

action is to provide adequate Class E airspace for aircraft executing the VOR/DME A SIAP at the airport.

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 10034; 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 will not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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—[AMENDED]

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996 and effective September 16, 1996, is amended as follows:

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

* * * * *

AEA NY E5 Weedsport, NY [New]

Whitfords Airport, NY

(Lat. 43°04'47"N, Long. 76°32'18"W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Whitfords Airport excluding that portion within the Syracuse, NY and Skaneateles, NY 700 foot Class E Airspace Area.

* * * * *

Issued in Jamaica, New York on October 21, 1996.

John S. Walker,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 96–28412 Filed 11–5–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 365 and 375

[Docket No. RM96–13–000]

Amendment to Filing Requirements and Ministerial Procedures for Persons Seeking Exempt Wholesale Generator Status; Order No. 591

Issued October 30, 1996.

AGENCY: Federal Energy Regulatory Commission, DOE

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is amending its regulations to provide that the Commission may, in its discretion for good cause shown, allow an applicant for exempt wholesale generator status to amend its application without paying an additional filing fee; however, the statutory sixty-day period for Commission action will be restarted on the date on which the Commission receives the amendment. The Commission believes that by allowing these applications to be amended to correct deficiencies, it will improve administrative efficiency. The Commission is also amending its regulations to delegate to the General Counsel the authority to act on uncontested amendments that do not present unusual or interpretation issues.

EFFECTIVE DATE: October 30, 1996.

FOR FURTHER INFORMATION CONTACT: Kimberly Bose, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D. C. 20426, Telephone: (202) 208–2284.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the Federal Register, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in the Commission's Public Reference Room, Room 2A, 888 First Street, N.E., Washington, D. C. 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin

board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397 if dialing locally or 1–800–856–3920 if dialing long distance. CIPS is also available through the Fed World System (by modem or Internet). To access CIPS, set your communications software to 19200, 14400, 12000, 9600, 7200, 4800, 2400 or 1200bps full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this final rule will be available on CIPS indefinitely in ASCII and WordPerfect 5.1 format for one year. The complete text on diskette in Wordperfect format may also be purchased from the Commission's copy contractor, Ladorn Systems Corporation, also located in Room 2A, 888 First Street, N.E., Washington, D. C. 20426.

Before Commissioners: Elizabeth Anne Moler, Chair; Vicky A. Bailey, James J. Hoecker, William L. Massey, and Donald F. Santa, Jr.

I. Introduction

This final rule amends 18 CFR Parts 365 and 375 to provide that the Commission may, in its discretion for good cause shown, allow an applicant for exempt wholesale generator (EWG) status to amend its application without paying an additional filing fee; however, the statutory sixty-day period for Commission action will be restarted on the date on which the Commission receives the amendment. The Commission is delegating to the General Counsel the authority to act on uncontested amendments that do not present unusual or interpretation issues.

II. Public Reporting Burden

The Commission estimates the public reporting burden for the collection of information under the final rule will remain unchanged for FERC–598, since the only modifications are to the Commission's procedures to allow an applicant for exempt wholesale generator (EWG) status to amend its application without paying an additional filing fee and to change the Commission's delegation authority.

This estimate includes the time for reviewing instructions, researching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The current annual reporting burden for the industry for the collection of information is estimated to be:

	Data collection FERC-598	Number of respondents	Number of responses	Hours per response	Total annual hours
Reporting		280	1	6	1,680

This order contains minor, technical amendments to Parts 365 and 375 of the regulations. The amendments are intended to allow an applicant for EWG status to amend its application without paying an additional filing fee. Therefore, these amendments will not have a significant impact on the estimated reporting burden that is submitted by the Commission to OMB.

