FAA found that the cite for the Class E2 airspace was omitted. With the exception of editorial changes, and the changes described above, this rule is the same as that proposed in the NPRM.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E airspace at Ankeny, IA, reconfiguring controlled airspace at Ankeny Regional Airport, Ankeny, IA, for the safety and management of IFR operations. This action also updates the geographic coordinates of the airport to coincide with the FAA's National Aeronautical Charting Office. This rule also cites the correct paragraph in which the Class E2 airspace is found in FAA Order 7400.9S.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at Ankeny Regional Airport, Ankeny, IA.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E. O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9S, Airspace Designations and Reporting Points, signed October 3, 2008, and effective October 31, 2008, is amended as follows:

Paragraph 6002 Class E airspace designated as surface areas.

* * * * *

ACE IA E2 Ankeny, IA [Amended]

Ankeny Regional Airport, IA
(Lat. 41°41′29″ N., long. 93°33′59″ W.)

Within a 4-mile radius of Ankeny Regional Airport, excluding that portion within the Des Moines Class C airspace area.

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface.

* * * * *

ACE IA E5 Ankeny, IA [Amended]

Ankeny Regional Airport, IA
(Lat. 41°41′29″ N., long. 93°33′59″ W.)

That airspace extending upward from 700 feet above the surface within a 7.1-mile radius of Ankeny Regional Airport, and within 2 miles each side of the 045° bearing from the airport extending from the 7.1-mile radius to 9.3 miles northeast of the airport, and within 2 miles each side of the 012° bearing from the airport extending from the 7.1-mile radius to 11.1 miles north of the airport, excluding that portion within the Des Moines Class C airspace area.

* * * * *

Issued in Fort Worth, Texas, on July 16, 2009.

Anthony D. Roetzel,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. E9–17863 Filed 7–27–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA–2008–N–0341]

RIN 0910–AG19

Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to require that the holder of a new drug application (NDA) submit certain information regarding authorized generic drugs in an annual report. We are taking this action as part of our implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA requires that FDA publish a list of all authorized generic drugs included in an annual report since 1999, and that the agency update the list quarterly.

DATES: This final rule is effective January 25, 2010.

ADDRESSES: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michelle D.D. Bernstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6362, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 29, 2008 (73 FR 56487), FDA published a direct final rule to amend § 314.3 (21 CFR 314.3) to add a definition of ''authorized generic drug'' and § 314.81 (21 CFR 314.81) to require that an NDA holder specifically report that it has marketed an authorized generic drug during the applicable time period. We explained that we issued this rule as a direct final rule because we believed it was noncontroversial and that there was little likelihood of receiving significant

adverse comments. We concurrently published in the **Federal Register** of September 29, 2008 (73 FR 56529) a companion proposed rule, identical in substance to the direct final rule, that provided a procedural framework from which to proceed with standard notice-and-comment rulemaking in the event we were required to withdraw the direct final rule because of significant adverse comments. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. Any comments received under the companion proposed rule were treated as comments regarding the direct final rule and vice versa. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

We received four comments on the proposed rule, which included several comments that were arguably significant adverse comments. Therefore, in the **Federal Register** of February 10, 2009 (74 FR 6541), we withdrew the direct final rule. This final rule summarizes and responds to the comments received on the direct final rule and proposed rule. See section III of this document for a discussion of the comments and FDA's responses.

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85, 121 Stat. 823). Section 920 of FDAAA adds new section 505(t) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(t)). Section 505(t) of the act requires that FDA take the following actions:

- Publish on its Internet site a complete list of all authorized generic drugs included in an annual report submitted to the agency after January 1, 1999, consisting of the drug trade name, the brand company manufacturer, and the date the authorized generic drug entered the market;
- Update the list quarterly; and
- Notify relevant Federal agencies, including the Centers for Medicare and Medicaid Services and the Federal Trade Commission, that the list has been published and will be updated quarterly.

For purposes of publishing the list, section 505(t)(3) of the act defines the term ''authorized generic drug'' as a ''listed drug (as that term is used in [section 505(j) of the act]) that has been approved under [section 505(c) of the act] and is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.'' On June 27, 2008, based on information available to FDA at that time, the agency initially published the list of authorized generic drugs on FDA's Web site at *http://www.fda.gov/cder/ogd/AG_Listing.htm*.

