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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis contributions and comments are invited.

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Participating Effectively in TRR Proceedings at the FTC

By JOEL E. HOFFMAN

Mr. Hoffman Is a Member of the Law Firm of Wald, Harkrader & Ross.

UNDER THE MAGNUSON-MOSS WARRANTY/FEDERAL TRADE COMMISSION IMPROVEMENT ACT OF 1975,[1] the Federal Trade Commission (FTC) is empowered to promulgate binding and enforceable Trade Regulation Rules (TRRs) declaring business practices to be unfair or deceptive. The food and drug industries are already embroiled in four of the new rulemaking proceedings. These would require affirmative disclosure of nutritional information in food advertising,[2] restriction to FDA-approved claims in advertising for over-the-counter (OTC) drugs,[3] affirmative disclosure of warnings in OTC antacid drug advertising[4] and a variety of restrictions and affirmative disclosures (including a "crepe label") in the advertising and labeling of protein supplements.[5] Many more such proceedings can be expected, especially in the OTC drug industry as the 25 or more monographs resulting from FDA's monumental OTC Drug Review are issued.[6]

While the new Act provides stronger sanctions for violations of FTC rules, however,[7] it also offers extensive new rights of participation in

[1] 88 Stat. 2183 (1975).

[2] 40 *F. R.* 23086 (May 28, 1975).

[3] 40 *F. R.* 52631 (Nov. 11, 1975).

[4] 41 *F. R.* 14534 (Apr. 6, 1976).

[5] 40 *F. R.* 41144 (Sept. 5, 1975). See also the proposed TRR's on prescription drug prices (40 *F. R.* 24031 (June 4, 1975)), on hearing aids (40 *F. R.* 26646 (June 24, 1975)) and on prescription eyeglasses (41 *F. R.* 2399 (Jan. 16, 1976)).

[6] See O'Keefe, Daniel F., Jr., 29 FOOD DRUG COSMETIC LAW JOURNAL (May, 1974).

[7] Under the new law, TRR violations by any industry member immediately expose him to court proceedings entailing

(Continued on next page.)

the Commission's rulemaking proceedings. The purpose of this paper is to describe the FTC's TRR procedures and to offer suggestions on effective participation.[8]

Rights of Participation in TRR Proceedings

The novel procedures mandated by Congress for the formulation of TRR's are built around so-called "informal" hearings (15 U. S. C. §§ 57a(b) and (c)), making TRR proceedings a cross between the traditional notice-and-comment rulemaking prescribed by the Administrative Procedure Act[9] and trial-type proceedings such as those required under § 701(e) of the Federal Food, Drug, and Cosmetic Act.[10] TRR proceedings are distinguished from notice-and-comment proceedings by: (1) mandatory public evidentiary hearings; (2) an opportunity to engage in (or to have the Presiding Officer conduct on behalf of participants) examination and cross-examination of witnesses; and (3) judicial review to ensure that each Rule is supported at least by substantial evidence. Unlike trial-type rulemaking, Magnuson-Moss proceedings are characterized by the absence of (1) formal rules of evidence, (2) testimony under oath, or (3) unlimited cross-examination.

Like many new statutory schemes, Magnuson-Moss leaves questions unanswered. The FTC has promulgated regulations to implement the statutory framework (16 CFR § 1.11 and following), but they put little flesh on the skeletal statute. The FTC's current practice provides interim answers to some outstanding questions however, and pointers can be gleaned on how to proceed.[11]

(Footnote 7 continued.)
extensive potential liability—including rescission or reformation of contracts, a refund of money, return of property, and payment of damages (15 U. S. C. § 57b(b))—and civil penalties of up to $10,000 for each day of violation (15 U. S. C. § 45(m)(1)(A) and (C)). Moreover, Magnuson-Moss abandoned the previous jurisdictional limitation confining the FTC to acts and practices "in" interstate commerce, and extended the FTC's jurisdiction to acts and practices "affecting" interstate commerce as well. (§ 201, 88 Stat. 2193 (1975), amending 15 U. S. C. §§ 45, 52.)

[8] In the interest of full disclosure, the author notes that his firm is participating on behalf of affected industry members in the TRR proceedings on OTC drug advertising, on antacid drug advertising, and on vocational school advertising.

[9] 5 U. S. C. § 553.

[10] 21 U. S. C. § 371(e); 5 U. S. C. §§ 553(c), 556, 557.

[11] Statements herein regarding the FTC's rulemaking practice, if not cited to a specific authority or to the record in one of the on-going rulemaking proceedings, are based on the experience of the author's firm in the over-the-counter drug, antacid, and vocational school proceedings, as well as on discussions with members of the FTC staff and the private bar involved in other proceedings.

Any "interested person" may participate in TRR proceedings (15 U. S. C. § 57a(c)(1); 16 CFR § 1.11). This includes not only affected business firms and trade associations, but consumer groups as well. Moreover, the Magnuson-Moss Act establishes a fund from which the Commission may provide compensation for the costs of participation to any party that lacks the resources effectively to participate and that has a material interest not already represented (15 U. S. C. § 57a(h); 16 CFR § 1.17). Reimbursable costs include costs of surveys and studies. and fees for expert witnesses and attorneys.

While these funds are intended primarily for consumer representatives —and are apparently breathing new life into organized consumer groups— businesses that would be regulated by a proposed Rule are eligible for up to 25 percent of the funds disbursed by the FTC each year (15 U. S. C. § 57a(h)(2)). The Commission is said to be receptive to industry applications. Small businesses as well as large may play a constructive role in FTC rulemaking, particularly in view of the statutory command that FTC "[take] into account the effect [of a rule] on small business * * *." (15 U. S. C. § 57a(d)(1); 16 CFR § 1.14(a)).

As of January 1977, the FTC has obligated more than $792,000 to over twenty groups participating in TRR proceedings. Roughly $30,000 of this has been obligated to the National Hearing Aid Dealers' Association, the only industry group ever to apply for funding. In the food nutrition advertising proceeding, funds were awarded to three separate organizations as representatives of consumer interests. A total of $61,000 has been divided among three consumer groups in the OTC drug advertising proceeding.

