

paragraphs (a) and (c) of this section, will be used.

(2) The term "primary capital" includes: common stock, preferred stock, capital surplus, undivided profits, reserves for contingencies and other capital reserves (excluding accrued dividends on preferred stock and limited life preferred stock), net worth certificates issued by the Federal Deposit Insurance Corporation, mandatory convertible instrument, and allowances for possible loan and lease losses.

(3) The term "secondary capital" includes both limited life preferred stock and subordinated notes and debentures to the extent set forth in paragraphs (f)(2) and (f)(3) of this section.

(4) The OCC expressly reserves the authority, in exigent circumstances, to waive the minimum maturity and amortization requirements and the restriction of Secondary Components to an amount no greater than fifty percent (50%) of the total of the Primary Components set forth above for the inclusion of limited life preferred stock and subordinated notes and debentures in the capital base of any national bank for capital adequacy purposes. The OCC further expressly reserves the authority, in exigent circumstances, to impose more stringent conditions than those set forth in this Interpretive Ruling in order for limited life preferred stock and subordinated notes or debentures to be included, in whole or in part, as part of a national banking association's capital bases for capital adequacy purposes.

#### § 7.7545 [Removed]

3. By removing 7.7545.

Dated: November 22, 1983.

C. T. Conover,

Comptroller of the Currency.

[FR Doc. 83-33806 Filed 12-20-83; 8:45 am]

BILLING CODE 4810-33-M

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### 15 CFR Part 369

#### Restrictive Trade Practices or Boycotts

AGENCY: International Trade Administration, Commerce.

ACTION: Interpretation.

SUMMARY: The Department is clarifying the application of its antiboycott

regulations (15 CFR Part 369) to situations involving the reportability of the receipt of an unsolicited invitation to bid or similar proposal that contains a reportable boycott term or condition if the person receiving the invitation does not respond.

EFFECTIVE DATE: December 20, 1983.

FOR FURTHER INFORMATION CONTACT: Paulette J. Moore, Compliance Policy Division, Office of Antiboycott Compliance, U.S. Department of Commerce (202/377-4550).

SUPPLEMENTARY INFORMATION: Section 369.6(a)(4) of the Regulations provides that receipt of an unsolicited invitation to bid or similar proposal that contains a reportable boycott term or condition need not be reported if the person receiving the invitation does not respond. During the past five years, the Office of Antiboycott Compliance has received numerous inquiries about the precise definition of "unsolicited" and whether any kind of "response," including a simple acknowledgment, will cause the invitation to be reportable. The Department has determined that it is appropriate at this time to provide to the general public its views on these questions in the form of an interpretation.

#### List of Subjects in 15 CFR Part 369

Boycotts, Foreign trade, Reporting requirements, Restrictive trade practices, Trade practices.

#### Interpretation

The principal author of this interpretation is Howard N. Fenton, Director Compliance Policy Division, Office of Antiboycott Compliance.

#### PART 369—[AMENDED]

The following Supplement 11 is added to Part 369 as follows:

#### Supplement 11—Interpretation

Definition of unsolicited invitation to bid.

Section 369.6(a)(4) states in part: In addition, a United States person who receives an unsolicited invitation to bid, a similar proposal, containing a boycott request has not received a reportable request for purposes of this section where he does not respond to the invitation to bid or other proposal.

The regulations do not define "unsolicited" in this context. Based on review of numerous situations, the Department has developed certain criteria that it applies in determining if

an invitation to bid or other proposal received by a U.S. person is in fact unsolicited.

1. The invitation is not unsolicited if, during a commercially reasonable period of time preceding the issuance of the invitation, a representative of the U.S. person contacted the company or agency involved for the purpose of promoting business on behalf of the company.

2. The invitation is not unsolicited if the U.S. person has advertised the product or line of products that are the subject of the invitation in periodicals or publications that ordinarily circulate to the country issuing the invitation during a commercially reasonable period of time preceding the issuance of the invitation.

3. The invitation is not unsolicited if the U.S. person has sold the same or similar products to the company or agency issuing the invitation within a commercially reasonable period of time before the issuance of the current invitation.

4. The invitation is not unsolicited if the U.S. person has participated in a trade mission to or trade fair in the country issuing the invitation within a commercially reasonable period of time before the issuance of the invitation.

Under § 369.6(a)(4), the invitation is regarded as not reportable if the U.S. person receiving it does not respond. The Department has determined that a simple acknowledgment of the invitation does not constitute a response for purposes of this rule. However, an acknowledgment that requests inclusion for future invitations will be considered a response, and a report is required.

Where the person in receipt of an invitation containing a boycott term or condition is undecided about a response by the time a report would be required to be filed under the regulations, it is the Department's view that the person must file a report as called for in the regulations. The person filing the report may indicate at the time of filing that he has not made a decision on the boycott request but must file a supplemental report as called for in the regulations at the time a decision is made [369.6(a)(6)].

Dated: December 16, 1983.

William B. Skidmore,  
Director, Office of Antiboycott Compliance.

[FR Doc. 83-33780 Filed 12-18-83; 1:13 pm]

BILLING CODE 3510-05-M

## DEPARTMENT OF ENERGY

Federal Energy Regulatory  
Commission

## 18 CFR Part 300

(Docket No. RM82-6-000)

Confirmation and Approval of the  
Rates of the Bonneville Power  
Administration

Issued December 15, 1983.