For copies of the OMB submission contact Michael Miller, Information Policy and Standards Branch, at (202) 208-1415. Comments on the requirements of this order should be directed to the Desk Officer for the Federal Energy Regulatory Commission, Office of Management and Budget, Room 3019NEOB, Washington, D.C. 20503, phone 202-395-3087, facsimile: 202-395-7285 or via the Internet at hillier_t@a;1/eop.gov. A copy of any comments filed with the Office of Management and Budget and comments regarding this burden estimate, or any other aspect of this collection of information, including suggestions for reducing this burden should also be sent to the following address at the Commission: Federal Energy Regulatory Commission, Information Services, Room 41-17, 888 First Street, N.E., Washington, D.C. 20426, (Attention: Michael Miller, Information Services Division, 202-208-1415), and to the Office of Information and Regulatory Affairs of the Office of Management and Budget (Attention: Desk Officer for the Federal Energy Regulatory Commission), FAX: (202) 395-7285, phone: (202) 395-3087.

III. Background

Section 32 of the Public Utility Holding Company Act of 1935 (PUHCA), as amended by the Energy Policy Act,¹ created a new category of entities known as EWGs that are exempt from regulation under PUHCA.² It requires that applicants for EWG status file applications for determination of their status by the Commission. An applicant that has applied in good faith for such a determination is deemed to be an EWG pending the Commission's determination. The Commission is required to render its determination

within 60 days of the receipt of an application.

The Commission's regulations (EWG Rules) set forth filing requirements and ministerial procedures for EWG applications.³ They provide that any person seeking EWG status must file a sworn statement containing certain information.⁴ The Commission publishes notices of filing of EWG applications in the Federal Register and permits comments or interventions.⁵

In adopting the EWG Rules, we stated that we will not issue deficiency letters,⁶ reasoning that the absolute sixty-day deadline for Commission action does not leave adequate time for review of deficiency responses.⁷ For the same reason, the Commission stated that it would not allow amendments to filings.⁸ The order on rehearing affirmed this decision, noting that the EWG filing requirements, which follow the requirements of section 32(a)(1) of PUHCA, are simple and straightforward.⁹

IV. Discussion

Since the Commission issued the EWG Rules, we have received applications that, for various reasons, did not meet the requirements set forth in 18 CFR 365.3. Some of these deficiencies have been extremely minor

³ 18 CFR Part 365.

⁴ The information required is: (1) A representation that the applicant is engaged directly, or indirectly through one or more affiliates as defined in section 2(a)(1)(B) of PUHCA, and exclusively in the business of owning or operating, or both owning and operating, all or part of one or more eligible facilities and selling electric energy at wholesale; (2) any exceptions for foreign sales of power at retail; (3) a brief description of the facility or facilities that are or will be eligible facilities and related transmission interconnection components; (4) any lease arrangements involving the facility and any public utility companies; (5) any electric utility company that is an affiliate or associate company of the applicant; and (6) any State commission determinations required by sections 32(c) and (d)(2) of PUHCA.

⁵ See 18 CFR 365.4.

⁶ Filing Requirements and Ministerial Procedures for Persons Seeking Exempt Wholesale Generator Status, Order No. 550, 58 FR 8897 (February 18, 1993) (as corrected at 58 FR 11886 (March 1, 1993)), FERC Stats. & Regs. Regulations Preambles (1991-1996) ¶ 30,964 at 30,778 (Order No. 550).

⁷ Id.

⁸ Id. n. 30.

⁹ Filing Requirements and Ministerial Procedures for Persons Seeking Exempt Wholesale Generator Status, Order No. 550-A, FERC Stats. & Regs., Regulations Preambles (1991-1996) ¶ 30,969 at 30,839-40 (1993).

or have been the result of drafting errors. In the past, when Commission staff has identified problems with an application that it believed would cause the application to be disapproved, Commission staff has telephoned the applicant to tell them of the problems. The applicant has generally chosen to withdraw the application and file a new one. This has meant that those applicants who will not be public utilities have had to pay new filing fees.¹⁰ This approach has proven to be costly to the applicants and cumbersome for the Commission.