For a participant in a TRR proceeding, the first decision to be made is the appropriate level of participation. Written comments and direct testimony might be submitted on each of the basic issues framed by the Presiding Officer.[12] Or, comments or testimony can be confined to those issues on which the client's interests differ from those of other participating parties. Or, an effort can be made to affect the designation of issues in the proceeding; to investigate, evaluate, and controvert the positions of the staff; to cross-examine adverse witnesses at the hearing; and to analyze and comment on post-hearing findings and conclusions.

It is difficult to provide general criteria for the appropriate participation level for different parties. Some of the factors to be considered

[12] Of course, more weight may be given to oral testimony—which is subject to cross-examination—than to the written record.

are: (1) whether others will vigorously represent the client's general interests; (2) whether the client has a perspective or position on the proposed rule not shared by others; (3) the number and variety of other participants; and, of course, (4) the client's own resources. Even if a decision is made to rely primarily on representation by others, however, there may be a substantial value in actively assisting and cooperating with them.

In the OTC drug advertising proceedings The Proprietary Association has taken the leading role, although several member manufacturers are providing supplementary comments and testimony. The advertising and broadcast industries are also participating. A similar pattern is found in the food nutrition advertising proceeding, where the Grocery Manufacturers of America, Inc. (GMA) has taken the lead while the allied industries have separately voiced their special perspectives.

The Initial Notice

A TRR proceeding begins with an "Initial Notice" published in the *Federal Register* and publicized through the FTC's normal channels. It is not uncommon to find, however, that the FTC staff, affected industry associations, and consumer groups have discussed the general problems sought to be resolved by the Rule prior to the first Notice.

The Initial Notice[13] generally contains: (1) the proposed Rule; (2) a brief statement of the reasons why the Commission believes the rule is necessary; (3) "Questions" drawing the public's attention to issues which the FTC considers particularly pertinent and on which comment is especially solicited; (4) an invitation to all interested persons to propose "disputed issues of specific fact"; and (5) an invitation to submit written comments on any issue of fact, law, or policy which may have some bearing upon the proposed Rule.[14]

One notable exception to this is the proposal on disclosure of warnings in OTC antacid drug advertising, which contained not a

[13] See 16 CFR § 1.11; 15 U. S. C. § 57a(b).

[14] These are the type of comments traditionally submitted in standard notice-and-comment rulemaking such as under § 701(a) of the Food, Drug, and Cosmetic Act (21 U. S. C. § 371(a)), and need not be further discussed here. The FTC's current practice is to announce that it will close the written comment period 45 days before hearings begin, which date will be announced subsequent to the Initial Notice. The uncertainty of the closing date requires that the proceeding be closely followed and the timing of a filing carefully planned, as developments after an early filing may cause a party to rethink its strategy. Extensions of filing dates are frequently granted, thus adding to the period in which the situation may change. See 16 CFR § 1.13(c)(1)(iii).

Rule but a list of topics upon which the Commission sought comment prior to formulation of a Rule. A similar course was followed in the food nutrition advertising proceeding,[15] where the Commission set out, in addition to a detailed proposed Rule, numerous staff proposals on which it also invited discussion.[16]

The first opportunity for participation is in the development of the list of factual issues in dispute. Sixty days are usually provided within which to file a Proposal Identifying Issues of Specific Fact, which the Presiding Officer will consider in preparing the final list of disputed issues. This list includes any issues determined to be "material and necessary to resolve" in the proceeding, and may, in the Commission's discretion, include any other issues (16 CFR § 1.13(d)(1)). Since the FTC's catalogue of disputed issues may serve as a basis for determining right to cross-examination, rebuttal submissions and compulsory process,[17] a proposed list of disputed issues should include everything you may later wish to explore.[18]

Despite the obvious importance of the process, however, the Commission has failed woefully in giving guidance as to how to identify disputed issues. Their proposal and selection has therefore been somewhat arbitrary. There are no standards for materiality or level of generality; no indication of the pertinence of elements of policy or "legislative facts"; no explanation of what issues are "necessary

[15] 41 *F. R.* 14534, 14535 (April 6, 1976) (antacids); 39 *F. R.* 39842 (Nov. 11, 1974), republished, 40 *F. R.* 23086 (May 28, 1975) (food).

[16] By thus consulting affected parties in advance, the Commission may be able to avoid taking unwise or impractical positions before adversary relationships harden. On the other hand, the less concrete the specifics of a proposed Rule, the greater the possibility that the proceeding will later be found to have been fatally flawed for lack of proper notice of the ultimate action—an issue already being pressed with vigor in the food nutrition advertising proceeding. The argument is that Magnuson-Moss requires the Commission to propose a specific Rule, so that after comments are received on the general issues proposed for discussion, a complete new Magnuson-Moss proceeding on a specific Rule will be required in any event, thus making the initial request for comments oppressive, unnecessary and unauthorized. See Petition of ANA to Expunge in the food nutrition advertising proceeding, June 28, 1976, pp. 1-2.

[17] 16 CFR §§ 1.13(d)(5) and (6); see 15 U. S. C. § 57a(c)(1)(B). In practice, however, cross-examination and written rebuttal have been allowed without regard to the designated issues, which by and large have been stated with extreme generality.

[18] The disputed issues may of course also serve to educate the Presiding Officer, to clarify the scope and direction of the proceeding throughout and, although not specifically so provided by statute or rule, to indicate issues on which the Commission has the burden of proof as proponent of the Rule. Compare 15 U. S. C. §§ 57a(d)(1) and (e)(3); 16 CFR §§ 1.13(f) and 1.14(a).

to resolve"; no clue to the kind of issue the Commission considers appropriate for cross-examination.

