DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 87C–0316]

Listing of Color Additives Exempt From Certification; Astaxanthin; Objection and Request for a Hearing; Staying Portions of the Regulation; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received one objection to the final rule for astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. The objection concerns a specification and the requirement for labeling of the color additive. The objection requests a hearing on the two issues. The submission of the objection stays the effective date of two paragraphs of the astaxanthin regulation until the agency can rule on them. FDA is confirming the effective date of May 16, 1995, for the remainder of this regulation that appeared in the **Federal Register** of April 13, 1995 (60 FR 18736).

DATES: Effective date confirmed: May 16, 1995, except for 21 CFR 73.35(b) for the specification for total carotenoids other than astaxanthin and 21 CFR 73.35(d)(3) for the labeling requirements.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3078.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 13, 1995 (60 FR 18736), FDA amended part 73 (21 CFR part 73) of its regulations to provide for the safe use of astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh.

FDA gave interested persons until May 15, 1995, to file objections and requests for a hearing on § 73.35 (21 CFR 73.35). The agency received from one color additive manufacturer objections to two provisions of the final rule. The objector requested a hearing on two issues: The specification for total carotenoids other than astaxanthin of not more than 4 percent under § 73.35(b) and the labeling requirement for the presence of the color additive in salmonid fish under § 73.35(d)(3). Under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)) the objection stays the effect of these two paragraphs of the astaxanthin regulation until the agency has ruled on the objections. Apart from § 73.35(b) and (d)(3), FDA is confirming the effective date of May 16, 1995, for the final rule that amended the color additive regulations to provide for the use of astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. The objections are on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, under the docket number found in the heading of this document.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that because of the objection and request for a hearing on the specification for total carotenoids other than astaxanthin of not more than 4 percent in § 73.35(b) and the labeling requirement for the presence of the color additive in salmonid fish in § 73.35(d)(3), these provisions are stayed until further notice. Accordingly, the amendments to § 73.35 issued on April 13, 1995 (60 FR 18736), became effective May 16, 1995, except for §§ 73.35(b) and (d)(3), which are stayed until further notice.

Dated: August 7, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–19946 Filed 8–11–95; 8:45 am]

BILLING CODE 4160–01–F

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2200

Rules of Procedure

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Review Commission has determined that it is in the public interest to adopt procedures that will permit the small employer who challenges an OSHA citation before the Commission to do so with minimal complexity and cost. Accordingly, it has decided to initiate a pilot E–Z Trial program for a one year period, beginning October 1, 1995. After the test period, the Commission will evaluate the results and determine whether it should continue the E–Z Trial program and, if so, what modifications should be made. The evaluation will involve surveying employers and employer representatives regarding their satisfaction with the fairness and efficiency of the process and analyzing data on the rate at which E–Z Trial cases go to a hearing, the length and cost of hearings and the cycle times of these cases as compared to those of conventional cases. We will also gather information from our Judges and the Solicitor of Labor and OSHA personnel regarding how well the process is working and how it might be changed or improved.

As the name implies, E–Z Trial is designed to simplify and accelerate adjudication for cases that warrant a less formal, less costly process. To ensure that the program is used sufficiently to enable the Commission to determine its success or failure, as well as its strengths and weaknesses, cases will be assigned to E–Z Trial by the Chief Administrative Law Judge. The Commission will also include explanatory materials on E–Z Trial in its Notice of Docketing to employers to make sure that (1) employers are well aware of the availability of the E–Z Trial option early in the process and (2) employers are clear on how they can apply for E–Z Trial. Together these mechanisms should encourage the use of E–Z Trial whenever appropriate. Parties who believe that an assigned case is inappropriate for E–Z Trial can present their reasons to the presiding Judge who, upon consultation with the Chief Judge, may order the case to proceed under conventional proceedings. In addition, a Judge assigned to a case could unilaterally direct that case to be tried under E–Z Trial proceedings. The Commission has also adopted certain rules and procedures designed to shorten the length of the proceedings. For example, the parties are required to disclose certain information to each other. Discovery, while not prohibited, is allowed only under the terms set by the presiding Judge, Interlocutory appeals are prohibited and, where practicable, the Judge is encouraged to render his or her decision from the bench. Any party dissatisfied with the disposition of the case may seek review of that decision as in conventional proceedings.

DATES: These revised rules will take effect on October 1, 1995. After September 30, 1996, § 2200.203(a) will no longer be in effect unless extended by the Commission by publication of a final rule in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Earl R. Ohman, Jr., General Counsel, One Lafayette Centre, 1120 20th St., N.W., 9th Floor, Washington, DC 20036–3419 Phone (202) 606–5410.