AGENCY: Federal Energy Regulatory  
Commission, DOE.ACTION: Order on reconsideration and  
response to comments on final rule.

**SUMMARY:** The Federal Energy Regulatory Commission is issuing an order granting in part and denying in part a petition for reconsideration and responding to comments filed on the final rule establishing procedures for the interim and final approval of rates submitted by the Bonneville Power Administration under section 7 of the Pacific Northwest Electric Power Planning and Conservation Act.

**DATE:** The amendments in this rule are effective January 20, 1984.

**FOR FURTHER INFORMATION CONTACT:** Kenneth J. Malloy, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, (202) 357-8033.

**SUPPLEMENTARY INFORMATION:** The Federal Energy Regulatory Commission (Commission) is granting in part and denying in part a petition for reconsideration of a final rule which established procedures for the interim and final approval of rates submitted by the Bonneville Power Administration (BPA) under section 7 of the Pacific Northwest Electric Power Planning and Conservation Act (Northwest Power Act or Act), 16 U.S.C. 839-839h (1982). In addition to denying a petition for reconsideration, the Commission is also responding to comments filed after the promulgation of its final rule.

## I. Background

The Northwest Power Act establishes a rate scheme in which responsibility for determining the rates that BPA will charge for power is shared by the BPA Administrator and the Commission. The Administrator establishes rates for sales to various customers both within and outside the Pacific Northwest region after extensive procedures detailed in the Act, 16 U.S.C. 839e(i)(1)-(5) (1982). The Administrator files these rates with the Commission which must confirm and approve them before they become effective. The Act authorizes the Commission to approve the rates

submitted by the Administrator on an interim basis.

On December 4, 1981, the Commission issued an interim rule governing interim approval of BPA rates, 46 FR 60813 (1981). The rule detailed the procedures for filing an interim rate, the information that must be filed, which included support for the proposed revenue level, six schedules, and standards to be used by the Commission in reviewing the request for interim rate approval.

On August 9, 1983, the Commission issued a final rule (18 CFR Part 300) governing both interim and final approval of the rates filed by BPA, 48 FR 37006 (August 16, 1983). The Commission's final rule substantially reflects the interim rule. Subpart A of the new regulation establishes the applicability of the part and various definitions in both the Northwest Power Act and the regulations. Subpart B contains the filing requirements. These filing requirements included the contents of the Administrator's Record of Decision, the Administrative Record, various statements, and analyses of the filed data. Subpart C establishes the procedures that the Commission adopted for both interim and final confirmation and approval, including public participation requirements, the standards of review, and the range of action open to the Commission when reviewing the rates.

The interim rule provides the filing requirements and the Commission's procedures for granting approval of rates on an interim basis. However, in addition to dealing with interim rate approval, the new § 300.21 also sets forth the procedures that will be used by the Commission to approve BPA's rates on a final basis. These new regulations establish the procedures and timing for final Commission action, although the requirements and standards for filing and reviewing the various rates of participants were already contained in the interim rule.

The Commission provided an opportunity for interested persons to comment on those aspects of the final rule that were being included for the first time. The Commission received a petition for reconsideration of the final rule by Southern California Edison Company (SoCal). In addition, the Commission received comments from the Bonneville Power Administration (BPA), Direct Service Industrials (DSI's), San Diego Gas & Electric (San Diego), Columbia River Inter-Tribal Fish Commission (CRITFC).

II. Discussion of Issues Raised by  
Commenters

## A. Interim Approval Issues

The final rule required that BPA file its revised rates and its request for interim and final approval with the Commission sixty days prior to the proposed effective date. After BPA files its request for interim approval, the final rule requires that the Commission give interested persons an opportunity to comment on the request for interim approval. The Commission then decides whether to grant interim approval to the application prior to the proposed effective date of BPA's rates, subject to final confirmation and approval.

The DSI's requested that the Commission limit its interim approval of BPA's rate to a reasonable period of no more than one year. The DSI's noted that under the present practice, interim rates can be in place indefinitely. Because of the prohibition against retroactive increases in rates, if Commission review is not completed early in the rate period, the DSI's believe it is impossible to give relief to aggrieved ratepayers and at the same time redevelop rates that will cover sufficient revenues to repay the treasury. The DSI's believe, therefore, that it is imperative that Commission review take place as quickly as possible so that parties can, if still dissatisfied, obtain rapid judicial review of those rates.

In a similar vein, the CRITFC requests that final approval of BPA's rates take place no more than 90 days after interim approval is granted. One of the main concerns of the CRITFC is a prompt implementation of fish and wildlife program measures, many of which are required to be funded by BPA under the Northwest Power Act, 16 U.S.C. 839b(H)(11)(a)(i)(1982). Unlike the protection afforded to regional utilities, the CRITFC believes that fish and wildlife interests are not protected by the refund provisions of the regulations. It advocates revenue levels high enough to fund protection, mitigation, and enhancement of fish and wildlife. This position is inherently different from the predominant position of BPA's customers, who argue that their rates should be kept lower. To rectify this problem, the CRITFC recommends that the Commission take final action on BPA's rates within 90 days of the grant of interim approval.