In the OTC drug advertising proceeding the participants proposed as many as 24 disputed issues[19] while the staff proposed four.[20] The Presiding Officer designated only three, basically adopting the staff's proposal. The Commission subsequently affirmed the Presiding Officer's decision, but invited comment on seven other points not mentioned in the Final Notice.[21] In the antacid warning proceeding the participants proposed as many as 45 issues[22] and the staff only four. And in so doing, the staff declined to indicate which of these four were "necessary to resolve" and which were not.[23] In contrast, participants in the food nutrition advertising proceeding are wrestling with 27 designated disputed issues of fact; a full 157 had been proposed.[24]

The Commission staff has argued that proposers of issues should be required to proffer evidence showing that each proposed issue is in fact disputed. In the OTC drug advertising proceeding, the argument is articulated as follows:

> "We believe that to establish the existence of a dispute a party must make at least a minimal factual showing or an offer of proof sufficient to provide the Presiding Officer with an indication that there is evidence which challenges a basis for the proposed rule or a provision thereof. This will provide the Presiding Officer with some basis for determining whether the criteria of § 1.13(d)(1)(i) of the Rules have been satisfied."[25]

That position has not been pressed upon the Commission, and the practice of private participants has been simply to list proposed issues. Nevertheless, in some circumstances it might be prudent to accompany the list with sufficient references to existing factual material or proposed factual development at the hearing to demonstrate to an observer unfamiliar with the industry—that is, the Presiding Officer—the existence of a true evidentiary dispute.[26]

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[19] Proposal of The Proprietary Association Identifying Issues of Fact, Mar. 12, 1976.

[20] Memorandum from Cynthia Ingersoll, staff attorney, to Roger Fitzpatrick, Presiding Officer, June 10, 1976.

[21] 41 *F. R.* 53355 (Dec. 6, 1976).

[22] Proposal of Plough, Inc., Identifying Issues of Fact, June 11, 1976.

[23] Memorandum from Cynthia Ingersoll, staff attorney, to Raymond Rhine, Presiding Officer, Oct. 6, 1976. There is not yet a Final Notice designating the issues in that proceeding.

[24] 41 *F. R.* 8980 (Mar. 2, 1976). See Proposal of Ass'n of National Advertisers, Inc., Identifying Issues of Specific Fact, July 24, 1975.

[25] Memorandum from Cynthia Ingersoll, staff attorney, to Roger Fitzpatrick, Presiding Officer, June 10, 1976, p. 8 (footnote omitted).

[26] Note that if inspection of other participants' proposed issues—or submissions of any sort (but see note 45 *infra*)—is desired, unless special arrangements are made with those filing the

(Continued on the next page.)

Preparation: The First Phase

In preparing evidence and arguments for written comments and oral testimony and in selecting witnesses for the hearings, the "Staff Statement" in particular deserves an early review. This document sets forth the views of the staff prosecuting the Rule on (1) the nature of the abuses to which the Rule is addressed and, (2) the manner in which the Rule is intended to remedy the abuses. While the FTC included the Staff Statement in the Initial Notice in the food nutrition advertising proceeding, it does not generally follow this practice and it is up to counsel to obtain a copy of the document, which is usually placed on the Public Record within a few weeks of the issuance of an Initial Notice.[27]

The Public Record (available for inspection at the FTC in Washington, D. C.), is the repository for the factual material gathered and relied upon by the FTC staff prosecuting the Rule. The Commission has directed that, "absent special circumstances warranting a different course," all evidentiary material considered in the formulation of a proposed TRR should be placed on the Public Record (*FTC Operating Manual,* ch. 8, ¶ .7 (1971)).[28] This Commission directive is generally ignored, however, and the filing of a Freedom of Information (FOI) Act[29] request to compel disclosure of all material in the possession of the FTC relating to the proposed Rule has now become standard operating procedure by those who are fully participating in the proceeding.

The Commission has recently proposed an amendment to its TRR Rules of Practice that would formally require such material to be placed on the Public Record at the beginning of the proceeding or as

(Footnote 26 continued.)
proposals it will be necessary to consult the Public Record. The rulemaking procedures have no provision for service (although the staff prosecuting the Rule automatically receives copies of all documents filed by private parties). But the procedures should be sufficiently flexible in practice to permit such matters as this to be remedied by formal or informal requests to other parties or the Presiding Officer. See 16 CFR § 1.13(c)(1).

[27] The Staff Statement focuses primarily on the legal theory underlying the rule. Citations to supporting evidence will probably be sketchy at best. Comprehensive documentation of the staff's case would be invaluable, permitting private parties to meet the staff on controverted issues in a direct and focused manner, and thus substantially contribute to the rational and expeditious progress of the proceeding.

[28] It should be noted that the Public Record in existing proceedings has been poorly organized and indexed, and neither the Staff Statement nor any other document has given a clue as to the way the staff intends to use the material on file. Thus, a review of the record—at any stage in the proceeding—may be of limited utility.

[29] 5 U. S. C. § 552. The FTC regulations implementing the Act appear at 16 CFR § 4.11.

soon thereafter as possible.[30] This would eliminate the need for FOI requests for that purpose. Material obtained or generated by the staff in the course of developing the Rule but not considered "relevant" so as to require inclusion in the Public Record will also be "publicly available."

The need for the proposed amendment was highlighted in the food advertising and antacid warning proceedings. In response to the ritual FOI requests, the staff there disclosed numerous memoranda of staff interviews with various physicians and scientists regarding the desirability of disclosing information in advertising. Yet, all of these individuals' names were blanked out. In the food proceeding, the case for disclosure had to be taken to court, and in the antacid proceeding an appeal to the Commission from the staff's refusal to fill in those blanks was necessary. Both prevailed.[31]

Such forays should be unnecessary, as the proposed amendments to the Rules of Practice recognize. It will expedite these proceedings substantially when the Staff Statement and all information and evidentiary material (both pro and con) obtained or generated in the course of developing the proposed Rule are placed in the Public Record "at the beginning of a rulemaking proceeding, or as soon as possible thereafter * * * ."[32] This is often done in rulemaking proceedings at the FDA, and the practice has worked well. The litigious posture heretofore assumed by the FTC staff on this aspect of TRR proceedings has done no more than assure a substantial amount of procedural fencing and motions practice, thereby producing substantial delay but no significant effect on the ultimate availability of the material involved.