A. The Proposed Rule

Currently, there is no requirement that an NDA holder specifically report that it is marketing an ''authorized generic drug.'' NDA holders are required to include information about distribution or certain changes to manufacturing or labeling in annual reports, which may indicate that an authorized generic is being marketed. However, annual reports may not include all the information necessary for FDA to publish the list required by FDAAA. For example, sponsors rarely include the date the authorized generic entered the market.

As stated in the proposed rule, to allow FDA to accurately report a complete list of all authorized generic drugs included in annual reports and to update the list in a timely fashion, we proposed to add a requirement that annual reports specifically and clearly include the information we are required to report. In addition, we proposed that the NDA holder report the date the authorized generic drug ceased being distributed to ensure that the list is as accurate and up-to-date as possible. The first annual report submitted after implementation of this regulation must provide information regarding any authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999.

B. Changes to the Proposed Rule

We received a number of comments on the proposed rule regarding submission of the required information. Some of the comments requested clarification about electronic submission of the information and urged speedy adoption of an electronic means for submission of the information. One comment opposed the provision requiring separate submission of the information by mail in either hard copy or electronic format in addition to submission as part of the annual report. We address all of the comments in section III of this document.

After considering the comments, we have concluded that it is appropriate to make a revision to the proposed rule to permit e-mail submission of the required information in addition to regular mail, including courier delivery. The final rule revises proposed § 314.81(b)(2)(ii)(b) to allow NDA holders to send the required information to the Authorized Generics electronic mailbox at *AuthorizedGenerics@fda.hhs.gov* with ''Authorized Generic Submission'' indicated in the subject line.

We also revised the last line of that section to clarify when separate submission of the authorized generics information is required by this rule. When information is included in an annual report about an authorized generic drug, the final rule requires that a copy of that portion of the annual report be sent to a central office in the agency that will compile the list of authorized generic drugs and update it quarterly. At such time as FDA requires electronic submission of annual reports through a system that allows for the extraction of relevant information from annual reports, separate submission of the information will no longer be required.

Finally, on our own initiative, we have also revised § 314.81(b)(2)(ii)(b) to provide a new mailing address (street address) for submissions made by regular mail.

II. Description of the Final Rule

We are amending our regulations in § 314.3 (21 CFR 314.3) to add a definition for the term ''authorized generic drug.'' The definition provides that an authorized generic drug is a listed drug (as defined in § 314.3 (21 CFR 314.3)) that has been approved under section 505(c) of the act and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark that differs from that of the listed drug.

We are also amending our regulations in § 314.81 (21 CFR 314.81) to require that an NDA holder specifically report that it has marketed an authorized generic drug during the applicable time period. Section 314.81(b)(2) requires that an NDA holder submit an annual report within 60 days of the anniversary date of approval of an NDA for every NDA it holds. We are amending § 314.81 by redesignating paragraph (b)(2)(ii) regarding distribution data as paragraph (b)(2)(ii)(a), and adding a new paragraph (b)(2)(ii)(b) regarding marketing of authorized generic drugs. Under this new paragraph, if an authorized generic drug was marketed under an NDA, or

ceased to be marketed, during the reporting year, the annual report must list the date the authorized generic drug entered the market, or the date the authorized generic drug ceased being distributed, and the corresponding trade or brand name. Each dosage form and/or strength is a different authorized generic drug and should be listed separately. The first annual report submitted after implementation of this regulation must include the required marketing information for any authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999.