Based on this experience, we have decided to revise the EWG Rules to provide that we may, in our discretion for good cause shown, allow applicants to amend their applications¹¹ without paying a new filing fee.¹² We will issue a notice of the filing of such an amendment in the Federal Register allowing interventions and/or comments. Filing of the amendment will restart the statutory sixty-day approval period.¹³

The General Counsel has delegated authority to grant certain EWG applications and to act on uncontested motions to withdraw such applications.¹⁴ Accordingly, we will delegate to the General Counsel similar authority to act on uncontested amendments to applications that do not present unusual or interpretation issues. The notice of the amendment in the Federal Register will serve as notification that the amendment has been accepted.

¹⁰ Order No. 550 created a separate filing fee category for EWGs that will not become public utilities upon the sale of electric energy at wholesale. This would include foreign EWGs, EWGs owning only eligible facilities located and selling wholly within the Electric Reliability Council of Texas, in Hawaii, in Alaska, in Puerto Rico, etc. FERC Stats. & Regs. Regulations Preambles (1991-1996) at 30,773.

¹¹ The Commission would not expect to accept an amendment if the result of such action is to effectively result in a new proposal.

¹² When the Commission does allow an amendment to a deficient application, the amended filing will receive the same docket number that the Commission assigned to the original application.

¹³ See 18 CFR 365.5.

¹⁴ Delegation of Authority to the Secretary, the Director of the Office of Electric Power Regulation and the General Counsel, 60 FR 62326 (Dec. 6, 1995).

¹ 15 U.S.C. 79z-5a (West Supp. 1994).

² Pub. L. 102-486, 106 Stat. 2776 (1992).

V. Environmental Statement

Commission regulations require that an environmental assessment or an environmental impact statement be prepared for any Commission action that may have a significant adverse effect on the human environment.¹⁵ The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment.¹⁶ No environmental consideration is necessary for the promulgation of a rule that is clarifying, corrective, or procedural.¹⁷ As explained below, this final rule is procedural in nature. Accordingly, no environmental statement is necessary.

VII. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act¹⁸ requires rulemakings either to contain a description and analysis of the impact the rule will have on small entities or a certification that the rule will not have a substantial economic impact on a substantial number of small entities. This final rule is procedural and ministerial in nature and will not add any burdens to any entities. Rather, it will make it easier and quicker for entities, including small entities, to receive approval for their applications. Therefore, the Commission certifies that promulgating this rule will not have a significant economic impact on a substantial number of small entities.

VIII. Information Collection Statement

Office of Management and Budget (OMB) regulations require OMB to approve certain information collection requirements imposed by an agency.¹⁹ The information collection requirements in the final rule are contained in FERC-598.

Title: FERC-598, Determinations for Entities Seeking EWG Status.

Action: Final Rule.

OMB Control No: 1902-0166

(Respondents shall not be penalized for failure to respond to this collection of information unless the collection of information displays a valid OMB control number.)

Respondents: Business or other for profit, including small businesses. Section 711 of the Energy Policy Act of 1992 (P.L. 102-46) amended the Public

Utility Holding Company Act of 1935 (PUHCA) to create a category of power producers known as EWGs. An applicant is an EWG when it files an application demonstrating that it is engaged directly, or indirectly through one or more affiliates as defined in the PUHCA section 2(a)(11)(B), and exclusively in the business of owning and/or operating all or part of one or more eligible facilities, and selling electricity at wholesale.

Frequency of Responses: On occasion.

Necessity of Information: This final rule amends Parts 365 and 375 of the Commission's regulations to provide that the Commission may, in its discretion for good cause shown, allow EWG applicants to amend their applications without paying new filing fees. The Commission believes that allowing these applications to be amended will improve administrative efficiency and will be less burdensome to applicants. The information is collected by the Commission in the form of a written application for determination of status as an EWG. The Commission uses the data to make a determination as to whether the applicant meets the statutory requirements for EWG status.