SUPPLEMENTARY INFORMATION:

Development of the Final Rules

On May 1, 1995, the Occupational Safety and Health Review Commission published in the **Federal Register** a proposal to revise its rules governing simplified proceedings and to institute a pilot E–Z Trial program (60 FR 21058). The notice explained the procedures followed by the Commission in developing its proposal and the basis and purpose of the proposed rules. The notice included a request for public comment.

In response, a number or organizations who would be affected by the revised rules filed comments with the E–Z Commission. The Office of the Solicitor of Labor, which represents the Secretary of Labor in all adjudicative proceedings before the Commission, filed comments on behalf of the Secretary of Labor. The following organizations, listed alphabetically, presented comments on the proposed revision to the rules: the Administrative Conference of the United States; the American Dental Association; Bell Atlantic Network Services, Inc.; General Building Contractors Association, Inc.; Gibson, Dunn & Crutcher; Jackson, Murdo, Grant & McFarland, P.C.; McDermott, Will & Emery; Morgan, Lewis & Bockius; the National Funeral Directors Association; the National Stone Association; Rader, Campbell, Fisher & Pyke; and Schottenstein, Zox & Dunn. The Commission gratefully acknowledges receipt of these comments and assures all commentators that their concerns about the proposed changes were fully considered, even though some are not specifically discussed here.

In developing the final rules set forth in this document, the Commission considered not only the concerns of the commentators, but also those of other interested parties. The Chairman and representatives of the Commission met with AFL–CIO affiliate unions on March 16, 1995, with members of the Solicitor's office on May 16, 1995, and on May 18, 1995, conducted two focus group sessions in Philadelphia, Pennsylvania, with attorneys, non-attorney representatives, and employers.

After careful consideration of all comments received, the Commission issues these E–Z Trial rules, amending its rules for simplified proceedings in order to promote more effective and efficient proceedings before the Commission's Judges while maintaining fairness to all its participants.

Eligibility for E–Z Trial

The Commission received several suggestions addressing § 2200.202, which sets forth which cases should be eligible for E–Z Trial. Several commentators noted that the importance and complexity of a case are often dependent on the required abatement, not the proposed penalty. One commentator suggested raising the $7500 penalty limitation, and including only those cases where the employer agrees that the cost of abatement would be $7500 or less. The Commission found this suggestion interesting because, as these commentators suggested, the higher the cost of abatement, the more complicated the issues in the case are likely to be. After considering the issue, however, the Commission has determined that the suggestion is not viable. While it is sometimes clear from the nature of the citation that the cost of abatement would be either substantial or relatively minor, the effect of the cost of abatement on the complexity of the case usually cannot be determined at the outset of the proceeding when the case file contains little more than the citation and notice of contest. Therefore, an instruction to the Chief Judge to exclude abatement over a certain dollar value would not be practicable. Similarly, it would be difficult to carry out one commentator's suggestion that only cases involving factual issues and not legal issues be directed for E–Z Trial. Certainly such cases would be most suitable for E–Z Trial. However, the Commission believes that such a separation of cases would be difficult, if not impossible, to perform, given the potential for legal issues arising in any case. We would expect that in most cases where the Chief Judge determines that the abatement called for in the citation would be expensive or the legal issues presented in the case are difficult, he would determine that the case is too complex to be a candidate for E–Z Trial.

The Commission has concluded that the $7500 limit originally proposed is too low. Upon examination of the Commission's case load, we are unable to discern a significant difference in complexity between cases with proposed penalties ranging from $7500 to $10,000. By considering cases for E–Z Trial with proposed penalties of not more than $10,000, the Chief Judge would have an expanded number of cases to choose from during this pilot project. Therefore, the Commission will instruct the Chief Judge to consider cases for E–Z Trial where the proposed penalties do not exceed $10,000 rather than $7500.

The Secretary suggested that the criteria used for Simplified Proceedings be adopted for E–Z Trial and that any case involving air contaminants (Subpart Z of Part 1910) be disqualified. The Secretary also suggested that cases which would appear to involve affirmative defenses should not be eligible for E–Z Trial because such cases usually require discovery and often become complicated. A commentator suggested that the specific requirements for E–Z Trial eligibility be set forth in the rule. The Commission agrees that the eligibility criteria be included in the rule. The Commission continues to believe, however, that during this pilot project, it should maintain the flexibility to apply broad eligibility criteria. Accordingly, the Commission expects that cases appropriate for E–Z Trial would generally include those with one or more of the following characteristics: (1) Relatively few citation items, (2) an aggregate proposed penalty of not more than $10,000, (3) no allegation of willfulness, (4) a hearing that is expected to take less than two days, or (5) a small employer whether appearing *pro se* or represented by counsel.