If information is included in the annual report with respect to any authorized generic drug, a copy of the portion of the annual report with that information must be sent to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drug Quality Assessment, Bldg. 21, rm. 2562, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, and marked ''Authorized Generic Submission''; or to the Authorized Generics electronic mailbox at *AuthorizedGenerics@fda.hhs.gov* with ''Authorized Generic Submission'' indicated in the subject line. This final rule assumes that the copy of the relevant portion of the annual report may currently be submitted in one of several different formats (e.g., a paper copy, a PDF document on a computer disc, or an e-mail containing the required information). Although annual reports may currently be submitted in electronic format to the relevant division responsible for reviewing a particular NDA, current capabilities do not permit us to create a centralized authorized generics database by extracting information from the relevant portion of the annual reports submitted in that format. However, FDA is committed to adapting its business practices to evolving technology, including using the significant advancements in Web-based, electronic systems. In anticipation of the future changes, this final rule provides that once an electronic submission format is mandated for annual reports and new requirements for electronic submission to the agency of annual reporting information are established, the authorized generics information will then be required to be submitted as part of the annual report submission in accordance with the new requirements. Separate submission of the information will no longer be required when FDA has a method of extracting the relevant information from annual reports.

III. Comments on the Proposed Rule and FDA's Responses

We received four comments in response to the proposed rule. Comments were received from individual consumers and industry organizations. A summary of the comments received and our responses follow.

A. General Comments

(Comment 1) Two comments generally supported the proposed rule. One of these comments urged FDA to require submission of additional information, such as the brand name associated with the authorized generic drug and whether a prescription is required, for inclusion on the list of authorized generic drugs.

(Response) FDA appreciates the supportive comments. Regarding the submission of additional information suggested by the commenter, note that this final rule requires, as we proposed, that annual reports list the date each authorized generic drug entered the market, the date each authorized generic drug ceased being distributed, and the corresponding trade or brand name. We do not believe it is necessary to also require prescription status to be reported to FDA and included on the list because such information is easily obtained from product labeling or other publicly available sources if the trade name is known. The information required to be reported under new § 314.81(b)(2)(ii)(b) of the regulations tracks the requirements of section 505(t) of the act and adequately informs the public of the marketing of an authorized generic drug. Thus, we decline to adopt the suggestion to require submission of prescription status information.

(Comment 2) One comment requested that we clarify the contents of the required submission, particularly with regard to distribution data that is required to be submitted under current § 314.81(b)(2)(ii) with the annual report.

(Response) As stated in section II of this document, the information we are requiring be submitted separately for authorized generic drugs is the date each authorized generic drug entered the market, the date each authorized generic drug ceased being distributed, and the corresponding trade or brand name. Current § 314.81(b)(2)(ii) requires that distribution data about a drug product marketed under an approved NDA be submitted with the annual report. In the codified of this final rule, § 314.81(b)(2)(ii) is renumbered as § 314.81(b)(2)(ii)(a), but otherwise remains unchanged. Distribution data is not required to be separately submitted under this rule for inclusion on the authorized generic drug list.

B. Comments on Electronic Submission

(Comment 3) One comment requested clarification about electronic submission of the required information. Another comment urged speedy adoption of an electronic means for submission of the required information.

(Comment 4) One comment opposed the provision requiring separate submission of the required information by mail in either hard copy or electronic format. The comment stated that this provision is contrary to FDA's long-standing record of encouraging and facilitating electronic regulatory submissions and to its goal to use information technology to facilitate the application and review processes. The commenter believes that for annual reports currently submitted in electronic format, FDA should not require separate submission of the authorized generic information to the Office of Pharmaceutical Science.

(Response) The purpose of this rule is to facilitate FDA's obligation to accurately report a complete list of all authorized generic drugs included in annual reports and to update the list in a timely fashion. To fulfill our obligation, we need ready access to the required information. Therefore, in this final rule, we are requiring that the section 505(t) of the act information be separately sent to us, as proposed. However, in response to the comments, we have modified the language in § 314.81(b)(2)(ii)(b) to provide that the authorized generics information may also be submitted to FDA using e-mail, in lieu of sending the information by regular mail or courier. FDA believes this will provide an alternative method of submission that may be more convenient for some sponsors. We encourage sponsors that currently elect to submit their annual reports in electronic format to continue to do so. At such time that electronic submission of annual reports is mandated by FDA and FDA develops the capability to readily retrieve information it needs to comply with section 505(t) of the act, separate submission of the authorized generic information will no longer be necessary, and the language in § 314.81(b)(2)(ii)(b) of the codified has been clarified to reflect this. Until electronic submission of annual reports is required and FDA can readily retrieve the authorized generics information from the annual reports database, sponsors must submit the authorized generics information separately by regular mail or e-mail (regardless of

what format the sponsor currently uses to submit its annual report).