Although the Commission recognizes that prolonged use of interim rates could result in inappropriate revenue collections, it declines to implement either of these recommendations. The

Commission believes that it should retain flexibility when reviewing rates. In some instances, it may not be reasonably possible to complete the review of BPA's rates within a 90-day or even a one year period. The Commission acknowledges that, in the past, there have been lengthy delays in the review of BPA's rates for final confirmation and approval. The Commission is cognizant of this fact and sensitive to the need to review these rates on a more expeditious basis. The Commission does not believe, however, that it should adopt restrictive measures since it may not be possible to provide reasonable or adequate review of rates within such constraints.

Commenters raise a second interim rate issue. Under the interim rule, the Director of the Commission's Office of Electric Power Regulation was authorized to notify BPA of any non-compliance in its filing and request for interim approval. BPA was allowed 30 days to cure this deficiency prior to Commission action on the request for interim approval. To allow BPA more flexibility in filing its rates, the Commission's final rule reduced from 90 to 60 days the time BPA's filing must precede a proposed effective date. Because of this change, the Commission acknowledged that there is not sufficient time both for staff to ascertain whether there are any defects in the filing and for BPA to cure these defects within the interim review period. Accordingly, under the final rule, BPA's filing must either be rejected because it was patently deficient or accepted subject to the condition that BPA cure any non-compliance after the rate becomes effective on an interim basis. Despite the CRITFC's comments that the Commission should require that BPA cure defects in its filing prior to the grant of interim approval, the Commission still believes its approach is both efficient and protective of the interests affected. If BPA's filing contains any major and potentially significant defects, the Commission would consider rejecting the filing outright and requiring that BPA file a new rate application.

#### B. Section 7(k) and Other "Hearing" Issues

The Northwest Power Act differentiates between procedures and standards of review under section 7(k) for reviewing rates for non-firm power sold outside the region, but within the United States (nonregional rates) and rates for all other power sold by BPA (regional rates) under section 7(a).

Some commenters believe that the Commission should review a section 7(k) rate *de novo*, that is, as if it were an

initial rate filing than had not been reviewed by another decisional authority. Others believe the Commission's role to be more limited and appellate in nature. Still other commenters request that the Commission amend its final rule to limit its section 7(k) review to only the consideration of matters not litigated in BPA's proceedings.

While the Commission has made clear that its role is appellate in nature when reviewing regional rates,<sup>1</sup> its function relative to non-regional rates is less clear. Thus far, the Commission has not delineated the exact scope of its role under that section. Accordingly, the final rule is silent on this issue, as is the statute, neither has the Commission taken a position on whether under section 7(k) should be limited to consideration of new matter.

The Commission does not believe that it is necessary to resolve these issues in the context of this particular rulemaking. It will either resolve those issues on a case-by-case basis, as particular facts under section 7(k) are presented to the Commission, or in the context of a new rulemaking, if experience demonstrates that generic resolution of the problem will more efficiently promote the Commission's consideration of these difficult and complex problems.

Section 7(k) of the Act states that any hearing held under that section shall be held "in accordance with the procedures established for ratemaking by the Commission pursuant to the Federal Power Act." SoCal filed a petition for reconsideration claiming that the Commission's final rule ignored this requirement of section 7(k). SoCal's petition acknowledges that, for the most part, the Commission's regulations relating to section 7(k) do not address the issue of whether the Federal Power Act hearing procedures would be used. SoCal argues, for example, that, under the Federal Power Act, a utility is required to file its data in a form consistent with the Commission's Uniform System of Accounts (18 CFR Part 101 (1983)) and that a filing utility is required to submit its case-in-chief with its initial filing. (18 CFR 35.13(e)(2) (1983)). SoCal states that the Commission's rule under section 7(k) does not contain a requirement that these regulations be followed.

Finally, SoCal focuses on the statement in the final rule in which the Commission adopted its general Rules of Practice and Procedure, except as they related to *ex parte*

communications. (18 CFR 300.1(a) (1983)). SoCal claims that, under section 7(k), the Commission cannot exempt BPA proceedings from the *ex parte* requirements because they are procedures under the Federal Power Act.

The Commission did not, in its final rule, address precisely how Federal Power Act procedures would be applied to section 7(k) hearings. In the final rule, the Commission intended only to establish the procedures that it would follow for confirming and approving BPA's rates on an interim and final basis, particularly the filing requirements. The Commission stated that interested persons would be given an opportunity to comment on whether it is necessary to hold a hearing on nonregional rates under section 7(k) of the Northwest Power Act. If the Commission determines that a hearing was necessary under section 7(k) of the Northwest Power Act, it will publish a separate order delineating the issues to be resolved at such hearing. The Commission's final rule also included, in § 300.21, a paragraph which set forth the substantive statutes under which the Commission would review BPA's nonregional rates.

By not referring to Federal Power Act procedures in the rule, the Commission did not intend to imply that there is any question about the applicability of those requirements to section 7(k) hearings. The Commission does not believe that any of the procedures adopted in the final rule are inconsistent with this provision of section 7(k). However, while the Commission is amending its final rule to reflect the statutory language that any section 7(k) hearing will be in accordance "with the procedures established for ratemaking by the Commission pursuant to the Federal Power Act," it does not here set forth what it believes the intended scope of that provision to be.