Procedures for Commencing and Discontinuing E–Z Trial

Many commentators objected to the language in § 2200.203(a) authorizing the Chief Judge to assign cases to E–Z Trial without either party's request or consent. Similarly, there was widespread belief that once selected for E–Z Trial, it would be very difficult to return the case to conventional proceedings. Generally, these commentators expressed concern over being forced into a proceeding that limited the availability of certain procedures, particularly discovery. One commentator even suggested that there be a ''presumption of correctness'' for employers wanting to opt out of E–Z Trial, and that the Judge be required to find ''overwhelming and compelling reasons why the case should be simplified.''

As we note, *infra*, the concern over the loss of discovery is overstated. Our paramount concern is always the conduct of a fair proceeding. The Commission does not intend to eliminate discovery. The rules

specifically grant authority to the presiding Judge to allow whatever discovery he finds appropriate.

Thus, where the Judge determines that extensive discovery is necessary, or finds some other reason for discontinuing E–Z Trial, § 2200.204(a) authorizes him to do so after consultation with the Chief Judge. The Commission does not foresee this consultation process as significantly restricting the presiding Judge from appropriately removing a case from E–Z Trial.

It is the Commission's view that making it too easy for the parties to opt out of E–Z Trial would run counter to the purpose of the program. Nonetheless, where a party believes that its case has been inappropriately assigned to E–Z Trial, § 2200.204(b) allows that party to move for the Judge to return the matter to conventional proceedings. The Commission expects that, upon a showing of good cause, most requests for returning a case to conventional proceedings will be granted. Joint motions to return a case to conventional proceedings shall be granted by the Judge and do not require a showing of good cause.

While the Commission recognizes the concern expressed by many commentators over the assignment of cases to E–Z Trial without the consent of the parties, it believes that such a mechanism is necessary. As the Commission stated in the preamble to the proposed E–Z Trial rules, the previous rules for Simplified Proceedings, which would take effect only upon a party's request, were rarely used. When Simplified Proceedings were requested by a party, the other party often filed and objection that was granted by the presiding judge. It is the Commission's goal that these E–Z Trial rules will increase the number of cases that use simplified proceedings to a significant level. The Commission hopes that after some experience with this process, litigants and their representatives will find it to be a useful alternative to our conventional trial process. Therefore, the Commission has set forth a sunset provision at § 2200.201(b). Under this provision, § 2200.203(a), which allows the Chief Judge to assign cases for E–Z Trial, will no longer be in effect after the conclusion of the plot program unless otherwise extended by the Commission.

Disclosure and Discovery

Most of the Commentators expressed reservations concerning the restrictions on discovery set for at § 2200.207. These commentators feared that the loss of discovery would severely curtail their ability to develop their case. A recurrent theme was that, without discovery, employers would be open to ''trial by ambush''and that the Secretary, by virtue of his inspection of the worksite, already had, in effect extensive discovery. Similarly, the Secretary of Labor was concerned that restrictions on discovery would prevent him from rebutting affirmative defenses raised by employers. Accordingly, the Secretary suggested that the rule be relaxed to allow discovery upon a showing of need.

We believe that these commentators have interpreted the intent of the rule. We are aware that E–Z Trial proceedings must be structured fairly. The proposed rule was designed to have the Judge take a more active role in the discovery process to ensure that it is limited to that which is necessary. By doing so, the Commission hoped to minimize delay and attendant costs. It appears that the role of discovery was too narrowly described in § 2200.200(b)(3) as being generally not permitted. We have modified this rule to more accurately reflect the intent of the Commission.

Because it is the intent of the Commission that E–Z Trial will enable the small employer to represent himself better, it is especially important that the Judge be involved in the discovery process. Few things could be more intimidating or confusing to a *pro se* employer than to receive a long list of interrogatories, requests for admission, or requests for production of documents or to have to partake in depositions. When such requests are made, the Commission expects that its Judges will restrict discovery that appears to be of marginal value.

It is the Commission's expectation that, as a result of reasonable restrictions on discover, the adjudicatory process will be substantially accelerated with significant cost savings being realized by both employers and the Secretary. The Commission expects that having the Judge take a more active role will expedite the case.

Several commentators observed that if discovery were to be restricted, the Secretary should be required to turn over his investigatory file to the employer early enough in the proceeding to enable the employer to evaluate the case against him and prepare a defense. We find this suggestion to be well-taken and have included a new § 2200.206 to require that the Secretary disclose to the employer certain information early in the proceeding. We note that it is already a general practice amongst some of the Commission's Judges to require the Secretary to turn over all or part of the investigatory file. In many other cases, the file is routinely turned over to the employer's counsel upon request. However, most *pro se* employers would not know that they have the right to request information contained in the investigative file. Therefore, by requiring that certain information in the file be turned over early in the proceeding, the employer would, in all cases, be given the basic documents necessary for the preparation of its defense.