The Final Notice

The Final Notice contains the Presiding Officer's list of disputed issues as well as the ground rules for the remainder of the proceeding. The Notice has generally been published from two weeks to six months after the submission of proposed disputed issues.

The Final Notice will include the detailed timetable for the remainder of the proceeding, instructions to would-be participants for

[30] 42 *F. R.* 2980 (Jan. 14, 1977), to amend 16 CFR § 1.18.

[31] *Ass'n of National Advertisers, Inc. v. FTC*, 1976-2 TRADE CASES ¶ 61,021 (D. D. C. 1976) (food). The antacid refusal was at first upheld, but this occurred contemporaneously with the district court's reversal of the Commission in the food proceeding, and without fanfare the staff thereafter produced new unexpurgated copies.

[32] 42 *F. R.* 2980 (Jan. 14, 1977) (preamble).

grouping themselves according to interest,[33] and—most importantly—the Presiding Officer's determination of the designated issues of disputed fact and a direction that participants who desire to conduct cross-examination on those issues at the hearing must, by a specified date (usually within 15 to 30 days), notify the Presiding Officer in writing of their interest and position with respect to each such issue. A recently emerging practice is for the Final Notice further to require that requests for cross-examination requests be "justified."[34]

The Notice of Interest and Position has typically been brief, focusing on the similarities and differences between the client's interest and position and the interest and position of other participants. Responding to the "justification" requirement regarding cross-examination has posed a dilemma: How to justify cross-examination of witnesses whose identity and testimony are not yet known. To date, participants have contented themselves with *pro forma* reiterations of the general desirability of cross-examination for eliciting a full and true disclosure of the facts. The effectiveness of requiring "justification" for cross-examination at this early stage is difficult to discern, and the Commission would do well to abandon the practice.

Soon after the filing of Notices of Interest and Position, the Presiding Officer will send a letter listing the groups into which participants have been divided and offering members of each group an opportunity themselves to select a representative.[35] The Presiding Officer will simply place his *imprimatur* on a representative agreed to by group members, and will name a representative for any group that cannot reach a consensus.[36]

This does not mean that the Presiding Officer selects your client's lawyer. The statute and regulations specifically provide that no participant shall be denied the right to examination or cross-examination if, after a good faith effort, agreement cannot be reached on a group represen-

[33] See 15 U. S. C. § 57a(c)(3)(A); 16 CFR § 1.13(d)(5)(ii).

[34] 16 CFR § 1.12. See, *e.g.*, the Notice in the OTC drug advertising proceeding, 41 *F. R.* 39768 (Sept. 16, 1976).

[35] The Presiding Officer may permit more than one person or firm to represent a group. He may, for example, permit different representation at hearings in different cities. However, such arrangements are disfavored due to problems of continuity.

[36] The FTC staff prosecuting the Rule will be assigned the status of a group representative and, at the hearing, will generally be treated like other group representatives (*e.g.*, for purposes of cross-examination). Overall, however, the staff has marked advantages over private parties, including easier access (*ex parte*) to the Presiding Officer and the Commission; the results of preproceeding investigations in which subpoena power was available; and the ear of the mass communications media.

tative. In such a case, the participant will be permitted appropriate examination and cross-examination on those designated issues that affect its particular interest.[37]

The selection of group representatives may be appealed to the Commission (16 CFR § 1.13(c)(2)(i)). First, however, both discretionary certification of the appeal by the Presiding Officer and permission to appeal from the Commission must be obtained. This is the procedure applicable to *any* interlocutory decision of the Presiding Officer.[38]

The one matter that may be appealed without certification by the Presiding Officer is the list of designated issues in the Final Notice. But even this appeal is permissive with the Commission itself. Within 10 days of publication of the Final Notice, any interested person may petition the Commission for addition, modification or deletion of a designated issue (16 CFR § 1.13(c)(2)(ii)). The appeal brief should show why the disputed issues on appeal are (or are not) material and necessary to resolve, that is, why cross-examination and rebuttal submissions on those issues should (or should not) be permitted. Of course the decision whether to file such an appeal will be influenced by the use to which it is anticipated the disputed issues will be put in the proceeding.

It is difficult to predict Commission action on such an appeal. As noted above, the standards for designating disputed issues are blurred. In the vocational school proceeding, an appeal was granted and 9 of 29 issues were deleted,[39] but the basis for the Commission's action was unarticulated and unfathomable, and bore no apparent relationship to the arguments raised by the parties to the appeal. The appeal in the OTC drug advertising proceeding did not result in any amendment of the issues, although in its order disposing of the appeal the Commission called for comments on seven additional questions not stated in the Final Notice.[40]

Publication of the Final Notice also triggers consideration of the need for compulsory process. The rules grant the right to petition the Presiding Officer to compel the attendance of persons at the hear-

[37] 15 U. S. C. § 57a(c)(3)(B); 16 CFR § 1.13(d)(5)(iii). A party seeking to preserve such a separate status would be well advised to make its position known to the Presiding Officer immediately upon receipt of the Presiding Officer's designation of representatives, although the rules do not specifically prohibit raising the matter at the hearing when examination or cross-examination is actually sought.

[38] This is not to say that interlocutory relief might not be sought in an extraordinary case even if the Presiding Officer refuses to certify. See 16 CFR § 1.20; *cf.* 28 U. S. C. § 1651.

[39] See 40 *F. R.* 55368 (Nov. 28, 1975).