The Final Rule will not change the reporting requirements of FERC-598. This final rule amends Parts 365 and 375 of the Commission's regulations to allow an applicant for EWG status to amend its application without paying additional filing fee. The Commission believes that by allowing these applications to be amended to correct deficiencies, it will improve administrative efficiency. This rule therefore is not subject to OMB review. The Commission is submitting a copy of the proposed rule to OMB for information purposes only.

Interested persons may obtain information on or submit comments concerning the reporting requirements by contacting the Federal Energy Regulatory Commission, 888 First Street, N.E. Washington, D.C. 20426 [Attention: Michael Miller, Information Service Division, (202)208-1415], and to the Office of Management and Budget [Attention: Desk Officer for the Energy Regulatory Commission (202)396-3087.]

IX. Administrative Findings and Effective Date

The Administrative Procedure Act (APA)²⁰ requires rulemakings to be published in the Federal Register. The APA also mandates that an opportunity for comments be provided when an agency promulgates regulations.

However, notice and comment are not required under the APA when the agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.²¹ The Commission finds that notice and comment are unnecessary for this rulemaking. As explained above, this final rule is procedural and ministerial in nature. The Commission is merely amending its rules to improve the efficiency with which certain routine items are processed. We therefore find good cause to make this rule effective immediately upon issuance.

X. Congressional Notification

The Small Business Regulatory Enforcement Fairness Act of 1996 requires agencies to report to Congress on the promulgation of certain final rules prior to their effective dates.²² That reporting requirement does not apply to this final rule because it falls within a statutory exception for rules relating to agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.²³

List of Subjects

18 CFR Part 365

Exempt wholesale generators.

18 CFR Part 375

Authority delegations (Government agencies), Electric power rates, Electric utilities, Reporting and recordkeeping requirements.

By the Commission.

Lois D. Cashell,

Secretary.

In consideration of the foregoing, the Commission amends Parts 365 and 375, Chapter I, Title 18, Code of Federal Regulations, as set forth below.

PART 365—FILING REQUIREMENTS AND MINISTERIAL PROCEDURES FOR PERSONS SEEKING EXEMPT WHOLESALE GENERATOR STATUS

1. The authority citation for Part 365 continues to read as follows:

Authority: 15 U.S.C. 79.

2. Part 365 is amended by revising § 365.2(b)(2), by redesignating § 365.5 as § 365.6, § 365.6 as § 365.7, and § 365.7 as § 365.8, and by adding § 365.5.

§ 365.2 Definitions.

(b) * * *

²¹ 5 U.S.C. 553(B).

²² Pub. L. 104-121, 110 Stat. 847 (1996).

²³ Pub. L. 104-121, 110 Stat. 847, 804(3)(C) (1996).

¹⁵ Regulations Implementing the National Environmental Policy Act, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles (1986-1990) ¶ 30,783 (1987) (codified at 18 CFR Part 380).

¹⁶ 18 CFR 380.4.

¹⁷ 18 CFR 380.4(a)(2)(ii).

¹⁸ 5 U.S.C. 601-612.

¹⁹ 5 CFR 1320.12.

²⁰ 5 U.S.C. 551-559.

(2) *Receipt of an application* means the date on which the Commission receives the application or an amendment allowed for good cause shown and the applicable filing fee, if any; and

* * * * *

§ 365.5 Amendment of Applications.

The Commission will allow amendments of applications for good cause shown without payment of additional filing fees. If the amendment is accepted, notice of the amended application will be published in the Federal Register, with further opportunity for comments.

PART 375—THE COMMISSION

1. The authority citation for part 375 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352.

2. In § 375.309, paragraph (g) is revised to read as follows:

§ 375.309 Delegations to the General Counsel.

* * * * *

(g) Grant uncontested applications for exempt wholesale generator status that do not involve unusual or interpretation issues; to act on uncontested motions to withdraw such applications; and to act on uncontested amendments to applications for EWG status that do not present unusual or interpretation issues.