C. Comment on Effective Date

(Comment 5) One comment opposed the proposed rule because it does not ''prioritize collection of information on currently distributed authorized generic drugs.'' The commenter suggested that FDA first require sponsors to report information about currently distributed authorized generic drugs and, at a later stage, require reporting of information on authorized generic drugs marketed after 1999 but subsequently discontinued. The same commenter requested that FDA provide for an effective date that would allow sponsors time for advance planning, revision of operating procedures governing preparation of annual reports, and review of historical records.

(Response) We have adopted an effective date of 6 months after publication of this final rule. We believe that 6 months will allow time for advance planning, revision of operating procedures, and any review of historical records that would be necessary to collect the required information on marketing of authorized generic drugs since 1999 that must be reported under new § 314.81(b)(ii)(b) of the regulations. Because we have adopted an effective date that permits adequate time for manufacturers/sponsors to collect and report information on both currently marketed authorized generic drugs and authorized generic drugs marketed since 1999, it is not necessary to adopt the two-stage reporting process recommended by the commenter. Accordingly, we decline to revise the final rule to adopt such a process.

D. Comment on Definition

(Comment 6) One comment stated that the definition of authorized generic drugs adopted in this rule has the effect of requiring the reporting of certain products (and capturing these products on the published list) that Congress did not intend to be reported as authorized generic drugs or included on a list of authorized generic drugs. The comment further stated that capturing and listing products that Congress does not consider authorized generic drugs complicates and slows the efficient and timely use of the information. The commenter urged FDA to exercise its enforcement discretion to collect information only for products that Congress considers authorized generic drugs.

(Response) The definition of authorized generic drugs we proposed is substantially identical to the definition Congress provided in section 505(t) of the act. Absent some clear indication that Congress did not intend to include in the scope of section 505(t) certain products which clearly fall within the plain language of the definition, it would be inappropriate for FDA to narrow or otherwise alter the statutory definition of authorized generic drug. FDA's mandate is to publish a complete list of authorized generic drugs as defined in section 505(t) of the act, and to update the list quarterly. Accordingly, we decline to adopt the commenter's suggestion to revise the definition of authorized generic drugs to collect information about a narrower range of products than Congress specified in the act.

IV. Legal Authority

The act, as amended by FDAAA, provides authority for FDA to issue this final rule. Section 505(t) of the act requires that FDA publish a complete list of all authorized generic drugs included in an annual report submitted to the agency after January 1, 1999, and to update that list quarterly. In addition, section 701(a) of the act (21 U.S.C. 371(a)) provides general authority for FDA to issue regulations for the efficient enforcement of the act. This final rule amends FDA's existing regulations regarding annual reports to ensure that the information necessary for the agency to fulfill its obligation under section 505(t) is clearly reported.

V. Environmental Impact

The agency has determined under 21 CFR part 25 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.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs 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). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule imposes only minimal regulatory obligations, the agency certifies that the 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 $130 million, using the most current (2007) 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.

The only costs of this final rule are associated with the Paperwork Reduction Act of 1995 (the PRA) burden, described in section VII of this document. If we assume an average hourly wage plus benefits of $56 for the reporting personnel, the annual cost is about $29,000 ($56 per hour × 520 hours).

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown with an estimate of the annual reporting and recordkeeping burden in table 1 of this document. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Applications for FDA Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

Description: This rulemaking requires the holder of an NDA to notify the agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We are taking this action as part of our implementation of FDAAA, which

requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal agencies that the list was published, and we will continue to update it.