The Secretary expressed the concern that requiring him to turn over the entire investigatory file in all cases would impose a substantial burden. Not only would the Secretary be required in every case to duplicate numerous documents, but he would also have to individually review each document to edit out any protected information. While we find these concerns to be well-founded, we note that mandatory pre-discovery disclosure is the trend in many jurisdictions, including the Federal Courts. For example, Federal Rule of Civil Procedure 26(a) requires the disclosure of certain basic information needed by parties to prepare for trial or make an informed decision about settlement.

For E–Z Trial, § 2200.206 sets forth the minimum disclosure requirements necessary for the parties to evaluate their case. The Commission has attempted to balance the employer's need for certain information necessary to its case against the burden it would impose on the Secretary to require the entire investigatory file to be turned over in every case. Therefore, the Commission has determined that it will require that two essential OSHA forms be turned over to the employer early in the proceeding: the compliance officer's narrative (Form OSHA–1A) and the worksheet (Form OSHA 1–B) or their equivalents. As part of his or her control over the discovery process, the presiding Judge would retain the authority to order that other materials be made available to the employer.

Simarily, the Commission believes that where an employer raises affirmative defenses, the Judge should require it to submit certain authenticating documents to the Secretary. For example, if an employer argues that a violation was the result of unpreventable employee misconduct, the Judge should, at a minimum, require it to submit to the Secretary a copy of the relevant portions of its safety manual and documentation establishing the scope and nature of employee discipline. The Commission has

codified this requirement at § 2200.206(b).

All rules after § 2200.206 have been renumbered to reflect the addition of the new rule § 2200.206, requiring the parties to disclose certain information.

Pre-Hearing Conference

Because the Commission will require the Secretary to provide certain information to the employer early in the proceeding, § 2200.207(a) has been modified to require that the pre-hearing conference be held only after the employer has had sufficient time to review the documents. Under § 2200.206(b), where affirmative defenses are raised, either before or at the pre-hearing conference, the Secretary will have the right, outside of discovery, to obtain certain authenticating documents from the employer. The Commission expects that, in the usual case, at the pre-hearing conference the Judge will be in the best position to determine what, if any, discovery should be allowed.

The Secretary of Labor suggested that a binding statement of all issues in dispute, including any affirmative defenses, be made part of a written conference order. The Secretary of Labor also requested that a rule be included requiring that a hearing date be set at the pre-hearing conference, and that the conference be held sufficiently in advance of the hearing date to allow the parties time to plan the presentation of the case.

It is the Commission's view that its Judges functions best when they have the flexibility to manage their cases in a manner that allows them to consider the requirements and idiosyncracies of the individual cases. However, the Secretary's suggestion that the rules specify that the pre-hearing conference be held sufficiently in advance of the hearing to allow the parties to prepare their case is well-taken. While we do not adopt a rule requiring when a hearing date be set, wherever practicable, the Judge should set a hearing date before the pre-hearing conference takes place. Accordingly, the Commission has modified § 2200.209(a) to clarify that the hearing be held ''as soon as practicable after the conclusion of the pre-hearing conference.'' Any agreements reached in the pre-hearing conference should be memorialized in a pre-hearing order.

Hearing

This proposed rule, now numbered § 2200.209, engendered comments in three areas.

Three commentators expressed reservations over § 2200.209(c), which makes the Federal Rules of Evidence inapplicable to E–Z Trial. These commentators suggested that elimination of the Federal Rules of Evidence would place the *pro se* employer at a disadvantage vis-a-vis the trained lawyers representing the Secretary; would result in the creation of a second, duplicative, system of evidentiary rules; and would allow the Secretary of Labor to introduce hearsay evidence that, when combined with the restrictions on discovery, the employer would be unable to refute.

The Commission adheres to its view that the efficacy of E–Z Trial will be enhanced, especially for the *pro se* employer, by not requiring the Judge to strictly adhere to the Federal Rules of Evidence. The Commission is confident that its Judges are fully able to deal with issues of the reliability and probative value of evidence. On the other hand, contrary to the contentions of the commentators, it seems obvious that *pro se* employers, with no legal training, would be at a substantial disadvantage in presenting their case if they were required to strictly adhere to the Federal Rules of Evidence.

Several commentators also objected to the prohibition on interlocutory appeals. One commentator noted that, because they are rarely used, the prohibition was probably unnecessary. Another commentator objected to the prohibition because the parties would have no immediate appeal should the Judge improperly force the case to continue under E–Z Trial. This latter comment underscores the reason why the Commission has concluded it is necessary to prohibit interlocutory appeals. Because of the unfamiliarity with these new procedures, we expect that some parties will try to opt out even when they are unable to show good cause why the case should not continue under E–Z Trial. To allow these parties to seek interlocutory review of the Judge's order, or to challenge other orders issued by the Judge, such as discovery orders, would gravely slow down the process and undermine the basic goal of E–Z Trial. We note that, despite the prohibition on interlocutory review, the parties retain the right, under § 2200.211, to petition the Commission to review the Judge's disposition.

