to determine whether a final rule will have a significant impact on small entities when an Agency issues a final rule ''after being required . . . to publish a general notice of proposed rulemaking.'' Although we are not required to perform a regulatory flexibility analysis because we were not required to publish a proposed rule prior to this final rule, we have nonetheless conducted a regulatory flexibility analysis for this final rule. Because the additional costs per entity of this rule are negligible if any, the Agency also concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

In 2003, FDA analyzed the economic impact of the proposed rule to require the establishment, maintenance, and availability of records requirements under the Bioterrorism Act (68 FR 25188 at 25199; May 9, 2003). The rule finalizing these requirements, published in 2004, contained an Economic Impact Analysis (69 FR 71562 at 71611) which revised the analysis set forth in the 2003 proposed rule in response to comments received and to account for the changes between the proposed and final rules.

In 2012, FDA issued the IFR amending certain requirements in the regulation on the establishment, maintenance, and availability of records to be consistent with changes to the FD&C Act made by section 101 of FSMA. The Economic Impact Analysis in the 2012 IFR explained and further revised the analysis set forth in the 2004 final rule by addressing the economic impact of the changes to the regulation to be consistent with the amendments to the FD&C Act made by section 101 of FSMA. This final rule adopts, without making any changes, the regulatory requirements established in the IFR.

FDA did not receive any comments that would warrant further revising the economic analysis of the IFR. Thus, this economic analysis affirms the economic impact analysis of the IFR. For a full explanation of the economic impact analysis of this final rule, interested persons are directed to the text of the economic impact analyses in the IFR (77 FR 10658 at 10660) and the 2004 final rule (69 FR 71562 at 71611).

## IV. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

A regulatory flexibility analysis is required only when an Agency must publish a notice of proposed rulemaking (5 U.S.C. 603, 604). FDA published the IFR without a notice of proposed rulemaking after finding good cause that the use of prior notice and comment procedures would be contrary to the public interest. Although FDA determined that it was not required to publish a notice of proposed rulemaking and, therefore, that no regulatory flexibility analysis is required, FDA has nonetheless conducted such an analysis and examined the economic implications of this final rule on small entities. Although this final rule is a significant regulatory action as defined by Executive Order 12866, FDA also concludes that this final rule will not

have a significant impact on a substantial number of small entities.

**V. Paperwork Reduction Act of 1995**

This final rule contains information collection provisions that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under 21 CFR 1.361.

**VI. Analysis of Environmental Impact**

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**VII. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

**List of Subjects in 21 CFR Part 1**

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

## PART 1—GENERAL ENFORCEMENT REGULATIONS

■ Accordingly, the interim rule amending 21 CFR part 1, which was published at 77 FR 10658 (February 23, 2012), is adopted as a final rule without change.

Dated: April 1, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–07550 Filed 4–3–14; 8:45 am]

BILLING CODE 4160–01–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R05–OAR–2013–0646; FRL–9908–72–Region 5]**

### Approval and Promulgation of Air Quality Implementation Plans; Michigan; PSD Rules for $PM_{2.5}$

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct Final Rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving revisions to Michigan's Prevention of Significant Deterioration (PSD) Program rules and definitions, including revisions to Parts 1 and 18 of Michigan's Air Pollution Control Rules into Michigan's State Implementation Plan (SIP). The revised rules address the Federal requirements for significant emission levels, and definitions for fine particulate matter ($PM_{2.5}$). The Michigan Department of Environmental Quality (MDEQ) submitted these revisions to EPA on August 9, 2013, and September 19, 2013.

**DATES:** This direct final rule is effective June 3, 2014, unless EPA receives adverse comments by May 5, 2014. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R05–OAR–2013–0646, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: damico.genevieve@epa.gov.*
3. *Fax:* (312) 886–0968.
4. *Mail:* Genevieve Damico, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Genevieve Damico, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

*Instructions:* Direct your comments to Docket ID No. EPA–R05–OAR–2013–0646. 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 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 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, 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.

*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, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Constantine Blathras, Environmental