[40] See 41 *F. R.* 53355 (Dec. 6, 1976).

ings, the production of documents or responses to written questions (16 CFR § 1.13(d)(6)). Subpoena petitions must include a showing that the testimony or material sought is relevant, reasonable in scope, appropriate and required for full and true disclosure with respect to the designated issues and not available through other means. If, as was the case in the OTC drug advertising proceeding, other Federal agencies such as the FDA seek to prohibit testimony,[41] compulsory process may be the only way to get desired testimony on the record.[42] Experience teaches, however, that there is a Commission presumption against granting such requests.[43]

Commission policy on this and other procedural issues arising under Magnuson-Moss reflects a view that the development of a comprehensive record is ensured by the liberal and flexible procedures for the proceedings, the usually large number of participants, and the abandonment of rules of evidence, so that discovery, subpoenas, sworn testimony, and other formal procedures are therefore generally unnecessary. This view is reinforced by the correlative Commission view that adversary jousts with respect to specific and detailed facts will normally be unnecessary or unproductive in the context of the broad factual setting pertinent to rulemaking governing an entire industry—a view reminiscent of the FDA's.

Prehearing Conference

Although not mentioned in the statute or regulations, prehearing conferences have been convened in the proceedings that have reached the hearing stage. They have been informal and off the record, and are a convenient forum in which to settle certain procedural questions concerning the hearings, including the standards that must be met in filing witness statements.[44]

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[41] Memorandum from Robert G. Pinco, Director, Division of OTC Drug Evaluation, FDA, to All OTC Panel Members, Jan. 12, 1977.

[42] Order of Roger Fitzpatrick, Presiding Officer, Jan. 14, 1977 (denying request for postponement of hearing to permit negotiations toward a compromise with FDA).

[43] The substantial number of requests have all been denied.

[44] The OTC advertising Final Notice required the following:

"Any witness not intending to deliver a full text of his or her oral presentation in advance is required to file with [the designated Commission representative] a written comprehensive outline of the oral presentation.

"The full text of the oral presentation or the outline of oral presentation must include a statement of each important fact, observation, conclusion and opinion that the party anticipates presenting and must indicate the basis for each conclusion and opinion, insofar as possible." 41 *F. R.* 39768, at 39769 (Sept. 16, 1976).

Unduly vague outlines will be respected, albeit with leave to refile. See also note 52 *infra*.

The prehearing conference may be used to establish informal methods for exchange of documents.[45] It is also an appropriate forum for determining the ground rules for examination, cross-examination and rebuttal. For example, the Presiding Officer will probably be ready to advise counsel as to the types of witnesses whose cross-examination by counsel—as opposed to cross-examination by means of written questions submitted to the Presiding Officer—will be permitted.[46] He may also announce the circumstances in which he will require a "justification" for cross-examination, and the specific form the justification should take.[47]

Other issues which might be considered at a prehearing conference are: (1) the possibility of settlement;[48] (2) outstanding questions regarding group designations or representation; (3) requests for compulsory process; (4) whether any or all witnesses will testify under oath[49] (sworn testimony is not favored); and (4) the physical arrangement and facilities for the hearings.

Prehearing Preparation and the Hearing

A statement or outline of expected testimony for each prospective witness must be prepared and filed by the deadlines set forth in the Final Notice. There are obvious time savings in filing an outline of the nature of expected testimony as opposed to a full-text, prepared statement,[50] but a full statement may be tactically more advantageous. In any event, the FTC is pressing for more and more complete "outlines,"[51] and is even considering eliminating the outline option altogether.[52]

Witnesses should be prepared for these hearings as they would for any other hearing in which they would be subject to cross-examination.

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[45] See note 26 *supra*. A recent development in the OTC advertising proceeding is the staff's voluntary service of evidentiary documents on announced active participants. This can only be applauded.

[46] See 15 U. S. C. § 57a(c)(2); 16 CFR § 1.13(c)(1)(iv).

[47] See 16 CFR § 1.13(d)(5)(i).

[48] However, even if the major parties can agree on the form of a Rule, the Magnuson-Moss Act requires public hearings and opportunity for comment (15 U. S. C. § 57a(b)) and, even once adopted by the Commission, a Rule would be subject to appeal by any interested person (15 U. S. C. § 57a(e)(1)). The value of settlement would thus presumably be primarily to limit and streamline, rather than circumvent, a proceeding.

[49] 16 CFR § 1.13(c)(1)(vii).

[50] If witnesses file outlines, they may nevertheless read from a prepared statement at the hearing. If they file prepared statements, they may deviate from or modify their statement at the hearing.

[51] See note 44 *supra*.

[52] See 16 CFR § 1.13(c)(1)(viii). The Final Notice in the OTC advertising proceeding reserved to the Presiding Officer the option to require a full text for any witness prior to hearing if in his judgment "the written outline submitted is not sufficiently detailed or factual." 41 *F. R.* 39768, at 39769 (Sept. 16, 1976).

Witnesses are free, within very broad bounds, to address any factual or policy aspects of the proposed Rule and—without being qualified as experts—to present opinion testimony. Accordingly, they should also be prepared to confront wide-ranging cross-examination.

At the hearings to date, the Presiding Officer has generally barred questions going to the character and veracity of the witness. But the scope of permissible questioning has been more liberal than a narrow reading of the rules might permit. Traditional rules of evidence have been almost totally disregarded,[53] and witnesses have been permitted to give their testimony in narrative form, in response to questions by counsel, or both.

Group representatives or those otherwise entitled to cross-examine can begin to prepare for cross-examination as soon as the statements of proposed testimony become available. A well-directed prehearing interview program may turn up additional soft spots in the opposition, although interviews with opposing witnesses were specifically disapproved by the Presiding Officer in the vocational school proceeding.[54]

All participants, whether or not authorized to conduct cross-examination, may prepare rebuttal testimony (though they may be limited therein to the designated issues).[55] There is no reason to believe that any relevant *written* rebuttal will be rejected, but the limits on the Commission's discretion to receive material are being probed in the food nutrition advertising proceeding. The Presiding Officer was asked to expunge nearly 25,000 pages of testimony taken in FDA's vitamin-mineral proceeding which had been thrown into the TRR record by the FTC staff at the very conclusion of the hearing. Vociferous objections were raised on the ground that this amounted to an entire new record that would need to be commented upon by industry. FTC's failure to strike the FDA transcript is now before the courts.[56]

The allowance of *live* rebuttal witnesses is discretionary with the Presiding Officer. To date, rebuttal testimony has been handled in

[53] The Commission generally inclines to let all testimony into the record and to apply traditional evidentiary standards to its weight rather than to its admissibility.