The Commission nevertheless believes that the provision in section 7(k) does not require the Commission to adopt every filing requirement and administrative procedure that the Commission would follow in a Federal Power Act proceeding.<sup>2</sup> Accordingly, the

<sup>2</sup> The Commission has in only one case interpreted this provision of section 7(k) to require that a hearing procedure required under the Federal Power Act be followed in a section 7(k) hearing. BPA recently argued that the burden of proof should rest with the parties challenging BPA's rates, in holding that BPA had the burden of proof, the Commission stated that the hearing before this Commission shall be held "in accordance with the procedures established for ratemaking by the Commission pursuant to the Federal Power Act." Under the Federal Power Act, the filing utility or proponent of a rate bears the ultimate burden of persuasion. We therefore conclude that BPA bears the same burden in this proceeding.

<sup>1</sup> Bonneville Power Administration, Order Remanding Rates Without Prejudice, 13 FERC ¶ 61,157 at page 61,338 (1980).

Continued

provision does not necessarily obligate the Commission to require the BPA file its rates in accordance with the Uniform System of Accounts,<sup>3</sup> nor does it require that BPA necessarily file its case-in-chief as part of its rate filing.

The Commission also does not believe that its treatment of the *ex parte* rule violates the provisions of section 7(k). The Commission has not yet taken a position on the extent to which the *ex parte* rule should apply to power marketing proceedings. In the final rule, the Commission did not include the *ex parte* rule as one of the rules of practice and procedure to be followed under section 7(k) because of "the difficulty of applying the *ex parte* restrictions used in public utility rate cases to the rate cases of a fellow federal agency." The Commission stated, however, that it will "ensure the fairness of its on-the-record proceedings consistent with the case law and applicable statutes dealing with *ex parte* communications." This approach, the Commission stated, "reflects only a preference for fashioning appropriate procedural requirements in each case if there exist uncertainties about which restrictions are appropriate generically." 48 FR at 37,009.

The Commission must balance the countervailing considerations of intergovernmental relations and adjudicatory fairness. This issue is presented in all PMA rate proceedings. Consequently, in a companion rulemaking, the Commission has requested comments on the "extent to which prohibitions against *ex parte* communications ought to be applied in general to [Power Marketing Agency] rate proceedings." "The results of that inquiry may affect the Commission's view of BPA-related procedures under the special requirements of section 7(k). The Commission makes clearer its intent to defer resolution of the *ex parte* issue and to follow applicable legal requirements by amending its final rule to state that the *ex parte* rule "will apply only as the Commission determines is appropriate under the law."

In conclusion, SoCal's petition is granted insofar as the Commission is making clear that it will follow Federal Power Act procedures when section 7(k) hearings are involved. The Commission denies the petition in all other respects.

With regard to other hearing-related issues, one commenter suggested that the Commission's final rule should be amended to allow for a prehearing conference within thirty (30) days of the grant of interim approval. Again, the Commission acknowledges the need for expeditious review of BPA's rate cases. It cannot, however, require that a prehearing conference be held within thirty days of the grant of interim approval. The Commission has not yet determined whether a section 7(k) hearing will be held in every BPA nonregional rate case, but allows an opportunity to comment on whether a hearing should be held and the issues to be resolved at such a hearing. Because of this comment opportunity, it would be impossible to hold a prehearing conference within thirty days of the grant of interim approval.

In its final rule, the Commission stated that one of the actions it might take upon a request of final confirmation and approval of BPA's rate is to order an evidentiary hearing, if there are questions of fact which cannot be resolved through examination of the record and other available data or staff evaluation. Two commenters argue that the Commission does not have the authority to order a hearing on regional rates submitted by BPA. They claim that the Commission must remand the rate to BPA if there are any questions of fact that were not resolved by the Administrator's record or decision.

While the Northwest Power Act clearly authorizes the Commission to hold a hearing with regard to non-regional rates, it is silent on the Commission's authority to hold a hearing on regional rates. In the absence of any clear statutory limitation, the Commission believes it has, and should retain, the authority to hold a hearing on regional rates. The Commission believes, that it would rarely be necessary to hold a hearing on BPA's regional rates. As the Congress appears to have recognized, the need arises mostly with respect to non-regional sales. Generally speaking, the Commission would prefer to remand to BPA any filing that contained significant omissions of fact. The Commission nevertheless believes that it should retain the flexibility to order a hearing should circumstances warrant it.

### C. Filing Requirements

The Bonneville Power Administration requests that the Commission make three clarifications to the filing the requirements established in the final rule. Section 300.11(b)(3)(ii)(C) requires a listing of "replacements made during the historic period." BPA argues that its accounting system does not separately identify individual replacements on a historic basis. Instead, replacements are added to the cost of the original project. BPA believes it will be unduly burdensome for it to separately identify past individual replacements which have already been added to the cost of the original project.

The Commission acknowledges that the final rule requires that BPA make certain adjustments in the way it handles "replacements." The Commission believes that these adjustments are necessary, however, because the Commission must review separately the interest rates being imputed for replacements from those imputed for initial investments to determine the adequacy of the rates filed by BPA. In addition, the Commission does not understand from BPA's arguments how these adjustments might unduly burden BPA, although it recognizes that some accounting changes are necessary as a result of the rule. In any case, it believes the importance of this separate accounting of interest rates warrants those changes in practice.