Two commentators also specifically objected to § 2200.209(f) which encourages Judges to issue decisions from the bench. They contended that without a written opinion, the rationale for the Judge's decision would be incomplete, making it difficult both for other parties to rely on the decision and for review of the decision on appeal. Because we never intended to allow decisions without a recorded rationale, we have clarified the rule accordingly. All our Judges' decisions must comply with the Administrative Procedure Act. Therefore, the revised language explicitly requires the Judge to state his or her findings of fact and conclusions of law for the record. Moreover, the Judge will be required to reduce his or her order to writing and to include in his or her order all paragraphs from the transcript that contain findings of fact and conclusions of law that support the decision. This written order will serve as the official decision for purposes of appeal.

Commission Review

Several comments suggested a misunderstanding as to when a case would be considered for Commission review. In the preamble to these proposed rules, the Commission stated that the decision to place a case under E–Z Trial would only be reviewed when the losing party can show that they have been materially prejudiced either by the use of E–Z Trial rather than conventional proceedings or by a lack of due process during those proceedings, provided objections to use the E–Z Trial procedure were raised in a timely fashion to the Judge. This limitation is intended to apply strictly to those instances where a party seeks review of the *decision* to place the case under E–Z Trial and, in no way, is intended to limit the availability of Commission review for any other allegation of error.

Other Issues

1. Effect of E–Z Trial on Settlement

The Secretary expressed the serious concern that the availability of E–Z Trial may have the unintended consequence of reducing the percentage of cases that settle before hearing. The Secretary pointed out that requiring parties to examine the merits of their case when responding to pleadings, and the very requirement that responses be filed often serve as inducements to settlement. By eliminating pleadings, the Secretary suggests that it will become easier for employers to simply let their cases drift toward a hearing. According to the Secretary, many of the benefits sought by E–Z Trial could be achieved through the simple expedient of extending the deadline for the filing of the complaint. This, he argues, would allow the parties more time for settlement negotiations and the drafting, execution and submission of settlement documents.

The Commission shares the Secretary's concern. The Commission

always has sought to encourage the amicable settlement of its cases. In no way do we desire to undermine this goal. It is the Commission's hope that by directing the Judge to take an active role in narrowing and defining the issues at the pre-hearing conference, parties will be more likely, not less likely, to determine that settling their cases rather than going to a hearing is in their best interest. The Commission would also stress to *pro se* employers, and would expect its Judges to transmit this point during the pre-hearing conference, that E–Z Trial only cuts out some procedural red tape and does not imply that it will be easier for employers to prevail in their contests. Nonetheless, we are acutely aware that a reduction in settlements may be an unintended consequence of E–Z Trial. This is a major reason for the pilot nature of this project. We will be watching this issue closely for the duration of the pilot project.

2. Convert into Mini-Trial Pilot

The Secretary suggested that the Commission convert E–Z Trial into a mini-trial pilot where a party could request a *de novo* proceeding under conventional rules before the Judge. The Secretary opines that this would give the small employer an opportunity to state its case to the Judge while protecting the interests of the litigants when they believe that their case could only be adequately presented under conventional proceedings.

The Commission finds no merit in this proposal. It is the Commission's opinion that in most cases the Secretary's proposal would amount to little more than giving the parties a ''second bite of the apple,'' and would further strain the Commission's limited resources. In some cases, the parties can invoke the Commission's settlement Judge rule, § 2200.101, to accomplish the same result. The purpose of E–Z Trial is to streamline and shorten the adjudicatory process; not to lengthen the process by giving every losing party an opportunity to retry their case.

The Secretary also suggested that, given the streamlining of the adjudicatory process, Judges' decisions rendered after E–Z Trial should have no precedential value. However, unreviewed opinions of Judges do not presently constitute precedent binding on the Review Commission. An unreviewed Judge's decision issued after an E–Z Trial would likewise not be binding on the Commission. Conversely, a Commission decision would have precedential value whether it resulted from E–Z Trial proceedings or regular proceedings. Additionally, if on review the Commission is of the view that due process had not been adequately provided, the case could be remanded to the Judge.

3. Grandfather Clause

One commentator suggested exempting those who currently practice before the Commission from having their cases assigned to E–Z Trial. We find no purpose to be served by granting an exemption to anyone who has previously represented parties before the Commission. E–Z Trial is designed to benefit parties, not their representatives. It would countermand the purpose of E–Z Trial to force a party to have a conventional proceeding for no reason other than its choice of legal representative.

List of Subjects in 29 CFR Part 2200

Administrative practice and procedure, Hearing and appeal procedures.

For the reasons set forth in the preamble, the Occupational Safety and Health Review Commission amends Title 29, Chapter XX, Part 2200 of the Code of Federal Regulations as follows:

PART 2200—RULES OF PROCEDURE

1. The authority citation continues to read as follows:

Authority: 29 U.S.C. 661(g).

