

DEPARTMENT OF ENERGY

Federal Energy Regulatory
Commission

18 CFR Part 385

[Docket No. RM98-13-002; Order No. 602-B]

Complaint Procedures

Issued September 29, 1999.

AGENCY: Federal Energy Regulatory
Commission.

ACTION: Order on rehearing.

SUMMARY: On July 28, 1999, the Commission issued Order No. 602-A, an order on rehearing and clarification of its final rule revising the Commission's complaint procedures (Order No. 602). On August 27, 1999, a request for rehearing of Order No. 602-A was filed. The petitioners are concerned that removal of references to "preliminary" and "interim" relief would somehow preclude a complainant from seeking what it characterizes as "immediate" or "early" Commission action. The order denies rehearing but clarifies that under the complaint regulations a potential complainant may request "immediate" action on the merits of its claims and that any complaint in which time is of the essence could be filed under the Fast Track procedure in § 385.206(h).

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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 Public Reference Room at 888 First Street, NE, Room 2A, Washington, DC 20426.

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On July 28, 1999, the Commission issued Order No. 602-A,¹ an order on rehearing and clarification of its final rule revising the Commission's complaint procedures (Order No. 602).² A request for rehearing has been filed urging the Commission to add the phrase "immediate remedial action" to the regulations to replace the references to preliminary relief that were deleted by Order No. 602-A.

Order No. 602 revised the Commission's regulations governing complaints filed under the Federal Power Act, the Natural Gas Act, the Natural Gas Policy Act, the Public Utility Regulatory Policies Act of 1978, the Interstate Commerce Act, and the Outer Continental Shelf Lands Act. Among other things, Order No. 602 provided that a complaint could include a request for preliminary relief pending a final merits decision on the complaint itself. The order stated that the standard for granting affirmative preliminary relief would be that employed by the courts for such relief: (1) likelihood of success on the merits; (2) whether irreparable injury to the complainant will occur if the relief is not granted; (3) whether the injury outweighs harm to the respondent or other parties if the relief is granted; and (4) other public interest considerations.³

In Order No. 602-A, responding to rehearing requests, the Commission eliminated the preliminary relief procedure and clarified what types of relief the Commission may provide under the complaint rule. The Commission made it clear that it would act only where it has authority under the various statutes administered by the Commission. The Commission acknowledged that use of certain

terminology in the final rule may have led to confusion and concern on the part of many parties. The Commission eliminated all references to preliminary relief other than stays or extensions of time in the complaint regulations. In addition, the standards in § 385.206 (b)(7)(i) through (iv), which were based on *Virginia Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921 (D.C. Cir. 1958), were deleted. These changes were designed to eliminate certain parties' concern that the Commission was attempting to establish procedures for granting relief akin to preliminary injunctions under standards different than those specified in the statutes administered by the Commission.

The Commission stated that there may be cases in which it could issue what could be categorized as an "interim" or "preliminary" order in a complaint proceeding pursuant to existing authorities. For example, the Commission stated that a complainant may assert that a respondent's conduct is so egregious or the evidence is so substantial supporting its case that the Commission needs to take some immediate action. A complainant could indicate that its evidence is so substantial as to establish a *prima facie* case of a violation of the relevant statutory standard or regulatory requirement. The Commission stated that if the Commission were to find the complainant's case compelling based upon substantial evidence, the Commission *sua sponte* could issue a show cause or declaratory order based on the facts known at that time prior to the answer being filed. The respondent would then be directed to address the requirements of the order rather than file an answer. The Commission stated that this type of relief may be appropriate in certain limited circumstances and is within the Commission's authority to grant. Further, the Commission stated that it could also take such other "interim" or "preliminary" actions, as it can now, such as issuing an order granting a stay or an order granting an extension of time, stop work order, or other orders contemplated by certificate or hydroelectric licensing conditions. Finally, the Commission stated that a complainant may request forms of relief which it believes is within the Commission's authority to grant and the Commission will decide whether the relief may be granted on a case-by-case basis.

On August 27, 1999, a request for rehearing of Order No. 602-A was filed by Undersigned Parties (hereinafter

¹ 64 FR 43600 (August 11, 1999), FERC Stats. & Regs. ¶ 31,076 (1999).

² 64 FR 17087 (April 8, 1999), FERC Stats. & Regs. ¶ 31,071 (1999).