In § 300.11(b)(3)(v), Statement C requires that "[f]or each year, the sum of unpaid individual investments or the unpaid portion of interest groups shown above must equal the unamortized investment shown in the power repayment study for that year." BPA requests clarification on what is meant by the phrase "for each year." BPA suggests that this phrase could mean the historic period, the cost evaluation period, or the entire period covered by the replacement study, or some other period of time. BPA believes that the requirement could be unduly burdensome, depending upon the period of time it is determined to cover. In addition, BPA finds unclear the distinction intended in that section between the phrases "sum of unpaid individual investments" and "unamortized investments." BPA believes that the concepts embodied in these two terms are identical.

BPA is essentially correct on both accounts. In fact, the purpose of this section was to emphasize that after all the calculations are made, these numbers *should* be the same, and to

<sup>3</sup> Bonneville Power Administration, Order Denying Rehearing, 23 FERC ¶ 61,469 at page 62,024 (1983) (footnote omitted).

<sup>4</sup> While the Commission does not believe section 7(k) requires BPA to keep its books in accordance with the Uniform System of Accounts, the Federal Power Act independently requires that "all agencies of the United States . . . shall be subject . . . to the provisions of section 301 and 302 the provisions requiring that public utilities shall follow the system of accounts established by the Commission." 16 U.S.C. 825b (1982). Thus, BPA must keep its books consistent with the Uniform System of Accounts, but not because of the operation of section 7(k) of the Northwest Power Act.

<sup>5</sup> Procedures and Filing Requirements for Rates of Power Marketing Agencies, 48 FR 49,301, 49,303 (October 25, 1983) (Notice of Proposed Rulemaking).

caution that, at any point in time, the aggregate of unpaid investments in Statement C must equal the total unamortized investment shown in the power repayment study.

BPA raises special concerns about the power repayment study in relation to WPPSSS and the Commission agrees with its assumptions. These bear repeating here. Section 300.12(b) states: "Unless otherwise required by statute, a [power repayment study] must contain only those investments in plant which will be in commercial operation during the proposed rate approval period, except replacements." BPA believes that this requirement does not present a problem with respect to BPA's contractual obligation to amortize the net billed portion of Washington Public Power Supply System Projects 1, 2, and 3, before those plants are placed in commercial operation.

BPA assumes this obligation through the new billing agreements for Projects 1, 2, and 3. This was recognized by Congress in the Public Works Appropriations Acts of 1970 and 71, Pub. L. 91-144, 83 Stat. 333 (1969) and Pub. L. 91-439, 84 Stat. 899 (1970), respectively. BPA believes that the two appropriations acts provide sufficient statutory authorization to permit pre-completion amortization of investments in those three generating units under the Commission's rule. The Commission agrees with BPA's observations.

#### D. Notice and Comment Issue

One commenter believed that the Commission was required to offer the opportunity for comment prior to the adoption of the final rule under section 553 of the Administrative Procedure Act, for certain provisions established for the first time in the final rule. In the final rule the Commission noted:

the final rule differs from the interim rule in \* \* \* respects that require further explanation pursuant to section 553(b) of the Administrative Procedure Act. [T]he final rule adds a section [section 300.21] that establishes procedures for final confirmation and approval. The Commission believes the Administrative Procedure Act does not require that the Commission provide additional opportunity for comment prior to making this part of the rule final. The final rate approval procedures do not impose new procedural burdens, such as filing requirements, on BPA or interested parties. They are designed only to standardize BPA proceedings before the Commission in terms of notice, opportunities for hearings, and to state the range of actions available to the Commission. The new provisions do not affect the substance of the rate case. As such, these procedural requirements for final confirmation and approval (section 300.21) are clearly matters of "agency organization, procedure, or practice" that do not require

notice and comment. 5 U.S.C. 553(b)(A) (1976).  
[48 FR at 37011]

The Commission accordingly believes that the final rule sufficiently explains the Commission's legal reasoning, so that additional notice and comment was not required prior to promulgation of the final rule.

#### III. Effective Date

The amendment made by this final rule will be effective January 20, 1984.

#### List of subjects in 18 CFR Part 300

Electric power rates.

#### PART 300—[AMENDED]

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

By the Commission,  
Kenneth F. Plumb,  
Secretary.

1. The authority citation for Part 300 reads as follows:

**Authority:** The Pacific Northwest Electric Power Planning and Conservation Act, 16 U.S.C. 839-839h; Federal Power Act, as amended 16 U.S.C. 792-828c; Bonneville Power Project Act; 16 U.S.C. 832-832i; Flood Control Act of 1944, 16 U.S.C. 825s; Federal Columbia River Transmission System Act, 16 U.S.C. 838-838k; Department of Energy Organization Act, 42 U.S.C. 7101-7352; E.O. 12009, 3 CFR Part 42 (1978).

2. Section 300.1(a) is revised to read as follows:

##### § 300.1 Applicability and definitions.

(a) *Applicability.* This part sets forth procedures governing the filing, review, and disposition of the rate schedules for the sale or transmission of power and energy established by the Administrator of the Bonneville Power Administration under the Pacific Northwest Electric Power Planning and Conservation Act (Northwest Power Act). Except as otherwise provided by rule or order, the Commission's General Rules of Practice and Procedure (Part 385 of this Chapter) will apply to any filings, hearings, or other procedures under this part, as applicable. Rule 2201 of Part 385 will apply only as the Commission determines is appropriate under law.