2. Subpart M is revised to read as follows:

Subpart M—E–Z Trial

Sec.
2200.200 Purpose.
2200.201 Application.
2200.202 Eligibility for E–Z Trial.
2200.203 Commencing E–Z Trial.
2200.204 Discontinuance of E–Z Trial.
2200.205 Filing of pleadings.
2200.206 Disclosure of Information.
2200.207 Pre-hearing conference.
2200.208 Discovery.
2200.209 Hearing.
2200.210 Review of Judge's decision.
2200.211 Applicability of Subparts A through G.

Subpart M—E–Z Trial

§ 2200.200 Purpose.

(a) The purpose of the E–Z Trial subpart is to provide simplified procedures for resolving contests under the Occupational Safety and Health Act of 1970, so that parties before the Commission may reduce the time and expense of litigation while being assured due process and a hearing that meets the requirements of the Administrative Procedure Act, 5 U.S.C. 554. These procedural rules will be applied to accomplish this purpose.

(b) Procedures under this subpart are simplified in a number of ways. The major differences between these procedures and those provided in subparts A through G of the Commission's rules of procedure are as follows.

(1) Complaints and answers are not required.

(2) Pleadings generally are not required. Early discussions among the parties and the Administrative Law Judge are required to narrow and define the disputes between the parties.

(3) The Secretary is required to provide the employer with certain informational documents early in the proceeding.

(4) Discovery is not permitted except as ordered by the Administrative Law Judge.

(5) Interlocutory appeals are not permitted.

(6) Hearings are less formal. The Federal Rules of Evidence do not apply. Instead of briefs, the parties will argue their case orally before the Judge at the conclusion of the hearing. In many instances, the Judge will render his or her decision from the bench.

§ 2200.201 Application.

(a) The rules in this subpart will govern proceedings before a Judge in a case chosen for E–Z Trial under § 2200.203.

(b) *Sunset Provision.* Section 2200.203(a), which permits the Chief Administrative Law Judge to assign a case for E–Z Trial, will no longer be effective after September 30, 1996 unless the rule is extended by the Commission by publication of a final rule in the Federal Register. After September 30, 1996, a case will only be assigned to E–Z Trial if the assignment is requested by a party.

§ 2200.202 Eligibility for E–Z Trial.

Those cases selected for E–Z Trial will be those that do not involve complex issues of law or fact. Cases appropriate for E–Z Trial would generally include those with one or more of the following characteristics:

(a) relatively few citation items,

(b) an aggregate proposed penalty of not more than $10,000,

(c) no allegation of willfulness,

(d) a hearing that is expected to take less than two days, or

(e) a small employer whether appearing *pro se* or represented by counsel.

§ 2200.203 Commencing E–Z Trial.

(a) *Selection.* Upon receipt of a Notice of Contest, the Chief Administrative Law Judge may, at his or her discretion, assign an appropriate case for E–Z Trial.

(b) *Party request.* Within twenty days of the notice of docketing, any party may request that the case be assigned for E–Z Trial. The request must be in writing. For example, ''I request an E–Z Trial'' will suffice. The request must be sent to the Executive Secretary. Copies must be sent to each of the other parties.

(c) *Judge's ruling on request.* The Chief Judge or the Judge assigned to the case may grant a party's request and assign a case for E–Z Trial at his or her discretion. Such request shall be acted upon within fifteen days of its receipt by the Judge.

(d) *Time for filing complaint or answer under § 2200.34.* If a party has requested E–Z Trial or the Judge has assigned the case for E–Z Trial, the times for filing a complaint or answer will not run. If a request for E–Z Trial is denied, the period for filing a complaint or answer will begin to run upon issuance of the notice denying E–Z Trial.

§ 2200.204 Discontinuance of E–Z Trial.

(a) *Procedure.* If it becomes apparent at any time that a case is not appropriate for E–Z Trial, the Judge assigned to the case may, upon motion by any party or upon the Judge's own motion, discontinue E–Z Trial and order the case to continue under conventional rules. Before discontinuing E–Z Trial, the Judge will consult with the Chief Judge.

(b) *Party Motion.* At any time during the proceedings any party may request that the E–Z Trial be discontinued and that the matter continue under conventional procedures. A motion to discontinue must be in writing and explain why the case is inappropriate for E–Z Trial. All other parties will have seven days from the filing of the motion to state their agreement or disagreement and their reasons. Joint motions to return a case to conventional proceedings shall be granted by the Judge and do not require a showing of good cause.

(c) *Ruling.* If E–Z Trial is discontinued, the Judge may issue such orders as are necessary for an orderly continuation under conventional rules.

§ 2200.205 Filing of pleadings.