Description of Respondents: Current holders of an NDA under which an authorized generic drug was marketed during the time period covered by an annual report submitted after January 1, 1999.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR 314.81(b)(2)(ii)(b)	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Authorized generic drug information in the first annual report submitted after the implementation of § 314.81(b)(2)(ii)(b)	60	6.7	400	1 hour	400
Authorized generic drug information submitted in each subsequent annual report	60	6.7	400	15 minutes	100
The submission of a copy of that portion of each annual report containing authorized generic drug information	60	6.7	400	3 minutes	20

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

During the past several years, FDA has been reviewing annual reports it has received under § 314.81(b)(2) to discern whether an authorized generic drug is being marketed by the NDA holder. Based on information learned from this review and based on the number of annual reports the agency currently receives under § 314.81(b)(2), we estimate that, after the implementation of § 314.81(b)(2)(ii)(b), we will receive approximately 400 annual reports containing the information required under § 314.81(b)(2)(ii)(b) for authorized generic drugs that were marketed during the time period covered by an annual report submitted after January 1, 1999. Based on the number of sponsors that currently submit all annual reports, we estimate that approximately 60 sponsors will submit these 400 annual reports with authorized generics. As indicated in table 1 of this document, we are estimating that the same number of annual reports will be submitted each subsequent year from the same number of sponsors containing the information required under § 314.81(b)(2)(ii)(b), and that the same number of copies of that portion of each annual report containing the authorized generic drug information will be submitted from the same number of sponsors. Concerning the hours per response, based on our estimate of 40 hours to prepare each annual report currently submitted under § 314.81(b)(2), we estimate that sponsors will need approximately 1 hour to prepare the information required under § 314.81(b)(2)(ii)(b) for each authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999; approximately 15 minutes to prepare the information required under § 314.81(b)(2)(ii)(b) for each subsequent annual report; and approximately 3 minutes to submit to FDA a copy of that portion of each annual report containing the authorized generic drug information.

The information collection provisions of this final rule have been submitted to the Office of Management and Budget (OMB) for review, as required by section 3507(d) of the PRA. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. 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 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 2. Section 314.3 is amended in paragraph (b) by alphabetically adding the definition for ''authorized generic drug'' to read as follows:

§ 314.3 Definitions.

* * * * *

(b) * * *

Authorized generic drug means a listed drug, as defined in this section, that has been approved under section 505(c) of the act and is marketed, sold, or distributed directly or indirectly to retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug.

* * * * *

■ 3. Section 314.81 is amended by redesignating paragraph (b)(2)(ii) as

paragraph (b)(2)(ii)(a) and by adding new paragraph (b)(2)(ii)(b) as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(b) *Authorized generic drugs.* If applicable, the date each authorized generic drug (as defined in § 314.3) entered the market, the date each authorized generic drug ceased being distributed, and the corresponding trade or brand name. Each dosage form and/or strength is a different authorized generic drug and should be listed separately. The first annual report submitted on or after January 25, 2010 must include the information listed in this paragraph for any authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999. If information is included in the annual report with respect to any authorized generic drug, a copy of that portion of the annual report must be sent to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drug Quality Assessment, Bldg. 21, rm. 2562, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, and marked ''Authorized Generic Submission'' or, by e-mail, to the Authorized Generics electronic mailbox at *AuthorizedGenerics@fda.hhs.gov* with ''Authorized Generic Submission'' indicated in the subject line. However, at such time that FDA has required that annual reports be submitted in an electronic format, the information required by this paragraph must be submitted as part of the annual report, in the electronic format specified for submission of annual reports at that time, and not as a separate submission under the preceding sentence in this paragraph.

* * * * *

Dated: April 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17963 Filed 7–27–09; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2009–0303(a); FRL–8936–2]

Approval and Promulgation of Implementation Plans; South Carolina; Transportation Conformity Memorandum of Agreement Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the South Carolina State Implementation Plan (SIP) submitted on November 28, 2008, through the South Carolina Department of Health and Environmental Control (SC DHEC). This revision consists of transportation conformity criteria and procedures related to interagency consultation and enforceability of certain transportation-related control measures and mitigation measures. The intended effect of this approval is to update the transportation conformity criteria and procedures in the South Carolina SIP.

DATES: This direct final rule is effective September 28, 2009 without further notice, unless EPA receives adverse comment by August 27, 2009. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2009–0303, by one of the following methods:

a. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

b. *E-mail: Wood.amanetta@epa.gov.*

c. *Fax:* (404) 562–9019.

d. *Mail:* EPA–R04–OAR–2009–0303, Air Quality Modeling and Transportation Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

e. *Hand Delivery or Courier:* Amanetta Wood, Air Quality Modeling and Transportation Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

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