[FR Doc. 96–28476 Filed 11–5–96; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 95N–0295]

Prominence of Name of Distributor of Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the labeling regulations for biological products to remove the requirement that the manufacturer's name be more prominent than that of the distributor and to permit the names of distributors to be prominently displayed on biological product container labels, package labels, and labeling. This change in labeling requirements is

intended to facilitate flexible manufacturing, packaging, distribution, and labeling arrangements, and to harmonize labeling regulations applicable to biologic products licensed under the Public Health Service Act (the PHS Act) with the corresponding labeling regulations for drugs approved under the Federal Food, Drug, and Cosmetic Act (the act).

EFFECTIVE DATE: November 18, 1996.

FOR FURTHER INFORMATION CONTACT:

Gloria J. Hicks, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the Federal Register of September 27, 1995 (60 FR 49811), FDA published a proposed rule to amend the labeling regulations to remove the requirement that the manufacturer's name be more prominent than the distributor's and to permit the names of distributors to be prominently displayed on licensed biological product container labels, package labels, and labeling. This final rule is being issued in accordance with the principles set forth in Executive Order 12866 and the Regulatory Reinvention Initiative announced in President Clinton's memorandum of March 4, 1995. Executive Order 12866 directs Federal agencies and the Office of Information and Regulatory Affairs to implement measures that will reform and streamline the regulatory process. As part of the Regulatory Reinvention Initiative, a report entitled "Reinventing Drug and Medical Device Regulations" was issued in April 1995 by the President and Vice President. This final rule completes a commitment made by FDA in that report to permit greater flexibility in the appearance of distributors' names on biological product container labeling, package labels, and labeling.

Under Executive Order 12866, FDA published a notice in the Federal Register of January 20, 1994 (59 FR 3043), announcing FDA's plan to review and evaluate all significant regulations for their effectiveness in achieving public health goals and in order to reduce or eliminate unnecessary regulatory burden. In the Federal Register of June 3, 1994 (59 FR 28821 and 28822, respectively), FDA published two notices announcing the review and evaluation of certain biologic and blood and blood product regulations by the Center for Biologics Evaluation and Research (CBER). The intent of the review and evaluation was

to identify those regulations that are outdated, burdensome, inefficient, duplicative, or otherwise unsuitable or unnecessary. Interested persons were given until August 17, 1994, to respond to the notices by submitting written comments to the Dockets Management Branch. In the Federal Register of August 17, 1994 (59 FR 42193), FDA extended the comment periods to November 15, 1994, in response to requests to allow for additional time for public comment. In the Federal Register of November 14, 1994 (59 FR 56448), FDA extended the comment periods to February 13, 1995, in response to requests to hold a public meeting regarding the biologics regulations under review.

FDA held a public meeting on January 26, 1995, that was announced in the Federal Register of January 9, 1995 (60 FR 2351). The notice of public meeting indicated that the public comment period was to close on February 13, 1995. The public meeting was a forum for the public to voice their comments regarding the review and evaluation of regulations being undertaken by CBER.

Some of the comments from the docket and public meeting questioned the need for the manufacturer's name to be the most prominent name on the label of a licensed biological product. FDA's regulation addressing the name of the selling agent or distributor on biological product labeling (§ 610.64 (21 CFR 610.64)) required that the name of the manufacturer of the biological product be more prominently displayed on the label than the name of the selling agent or distributor. These comments requested that CBER consider revising the labeling regulations so that developers of innovative new products could place their names prominently on the label, even if they contract out the manufacturing of the product. In response to the comments, FDA published a proposed rule (60 FR 49811) to amend the labeling regulations to permit the names of distributors to be prominently displayed on biological product container labels, package labels, and labeling.

II. Highlights of the Final Rule

The final rule is intended to facilitate flexible manufacturing, packaging, distribution, and labeling arrangements. FDA recognizes that small innovator firms may not have the facilities to manufacture commercial quantities of a biological product. Such innovator firms that do not hold the license for the product will no longer be required to feature the license holder's name more prominently on the label. Manufacturers and distributors will have the option to