(a) *Complaint and answer.* Once a case is designated for E–Z Trial, the complaint and answer requirements are suspended. If the Secretary has filed a complaint under § 2200.34(a), a response to a petition under § 2200.37(d)(5), or a response to an employee contest under § 2200.38(a), and if E–Z Trial has been ordered, no response to these documents will be required.

(b) *Motions.* A primary purpose of E–Z Trials is to eliminate, as much as possible, motions and similar documents. A motion will not be viewed favorably if the subject of the motion has not been first discussed among the parties.

§ 2200.206 Disclosure of Information.

(a) *Disclosure to employer.* Within 12 working days after a case is designated for E–Z Trial, the Secretary shall provide the employer, free of charge, copies of the narrative (Form OSHA 1–A) and the worksheet (Form OSHA 1–B), or the equivalent. The Judge shall act expeditiously on any claim by the employer that the Secretary improperly withheld or redacted any portion of the documents on the grounds of confidentiality or privilege.

(b) *Disclosure to the Secretary.* Where the employer raises an affirmative defense, the presiding Judge shall order the employer to disclose to the Secretary such documents relevant to the affirmative defense as the Judge deems appropriate.

§ 2200.207 Pre-hearing conference.

(a) *When held.* As early as practicable after the employer has received the documents set forth in § 2200.206(a), the presiding Judge will order and conduct a pre-hearing conference. At the discretion of the Judge, the pre-hearing conference may be held in person, or by telephone or electronic means.

(b) *Content.* At the pre-hearing conference, the parties will discuss the following: settlement of the case; the narrowing of issues; an agreed statement of issues and facts; defenses; witnesses and exhibits; motions; and any other pertinent matter. Except under extraordinary circumstances, any affirmative defenses not raised at the pre-hearing conference may not be raised later. At the conclusion of the conference, the Judge will issue an order setting forth any agreements reached by the parties and will specify in the order the issues to be addressed by the parties at the hearing.

§ 2200.208 Discovery.

Discovery, including requests for admissions, will only be allowed under the conditions and time limits set by the Judge.

§ 2200.209 Hearing.

(a) *Procedures.* As soon as practicable after the conclusion of the pre-hearing conference, the Judge will hold a hearing on any issue that remains in dispute. The hearing will be in accordance with Subpart E of these rules, except for §§ 2200.73 and 2200.74 which will not apply.

(b) *Agreements.* At the beginning of the hearing, the Judge will enter into the record all agreements reached by the parties as well as defenses raised during the pre-hearing conference. The parties and the Judge then will attempt to resolve or narrow the remaining issues. The Judge will enter into the record any further agreements reached by the parties.

(c) *Evidence.* The Judge will receive oral, physical, or documentary evidence that is not irrelevant, unduly repetitious or unreliable. Testimony will be given under oath or affirmation. The Federal Rules of Evidence do not apply.

(d) *Reporter.* A reporter will be present at the hearing. An official verbatim transcript of the hearing will be prepared and filed with the Judge. Parties may purchase copies of the transcript from the reporter.

(e) *Oral and written argument.* Each party may present oral argument at the close of the hearing. Post-hearing briefs will not be allowed except by order of the Judge.

(f) *Judge's decision.* Where practicable, the Judge will render his or her decision from the bench. In rendering his or her decision from the bench, the Judge shall state the issues in the case and make clear both his or her findings of fact and conclusions of law on the record. The Judge shall reduce his or her order in the matter to writing and transmit it to the parties as soon as practicable, but no later than 45 days after the hearing. All relevant transcript paragraphs and pages shall be excerpted and included in the decision. Alternatively, within 45 days of the hearing, the Judge will issue a written decision. The decision will be in accordance with § 2200.90. If additional time is needed, approval of the Chief is required.

(g) *Filing of Judge's decision with the Executive Secretary.* When the Judge issues a written decision, it shall be filed simultaneously with the Commission and the parties. Once the Judge's order is transmitted to the Executive Secretary, § 2200.90(b) applies, with the exception of the 21 day period provided for in rule § 2200.90(b)(2).

§ 2200.210 Review of Judge's decision.

Any party may petition for Commission review of the Judge's decision as provided in § 2200.91. After the issuance of the Judge's written decision or order, the parties may pursue the case following the rules in Subpart F.

§ 2200.211 Applicability of Subparts A through G.

The provisions of Subpart D (except for § 2200.57) and §§ 2200.34, 2200.37(d)(5), 2200.38, 2200.71, 2200.73 and 2200.74 will not apply to E–Z Trials. All other rules contained in Subparts A through G of the Commission's rules of procedure will apply when consistent with the rules in this subpart governing E–Z Trials.

Dated: August 8, 1995.

Earl R. Ohman, Jr.,

General Counsel.