[54] The Presiding Officer admonished parties against investigative contacts with adverse witnesses, and stated that he was prepared to question witnesses on the record about prehearing contacts by opposing counsel. Transcript, at 4072-77 (Dec. 5, 1975). This unconventional approach reflects the general FTC philosophy that participation in rulemaking proceedings should be informal and unintimidating so as to encourage the broadest possible participation by all affected persons.

[55] 16 CFR § 1.13(d)(5).

[56] *Ass'n of National Advertisers, Inc. v. FTC*, No. 76 Civ. 3277 (S. D. N. Y.).

various ways, depending on such factors as its importance, the availability of time and the advantage of an oral over a written presentation. Notice of any proposed rebuttal witnesses should be given as early as possible; scheduling might be requested immediately subsequent to the testimony to be rebutted, at the end of that day's hearing, or at the end of the hearings.

Cross-examination by group representatives (though not necessarily other parties) will probably be permitted without the "justification" mentioned in the regulations.[57] The Presiding Officer is likely to permit cross-examination by counsel—rather than insist on conducting cross-examination himself on behalf of a party—except in the case of witnesses he anticipates will be particularly vulnerable to intimidation (for example, student witnesses appearing at the vocational school hearings).[58] Time constraints may be stressed by the Presiding Officer, however, with the result that judgments may have to be made on the relative importance of various lines of attack. Cross-examination and rebuttal submissions by group representatives will probably not be confined to the designated issues[59] (although, as noted, "independent" parties may be treated more strictly).

Post-Hearing Procedures

After the hearings, the Presiding Officer prepares a summary of the written and oral record, with factual findings and conclusions on the designated issues and such other issues as he sees fit to discuss.[60]

[57] 16 CFR § 1.13(d)(5)(i).

[58] The FTC apparently recognizes that it is generally preferable for group representatives to conduct cross-examination. The Presiding Officer, even if he has had questions submitted by counsel in advance, is not as well equipped to ask follow-up questions and probe testimony in depth, and the conduct of cross-examination distracts him from his primary functions of evaluating the testimony and presiding over the hearing. The Presiding Officer can control cross-examination adequately by limiting its time, scope, and manner.

[59] This is surely a sound policy in that it eliminates time-consuming bickering over what issues *are* within the disputed issues, permits the maximum amount of evidence into the record (consistent with the full-and-open-record policy), and reduces the risk of reversal in the appellate courts. See 15 U. S. C. § 57a(e)(3)(B). Moreover, as indicated earlier, the selection of designated issues is by and large arbitrary and provides an unsound base for procedural control of the hearing.

[60] 16 CFR § 1.13(f). The Presiding Officer's report need not include recommendations for the final Rule. It is unfortunate that the Presiding Officer is not required to develop recommendations, since he might be expected to do so with a more balanced perspective than the prosecuting staff. However, the impartiality of the Presiding Officer himself is cast in doubt by the fact that he is a staff member within the FTC's Bureau of Consumer Protection, the Bureau from which is drawn the staff in support of the Rule, and that there are no prohibitions whatever

(Continued on the next page.)

Although there is no established procedure for the participants to submit proposed findings and conclusions prior to the Presiding Officer's report, there is no apparent reason why such a procedure for assisting the Presiding Officer to put the public record into some order could not be followed, especially if the record is left open for a designated period at the conclusion of the hearing.

The FTC staff prosecuting the Rule must make its own analysis of the record as well as recommendations for the form of the final Rule, taking into account the Presiding Officer's report.[61] That report is therefore made public first, followed by the staff's analysis and recommendations. The public then has 60 days to file written comments on both items.[62] If major Rule revisions have been proposed by the Presiding Officer, the staff or the parties, further hearings or opportunities for comment prior to final Commission action may be appropriate.

Finally, the Commission reviews the entire record and may issue, modify or decline to issue a Rule. A final TRR must be accompanied by a Statement of Basis and Purpose which includes a statement as to the prevalence of the acts or practices treated by the Rule and the extent to which such acts or practices are unfair or deceptive. The Statement must also evaluate the effect of the rule on state and local laws, and the economic effect of the Rule, taking into account the effect on small business and consumers.[63] In a provision of mystifying import, the Magnuson-Moss Act specifically exempts the Statement of Basis and Purpose (as opposed to the Rule itself) from judicial review.[64]

(Footnote 60 continued.)
on *ex parte* communications between the staff in support of the Rule and the Presiding Officer. (Private parties are also permitted *ex parte* contacts with the Presiding Officer, but these are not, as a practical matter, likely to have the same frequency or impact.) More properly, the Presiding Officer should be independent of the Bureau of Consumer Protection, *e.g.*, an Administrative Law Judge, and insulated from any substantive *ex parte* contacts. The American Bar Association's Section of Administrative Law so recommended when the FTC's procedures for implementing Magnuson-Moss were being formulated. *Ex parte* contacts with the Commission subsequent to the issuance of the Initial Notice, now permitted, should similarly be banned; such relief has been requested in the vocational school proceeding along with remedies for several other alleged procedural inadequacies. Application of Ass'n of Independent Colleges and Schools for Prohibition of Ex Parte Communications and Other Relief, Jan. 26, 1977.

[61] 16 CFR § 1.13(g).

[62] 16 CFR § 1.13(h).

[63] 16 CFR § 1.14(a).

[64] 15 U. S. C. § 57a(e)(5)(C).

Within 60 days of the promulgation of a Rule, any interested person may seek review in a federal court of appeals.[65] The rule is not, however, automatically stayed by the appeal.[66] The evidentiary standard for appellate review is the familiar "substantial evidence in the rulemaking record * * * taken as a whole * * *" (15 U. S. C. § 57a(e)(3)).