³ *Virginia Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir. 1958).

referred to as the Petitioners).⁴ The Petitioners assert that a complainant's right to some form of prompt or immediate Commission remedy is essential in a complaint procedure responsive to the needs of the restructured gas and electric power industries. The Petitioners submit that some form of Commission remedial action as soon as possible after the filing of a formal complaint must be available. The Petitioners contend that to suggest that such remedies might be within the Commission's authority to grant while removing from the Commission's new and comprehensive complaint regulations any reference to such remedies, creates ambiguity about whether the Commission truly intends to make early remedial action a component of its revised complaint procedure. The Petitioners argue that where, as here, the Commission is adopting a comprehensive new complaint procedure, it should include therein some codification of each element of its new complaint policy.

The Commission finds it unnecessary to modify the regulations as requested because they already encompass the kind of relief sought. In the Commission's view, there is a difference between preliminary and interim relief on the one hand, and what the Petitioners refer to as "immediate" or "early" Commission action on complaints on the other hand. References to preliminary and interim relief, as well as the use of the *Virginia Jobbers* standards, led many parties to believe that the Commission would be granting relief akin to temporary restraining orders or preliminary injunctions, and that such relief would be based on standards other than those contained in the applicable statutes. Order No. 602-A eliminated such references to make clear that the Commission would not and could not exercise any authority beyond its statutory authority.

The elimination of the references to preliminary and interim relief does not mean that the Commission lacks the authority to address complaints quickly. The Petitioners have recognized that the Commission may issue an interim order, which resolves some issues while leaving others to be determined at a later time, that is based on findings made pursuant to the standards contained in NGA section 5 or FPA

section 206. Moreover, as recognized in Order No. 602-A, the Commission could also take such interim actions as granting a stay, granting an extension of time, issuing stop work orders or others orders contemplated by certificate or hydroelectric license conditions, or issuing show cause orders. Other actions, such as issuing show cause or declaratory orders, while not final action, also convey a message to the parties that in the Commission's view a complainant has presented a solid case for the relief sought that will be granted in the absence of convincing evidence to the contrary.

The Commission recognizes that timely redress of a complaint is essential in today's constantly evolving energy markets. In Order No. 602, the Commission introduced the Fast Track procedures precisely for this reason. Because the Commission realizes that time is of the essence in many complaint proceedings, it committed to issuing merits order on Fast Track complaints within 20 days after the answer is filed.⁵ The Commission also stated that if the development of a factual record was necessary to the resolution of a complaint, hearing procedures could be compressed into a few days.

The Petitioners request for rehearing essentially deals with the timing of Commission action, hence their use of the words "prompt," "immediate" and "early." In the Commission's view, the Petitioners' concerns can be adequately addressed under the regulations adopted because any complaint in which time is of the essence can be filed under the Fast Track procedure in § 385.206(h). A party filing such a complaint can show that the standard complaint resolution process may not provide timely relief as quickly as circumstances may demand and that expedited resolution under the Fast Track is thus appropriate. In resolving the merits of a complaint, whether under the Fast Track or standard procedures, the Commission must apply the standards contained in the statutes it administers. The Commission thus can reach a final resolution under its governing statutes through standard procedures or using expedited processing.

The modifications contained in Order No. 602-A were not meant to suggest that complaints could only be resolved through a lengthy administrative

hearing. As § 385.206(h)(1) states, "Fast Track procedures may include expedited action on the pleadings by the Commission, expedited hearing before an ALJ, or expedited action on requests for stay, extension of time, or other relief by the Commission or an ALJ." The revised complaint regulations do not prevent a potential complainant from requesting "immediate" action on the merits of its claims, but rather, are specifically designed to address particular situations that demand the immediate resolution requested by the Petitioners. The Petitioners' concerns thus already have been taken into account and incorporated into the regulations to provide for the prompt and immediate resolution they seek.

List of Subjects in 18 CFR Part 385

Administrative practice and procedure, Electric power, Penalties, Pipelines, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission denies rehearing.

By the Commission.

David P. Boergers,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

RIN 0910-AA89

[Docket No. 98N-0237]

New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its new drug and biological product regulations to identify the information needed to provide substantial evidence of the efficacy of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances. This proposal would apply when the traditional efficacy studies in humans are not feasible and cannot be ethically

⁴ The Undersigned Parties consist of the Pipeline Customer Coalition, American Public Power Association, Transmission Access Policy Study Group, National Rural Electric Cooperative Association, Pennsylvania Office of Consumer Advocate, and Transmission Dependent Utility Systems.

⁵ See, for example, *North American Energy Conservation, Inc. v. CNG Transmission Corporation*, 88 FERC ¶ 61255 (1999), where the answer to the complaint was filed on September 3, 1999, and the order on the merits of the complaint was issued September 17, 1999.