[FR Doc. 95–19975 Filed 8–11–95; 8:45 am]

BILLING CODE 7600–01–M

DEPARTMENT OF COMMERCE

Assistant Secretary for Technology Policy

37 CFR Part 401

[Docket No. 950615153–5153–01]

RIN 0692–AA14

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements; Electronic Filing of Written Submissions; Definition of the Term ''Patent Application'' or ''Application for Patent''

AGENCY: Assistant Secretary for Technology Policy, Commerce.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule (1) authorizes certain government contractors and grantees to report electronically to the funding agencies their inventions and respective election of title on agency-approved systems; (2) recognizes that the law now authorizes the filing of provisional U.S. patent applications by defining the term ''patent application'' or ''application for patent'' to include provisional patent applications; and (3) updates the name and address of the office to where all submissions and inquiries should be sent.

Federal agencies each year enter into many research funding agreements with nonprofit organizations and small business firms, which require them to submit written reports and other information to the agencies relating to inventions made under the funding agreements. The reports and information must then be manually processed by the agencies. A number of these contractors, grantees and agencies have established computer systems for keeping track of their inventions. It is desirable to utilize these systems to facilitate the invention reporting requirements by permitting contractors and grantees to submit reports and information to the agencies in electronic form. This would result in a reduction of time, paper and postage for the contractors and grantees and allow the agencies to more easily keep track of the inventions.

DATES: Interim rule effective August 14, 1995; comments must be received on or before September 13, 1995.

ADDRESSES: Comments may be mailed to Mr. Jon Paugh, Director, Technology Competitiveness Staff, Office of Technology Policy, Room 4418, Herbert C. Hoover Building, U.S. Department of Commerce, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Paugh at telephone: (202) 482–2100.

SUPPLEMENTARY INFORMATION: Under the authority of 35 U.S.C. 206 and the delegation by the Secretary of Commerce in sec. 3(g) of DOO 10–18, the Assistant Secretary of Commerce for Technology Policy may issue revisions to 37 CFR Part 401.

Under the rule now in effect, contractors and grantees must report in writing to the funding agencies their inventions and respective election of title. They may also be required to indicate if an invention was not made. The reports are then manually placed by the agencies in their respective contract or grant files, a very burdensome and time consuming task.

Therefore, in order to facilitate reporting by contractors and grantees, new §§ 401.16 (a) and (b) are being added to 37 CFR Part 401 to authorize certain government contractors and grantees to report electronically to the funding agencies their inventions and respective election of title on agency-approved electronic or optical-electronic systems. These changes will help the agencies to maintain an up-to-date record of government-funded inventions which can be used to automatically track the status of these inventions so that rights in valuable inventions are not inadvertently lost.

New § 401.16(c) is being added to authorize a government contractor and grantee to electronically submit the close-out report in § 401.5(f)(1) and the information identified in §§ 401.5(f) (2) and (3), which at the present time, although not required, are usually submitted in writing to the agencies.

This rule change does not require contractors and grantees to electronically report their inventions to the Federal agencies and some may wish to continue to communicate in writing. However, since a number of contractors and grantees have established computer systems to track their own inventions, it is expected that they would be interested in reporting their inventions electronically to the agencies. For this purpose, an electronic system named ''EDISON'' is being developed by the Division of Extramural Invention Reporting of the National Institutes of Health which will allow various contractors and grantees to submit certain information on their inventions by computer to the agencies. For information on EDISON, Sue Ohata, Acting Director, Division of Extramural Invention Reporting, NIH may be contacted at (301) 402–0850, by fax (301) 480–8443 or by e-mail at ohata@NIHOD1.bitnet.

New paragraphs (k) and (l) are being added to § 401.2 in order to define the terms ''electronically filed'' and ''electronic or optical-electronic system'' which are used in the new § 401.16.

Section 401.2(j) is being amended to define the term ''Secretary'' as the Assistant Secretary of Commerce for Technology Policy to conform with the authority citation for 37 CFR Part 401.

Public Law 103–465 amended 35 U.S.C. 111 to provide for the filing of provisional applications on or after June 8, 1995. To reflect this change in the law, the Patent and Trademark Office (PTO) amended 37 CFR Parts 1 and 3 to cover these provisional applications as indicated in the **Federal Register**, 60 FR 20195, April 25, 1995. The changes to 35 U.S.C. 111 and 37 CFR Parts 1 and 3 also affected 37 CFR Part 401. Accordingly, new paragraph (m) is being added to § 401.2 to recognize these changes by defining the term ''patent application'' or ''application for patent'' to include a provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

New paragraph (n) is being added to § 401.2 to define the term ''initial patent application'' as a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3) to make it clear that the requirements stated in paragraph (c) of the standard clause at § 401.14(a) and in paragraph (c) of § 401.13 are not being changed. These paragraphs are based on 35 U.S.C. §§ 202(c) and 205, respectively, which refer to a U.S. national patent application filed under 35 U.S.C. 111 before it was amended by the Uruguay Round Agreements Act (Public Law 103–465).