3. Section 300.21(b) is revised to read as follows:

##### § 300.21 Final confirmation and approval.

(b) *Proceedings under section 7(k).* The Commission will publish a separate order if it determines that a hearing is necessary under section 7(k) of the

Northwest Power Act. This order will, if appropriate, delineate the issues to be resolved at such hearing. Such hearing will be held in accordance with the procedures established for ratemaking by the Commission pursuant to the Federal Power Act.

[FR Doc. 83-33828 Filed 12-20-83; 8:45 am]

BILLING CODE 6717-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. 83C-0113]

#### Chlorophyllin-Copper Complex, Oil Soluble; Listing as a Color Additive for Use in Polymethylmethacrylate Bone Cement

**AGENCY:** Food and Drug Administration.  
**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of chlorophyllin-copper complex, oil soluble, for coloring polymethylmethacrylate (PMMA) bone cement in conjunction with orthopedic surgical procedures. FDA is taking this action in response to a petition filed by E.M. Industries, Inc.

**DATES:** Effective January 23, 1984; objections by January 20, 1984.

**ADDRESS:** Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Carl A. Larson, National Center for Devices and Radiological Health (HFK-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7156.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of April 22, 1983 (48 FR 17389), FDA announced that a color additive petition (CAP 3C0175) had been filed by E.M. Industries, Inc., 5 Skyline Drive, Hawthorne, NY 10532, proposing that FDA's color additive regulations be amended to provide for the safe use of chlorophyllin-copper complex, oil soluble, for coloring PMMA bone cement. This device is indicated for achieving a rigid fit between the bony walls of a surgical cavity and an orthopedic prosthesis. The petition was filed under section 706 of the Federal

Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94-295), Congress mandated the listing of color additives for use in or on medical devices where the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of the chlorophyllin-copper complex, oil soluble, presented in the color additive petition now before the agency is subject to this listing requirement. This color additive is added to the PMMA bone cement in such a way that at least some of this color additive will come in direct contact with the body after implantation and will remain in such contact over a long period, depending on the medical situation. Thus, the color additive is subject to regulation under section 706 of the act.

The color additive is chlorophyllin-copper complex, oil soluble. This color additive, which is extracted from a mixture of fescue and rye grasses, is an intensely dark green oil solution, diluted to a 5-percent pigment concentration. The color additive is obtained by acid treatment of native chlorophyll to remove the chelated magnesium which is replaced with hydrogen. The hydrogen is in turn replaced with copper. The resultant pigment concentration is further diluted to a 5-percent concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

The intended technical effect of the color additive is to impart a green tint to the PMMA bone cement, so that the bone cement can be readily distinguished from physiologic bone or bony fragments within the surgical field, either at the primary implantation or during revision surgery. The petitioner's PMMA bone cement with the color additive chlorophyllin-copper complex, oil soluble, present at a level of 0.003 percent by weight has been used clinically in Europe in an estimated 11,000 patients (Introduction to premarket approval application, P810020, Volume 3). On recent evaluation at revision surgery of total hip replacements (3 or more years post implantation), European surgeons reported that the green coloration of the petitioner's PMMA bone cement with chlorophyllin-copper complex, oil soluble, facilitated removal of all acrylic debris.

Only a small amount of the color additive is required to tint the PMMA bone cement. For example, in a typical application for a total hip replacement, 1.414 milligrams of chlorophyllin-copper complex, oil soluble, is used per 56.5

grams of the PMMA bone cement, i.e., 0.0024 percent by weight. The petitioner has petitioned for the use of the chlorophyllin-copper complex, oil soluble, in PMMA bone cement at a level of 0.003 percent by weight.

The agency has evaluated data from sources other than the petition on the safety of chlorophyllin-copper complex, oil soluble, and finds that this substance is safe for use in coloring PMMA bone cement at the level specified in the petition. The agency notes that the normal diet includes large quantities of chlorophyll from such sources as green leafy vegetables. The World Health Organization has stated that the acceptable daily intake for humans of chlorophyllin-copper complex is 15 milligrams per kilogram of body weight (Ref. 1), an amount that far exceeds the possible exposure to this color additive from its use in bone cement. Sodium potassium chlorophyllin-copper complex has been fed to rats at dietary levels of up to 3 percent for up to 2 years (Ref. 2). The results of this study showed no toxic effects except for slight pigmentation (greenish color) of the liver of the high-dose group. (See 21 CFR 73.1125 and supporting administrative record.)

The agency's conclusion about the safety of the petitioned use of the color additive is buttressed by the results of several studies submitted by the petitioner. Some of these studies were done under an investigational exemption for a new drug (IND 12469) and included evaluations of intraperitoneal injection, intravenous injection, intraperitoneal implantation, and intramedullary femoral implantation of PMMA bone cement containing chlorophyllin-copper complex, oil soluble, in both rats and dogs. One lifetime study evaluating oncogenic effects in rats of femoral implantations also was done (Ref. 3). No adverse effects attributable to the color additive were observed in any of these studies. In fact, in the oncogenic study, no differences were found between a control group that was treated with uncolored bone cement and the test group that was treated with bone cement that contained the color additive.