Conclusion

Magnuson-Moss rulemaking proceedings tend to be long, complex and unwieldy. Despite their failings, however, such proceedings now appear to be the wave of the future at the FTC where the food and drug industries are involved. In view of the profound impact TRRs will henceforth have on industry practices, and the opportunities that the Magnuson-Moss procedures offer for public participation in formulating a final Rule, affected firms run an unnecessary business risk in ignoring the FTC rulemaking process. The difficulties and expense of participating may be great, but the adverse consequences of not participating may be even greater. **[The End]**

[65] 15 U. S. C. § 57a(e)(1)(A). Review of the evidentiary basis of the rule under the Administrative Procedure Act, outside this special statutory proceeding, is *not* available. 15 U. S. C. § 57a-(e)(5)(C).

[66] *Cf.* 15 U. S. C. § 57a(e)(3). The Commission can look for supporting evidence outside the record developed below, see 15 U. S. C. § 57a(e)(1)(B), but any such additional evidence which the Commission considers must be included in the record on review in the courts. Compare 15 U. S. C. § 57a(e)-(1)(B) with § 57a(e)(3). It should be noted that any person to whom a final TRR applies may petition the Commission for an exemption therefrom. 15 U. S. C. § 57a(g)(1). The grounds for exemptions have not been articulated, but some guidance may be provided by pre-Magnuson-Moss case law. See, *e.g.*, *National Petroleum Refiners Ass'n v. FTC*, 482 F. 2d 672, 692 (D. C. Cir. 1973), *cert. denied*, 415 U. S. 951 (1974).

Submissions and Petitions Under the FDA's Procedural Regulations

By MICHAEL P. PESKOE*

Mr. Peskoe Is Associate Chief Counsel for Drugs, Food and Drug Administration.

MY REMARKS have been entitled "Submissions and Petitions." What I hope to do is to weave through Subpart A[1] of the Food and Drug Administration's (FDA's) administrative regulations to demonstrate how those regulations relate to the Agency's taking of regulatory action through the notice and comment provisions of Section 4 of the Administrative Procedure Act,[2] and Section 701(a) of the Food, Drug and Cosmetic Act.[3] In so doing, I plan to discuss at least briefly most of the sections of Subpart A. Other sections will be discussed by those persons sharing the podium. Together, hopefully, we will present an understandable and meaningful capsulated version of Subpart A both as an introduction to the Subpart and to provide some guidance to those who may have to deal more extensively with these provisions in the future.

Initiation of Administrative Proceedings

I would like to begin with the initiation of administrative proceedings as specified in Section 2.6.[4] Briefly, the section provides for the initiation of administrative action in three ways. First, by an interested person, who may petition the Commissioner to issue, amend or revoke a regulation or order, or take or refrain from taking any

* The opinions expressed in this article are those of the author and not necessarily those of the Food and Drug Administration.

[1] Subpart A was initially codified at 21 CFR §§ 2.1-2.25. On March 22, 1977 (42 *F.R.* 15223), as part of a complete recodification of Subchapter A of Food and Drug Administration regulations, Subpart A was reorganized and recodified at 21 CFR Part 10. The text of the speech as presented utilizes the old section numbers for convenience; new section numbers [all are 21 CFR] are indicated in the footnotes.

[2] 5 U. S. C. § 553.

[3] 21 U. S. C. § 371(a).

[4] Now § 10.25.

other form of administrative action. Such action would normally entail use of the citizen petition, requirements for which are set forth in Section 2.7,[5] and to which I will speak shortly. Apart from the initiation of administrative action by interested persons, Section 2.6[6] also provides for the initiation of administrative action by the Commissioner. This, in effect, is the way most of the Agency's informal rulemaking begins; that is, by an Agency-initiated proposed regulation that seeks either to take wholly new action, or seeks to amend or change an existing regulation. An adjunct to the Agency's own initiation of administrative action is the position expressed in Section 2.6 (b),[7] that the Agency expects that the initiation of matters within its jurisdiction will be first brought to its attention, prior to any person seeking a judicial remedy. Thus, the Agency will request a court to dismiss, or hold in abeyance, or refer to the Agency, any issue which has not previously been brought to the Agency for resolution. This should not be confused with the related matter of the exhaustion of administrative remedies, which is covered by Section 2.11,[8] and which generally relates to objections taken to administrative action that has already been taken. Here we are dealing simply with the Agency's insistence that it first be requested to take action which it is authorized to take, before any person seeks to have a court require the Agency to take such action.

The third way in which Agency action may be initiated is whenever a court, apart from any request by the Agency, holds in abeyance or refers a matter to the Agency for decision. The requirements governing the Agency's response to a referral by a court are covered in Section 2.14.[9] Briefly, they authorize the Commissioner to either accept or reject the referral and, if accepted, provide for the use of the various forms of administrative proceedings to resolve the matter.

Citizen Petition

The method by which interested persons officially request the Agency to take administrative action is through the use of the citizen petition. The citizen petition requirements are found in Section 2.7.[10] I would refer you particularly to the requirements for form and content which are set forth in Section 2.7(b).[11] They require a precise statement of the grounds or basis for the request and information on both environmental and inflationary considerations, although the

[5] Now § 10.30.
[6] Now § 10.25.
[7] Now § 10.25(b).
[8] Now § 10.45.
[9] Now § 10.60.
[10] Now § 10.30.
[11] Now § 10.30(b).

latter need not be included unless specifically requested by the Agency after review of the petition.

Following the Agency's receipt of a citizen petition, the FDA's Hearing Clerk files the document and provides it with a Docket Number. The filing of a petition or of any document does not automatically mean that the Agency has determined that it meets all of the applicable form and content requirements. The Hearing Clerk will file the document if it appears on its face to meet applicable requirements. However, if a later review of the document indicates that it is materially deficient, the Hearing Clerk is authorized under Section 2.5[12] (which deals with the submission of documents to the Hearing Clerk generally) to return the document to the petitioner, indicating why the document is deficient. The petitioner would then have the option of resubmitting the document, having modified it to conform to the requirements.