Having reviewed the data in the petition, the premarket approval application, and other relevant material, and based upon the composition of the color additive, available toxicity data, the small quantity of color additive added to the PMMA bone cement, and the process by which the color additive is manufactured, FDA finds that the color additive chlorophyllin-copper complex, oil soluble, is suitable and safe

for use in coloring PMMA bone cement at a level not to exceed 0.003 percent. In addition, to further assure the safety of this color additive, FDA is establishing specifications in the listing regulation. However, on the basis of the factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of the color additive is not necessary for the protection of the public health.

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the National Center for Devices and Radiological Health by appointment with the information contact person listed above. As provided in § 71.15(b), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment. Therefore, an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

#### References

The following information has been placed on display in the Dockets Management Branch (address above) and may be reviewed by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Joint FAO/WHO Expert Committee on Food Additives, "Toxicological Evaluation of Some Food Colors, Emulsifiers, Stabilizers, Anti-Caking Agents, and Certain Other Substances," *WHO/Food Additives*, 46A(13):14-17, 1969.
2. Harrison, J. W. E., J. E. Levin, and B. Trabin, "The Safety and Fate of Potassium Sodium Copper Chlorophyllin and Other Copper Compounds," *Journal of the American Pharmaceutical Association*, 43:722-737, 1954.
3. Hwang, S. W. and D. P. Sinha, "Bone Implant Oncogenicity in Rats," Report P4357 (Unpublished), November 18, 1977.

#### List of Subjects in 21 CFR Part 73

Color additives, Cosmetics; Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376)) and under authority delegated to the Commissioner of Food and Drugs (21

CFR 5.10), Part 73 is amended by adding new § 73.3110 in Subpart D, to read as follows:

**PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION**

**§ 73.3110 Chlorophyllin-copper complex, oil soluble.**

(a) *Identity.* The color additive is chlorophyllin-copper complex, oil soluble. The chlorophyllin is obtained by extraction from a mixture of fescue and rye grasses. The chlorophyll is acid-treated to remove chelated magnesium which is replaced with hydrogen, which is then replaced with copper. This mixture is diluted to a 5 percent concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

(b) *Specifications.* The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Moisture, not more than 0.5 percent.  
Nitrogen, not less than 0.2 percent and not more than 0.3 percent.  
Total copper, not less than 0.2 percent and not more than 0.4 percent.  
Free copper, not more than 200 parts per million.  
Lead, not more than 20 parts per million.  
Arsenic, not more than 5 parts per million.  
Sulfated ash, not more than 2.5 percent.  
Total color, not less than 4.5 percent and not more than 5.5 percent.

(c) *Uses and restrictions.* (1) The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), may be safely used to color polymethylmethacrylate bone cement. Chlorophyllin-copper complex may be used at levels that do not exceed 0.003 percent by weight of the bone cement.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the polymethylmethacrylate bone cement in which chlorophyllin-copper complex, oil soluble, is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

Any person who will be adversely affected by the foregoing regulation may

at any time on or before January 20, 1984 filed with the Dockets Management Branch (address above) written objections thereto. Objections shall show how the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issue for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

*Effective date.* This regulation shall become effective January 23, 1984, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the Federal Register.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

Dated: December 15, 1983.

William F. Randolph,  
Acting Associate Commissioner for  
Regulatory Affairs.

[FR Doc. 83-32751 Filed 12-20-83; 8:45 am]

BILLING CODE 4180-01-M

**ENVIRONMENTAL PROTECTION AGENCY**

**21 CFR Parts 193 and 561**

[FAP 3H5391/R621; FAP 3H5391/R622; PH-FRL 2493-7]

**Tolerances for Pesticides in Food and Animal Feeds Administered by the Environmental Protection Agency; 5-(Chlorophenyl)-2,3-Diphenylthiophene**

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

**ACTION:** Final rule.

**SUMMARY:** These rules establish food and feed additive regulations to permit residues of the insecticide 5-(4-chlorophenyl)-2,3-diphenylthiophene in or on certain food and feed commodities in accordance with an experimental program. These regulations to establish maximum permissible levels for the

pesticide in or on the commodities were requested in a petition by Uniroyal Chemical.

**EFFECTIVE DATE:** Effective on December 21, 1983.

**ADDRESS:** Written objections may be submitted to the Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, D.C. 20460.

**FOR FURTHER INFORMATION CONTACT:**  
By mail:

Jay Ellenberger, Product Manager (PM)  
12, Registration Division (TS-767C),  
Environmental Protection Agency, 401  
M St., SW., Washington, D.C. 20460.  
Office location and telephone number:  
Rm. 202, CM#2, 1921 Jefferson Davis  
Highway, Arlington, VA 22202, (703-  
557-2386).

**SUPPLEMENTARY INFORMATION:** EPA issued notices, published in the Federal Register of April 27, 1983 (48 FR 19078), which announced that Uniroyal Chemical, 74 Amity Rd., Bethany, CT 06525, had submitted a food/feed additive petition (FAP) proposing to amend 21 CFR Parts 193 and 561 by establishing regulations permitting residues of the insecticide 5-(4-chlorophenyl)-2,3-diphenylthiophene in or on certain food and feed commodities as follows:

1. *FAP 3H5391.* Proposed amending 21 CFR Part 193 by establishing a regulation permitting residues of the insecticide 5-(4-chlorophenyl)-2,3-diphenylthiophene in the food commodity citrus oil at 40.0 parts per million (ppm) resulting from applications of this chemical to oranges and grapefruit in connection with an experimental program. The petition was later amended by increasing the tolerance proposal for citrus oil from 40.0 ppm to 100.0 ppm.

2. *FAP 3H5391.* Proposed amending 21 CFR Part 561 by establishing a regulation permitting residues of 5-(4-chlorophenyl)-2,3-diphenylthiophene in the feed commodity dried citrus pulp at 2.0 ppm resulting from application of this chemical to oranges and grapefruit in connection with an experimental program.

The petition was later amended by increasing the tolerance proposal for dried citrus pulp from 2.0 ppm to 3.0 ppm.

There were no comments received in response to the notices of filing.

The pesticide may be safely used in the prescribed manner when such use is in accordance with the label and labeling registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 751, 7

U.S.C. 135(a) et seq.). It has further been determined that since residues of the pesticide may result in citrus oil and dried citrus pulp from the agricultural use provided for in the experimental use permit, the food and feed additive regulation should be established and should include a tolerance limitation.

The data submitted in the petition and other relevant material have been evaluated. The toxicological data submitted in support of the tolerances include a 90-day rat-feeding study with a no-observed-effect level of 100 ppm (5.0 mg/kg); a 6-month dog-feeding study with a NOEL of 100 ppm; and a rat teratology study that was negative at up to 2,000 mg/kg. Studies on mutagenicity demonstrated negative potential.

Based on the 6-month dog-feeding study with a 100-ppm (2.5 mg/kg) NOEL, and using a safety factor of 100, the acceptable daily intake (ADI) for man is 0.025 mg/kg of body weight (bw)/day.

The pesticide is considered useful for the purpose for which the regulations are sought. Therefore, the regulations are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this notice in the *Federal Register*, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted these rules from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-534, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new food or feed additive levels or conditions for safe use of additives, or raising such food or feed additive levels, do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the *Federal Register* of May 4, 1981 (46 FR 24945).

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 346(c)(1)))

List of Subjects in 21 CFR Parts 193 and 561

Food additives, Animal feeds, Pesticides and pests.

Dated: December 8, 1983.

Edwin L. Johnson,  
Director, Office of Pesticide Programs.

#### PART 193—[AMENDED]

Therefore, Chapter I of 21 CFR is amended as follows:

1. In Part 193, new § 193.469 is added, to read as follows:

##### § 193.469 5-(4-Chlorophenyl)-2,3-diphenylthiophene.

(a) [Reserved].

(b) An interim tolerance of 100.0 parts per million is established for residues of the insecticide 5-(4-chlorophenyl)-2,3-diphenylthiophene in the food commodity citrus oil resulting from applications of this chemical to oranges and grapefruit in connection with an experimental program. The expiration date for this tolerance is December 9, 1984.

#### PART 561—[AMENDED]

2. In Part 561, new § 561.433 is added, to read as follows:

##### § 561.433 5-(4-Chlorophenyl)-2,3-diphenylthiophene.

(a) [Reserved].

(b) An interim tolerance of 3.0 parts per million is established for residues of the insecticide 5-(4-chlorophenyl)-2,3-diphenylthiophene in the feed commodity dried citrus pulp resulting from application of this chemical to oranges and grapefruit in connection with an experimental program. The expiration date for this tolerance is December 9, 1984.

[FR Doc 83-33770 Filed 12-20-83; 8:45 a.m.]

BILLING CODE 6560-50-M

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Change of Sponsor; Central Soya Co. Inc.

AGENCY: Food and Drug Administration.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of supplemental new animal drug applications (NADA's) providing for a change of sponsor from Good-Life, Inc., to Central Soya Co., Inc.

**EFFECTIVE DATE:** December 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** John W. Borders, Bureau of Veterinary Medicine (HFV-238), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

**SUPPLEMENTARY INFORMATION:** Central Soya Co., Inc., 1300 Fort Wayne Bank Bldg., Fort Wayne, IN 46802, has informed the FDA that it has purchased the assets, including NADA's for medicated premix approvals, and trademark name, of Good-Life, Inc. Good-Life, Inc., has confirmed the change of ownership by letter. The NADA's affected are 110-045, tylosin premixes; 128-411, tylosin/sulfamethazine premix; and 134-286, pyrantel tartrate premix. The supplements are approved and Parts 510 and 558 are amended to reflect the change of sponsor.

This action concerns a change of sponsor and does not involve any changes in manufacturing facilities, equipment, procedures, or production personnel. Under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this is a Category I change that does not require reevaluation of the safety and effectiveness data in the parent applications.

#### List of Subjects

##### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

##### 21 CFR Part 558

Animal drugs, and Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 510 and 558 are amended as follows:

#### PART 510—NEW ANIMAL DRUGS

##### § 510.600 [Amended]

1. 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* in paragraph (c)(1) by removing the entry "Good-Life, Inc." and in paragraph (c)(2) by removing the entry "021810."

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

2. Part 558 is amended:

a. In § 558.485 by revising paragraph (a)(14) to read as follows:

§ 558.485 *Pyrantel tartrate.*

(a) \* \* \*