Once a petition is filed by the Hearing Clerk it is placed on public display in the Hearing Clerk's Office. Interested persons are entitled to submit comments on the petition. These comments will be considered by the Commissioner in deciding whether to grant or deny the petition. Following the submission of a petition by an interested person, the petitioner may supplement, amend or withdraw his petition. Once the petition has been ruled upon or referred for a hearing, however, a petition may only be withdrawn by the permission of the Commissioner, and the regulations provide that in granting such a withdrawal the Commissioner may make the grant with prejudice against a resubmission of the petition. These requirements are found in Section 2.7(g).[13]

Form Requirements

During the rulemaking proceeding establishing Subpart A, several comments objected that the form requirements for citizen petitions were too rigid. The Agency rejected these arguments. In its view, the form and content requirements for citizen petitions are necessary to provide the Agency with a minimum of information on which to proceed further. And the requirements are not nearly so onerous as the complainants might have one believe. In essence, what they require is some familiarity by the petitioner with the nature and background of his request. In acting on petitions the Agency expends substantial resources, and in order to do that effectively it must have

[12] Now § 10.20.

[13] Now § 10.30(g).

at least a cogent expression from the interested party as to what type of action is being requested.

A substantial way in which the final regulations differ from those proposed is found in Section 2.7(e),[14] where the final regulations require the Agency to respond to every citizen petition within 180 days. That response can either be an approval of the petition, which could result in the publication of a *Federal Register* notice proposing to take certain action, a denial of the petition, which would usually be in the form of a letter to the petitioner, or a tentative response, which would indicate why the Agency has been unable to reach a final decision on the merits of the petition. A tentative response may also include the anticipated Agency response to the petition, and when that response may likely be furnished. The proposed order had not obligated the Agency to respond to petitions within a specified time period. However, in light of criticism that the Agency was overlooking petitions, we decided in these final regulations to obligate the Agency to respond to petitions, at least tentatively, within a 180-day period. It is hoped that this provision and the Agency's adherence to it will promote public confidence in the Agency's ability to deal with requests from the public.

Appealing Affirmative Agency Action

Following the Commissioner's decision on a petition, if it is contrary to the wishes of the petitioner, he may ask for reconsideration of the decision, utilizing the provisions of Section 2.8,[15] or request a stay of the Commissioner's decision under Section 2.9.[16] While these remedies are also available in appealing affirmative Agency action it should be stressed that they are also available with respect to the Commissioner's decision to deny a petition.

Now I would like to turn to the proceeding and decision which follow the Agency's initiation of action. These requirements are found in Section 2.10,[17] which is entitled, "Promulgation of Regulations for the Efficient Enforcement of the Law." The section is essentially a step-by-step description of the way Agency regulations are promulgated under informal rulemaking procedures. To begin with, under Section 2.10(b),[18] most action will be initiated in the form of a notice of proposed rulemaking that is published in the *Federal Register*. The notice is required to contain a general statement that describes the

[14] Now § 10.30(e).
[15] Now § 10.33.
[16] Now § 10.35.
[17] Now § 10.40.
[18] Now § 10.40(b).

substance of the document in easily understandable terms, a preamble that summarizes the proposal and the facts and policy that underlie it, references to data and information on which the Commissioner relies, the authority under which the regulation is proposed, and, usually, the terms of the proposed regulation. The proposal will also contain a tentative effective date and a reference to the need for an environmental impact statement. It will further specify the time, place and method for interested persons to submit comments.

Requirements for the submission of comments, as well as for other submissions, are found in Section 2.5[19] of the regulations. This section sets forth the form, content and public availability of submissions to the Hearing Clerk. Form requirements for specific types of submissions are also specified in other sections of the regulations (that is, Section 2.8[20] for petitions for reconsideration). Section 2.5[21] specifies that submissions to the Hearing Clerk shall be filed in four copies, which is a change from the previous five, and that a submission must be signed by the person who makes the submission or by an attorney or other authorized person. Section 2.5[22] also requires that any data or information upon which the comment relies be included with the submission, unless the same information has already been incorporated into the same file or if the reference or source is one of four specifically described types of material.[23]

Section 2.5[24] further contains other general requirements governing all submissions to the Hearing Clerk. Examples are that submissions containing material that is in a foreign language be accompanied by an English translation, that irrelevant matter that is readily excisable be excised, that matters dealing with the personal privacy of subjects be omitted, and that defamatory, scurrilous or intemperate material be deleted. Again, failure to conform to the requirements is grounds for rejection of the submission by the Hearing Clerk.

Agency Documents

The Hearing Clerk is the custodian of publicly available Agency documents. Thus, all material that is submitted to the Hearing Clerk will be placed in files in the Hearing Clerk's Office and will be avail-

[19] Now § 10.20.
[20] Now § 10.33.
[21] Now § 10.20.
[22] *Id.*
[23] The four are a reported Federal court case, a Federal law or regulation, a Food and Drug Administration document that is routinely and publicly available, and material from a recognized medical or scientific textbook that is readily available to the agency. See § 10.20(c)(1).
[24] Now § 10.20.

able to any member of the interested public upon his or her request. The Hearing Clerk is not equipped to respond to requests for confidentiality. Thus, it should be clearly understood that the filing of material with the Hearing Clerk will, in virtually all circumstances, result in that material being publicly available.

Following the submission of comments, Section 2.10(c)[25] provides for the Agency to review the record in the proceeding to attempt to come to a decision on the merits.[26] After the time for comment on a proposed regulation has expired, the Commissioner will review the entire administrative record on the matter and will either terminate the proceeding, issue a new proposal, or promulgate a final regulation by notice published in the *Federal Register*. The Commissioner's decision is required to be based solely on the administrative record.

Section 2.10[27] also specifies the requirements for final regulations, which are published in the *Federal Register*. It requires each final regulation to contain references to prior notices that relate to the same matter, a general statement describing the substance of the document, and a summary of each type of comment submitted on the proposal and the Commissioner's response. In short, the preamble is required to contain a thorough and comprehensive articulation of the basis of the Commissioner's decision. Each notice will also specify an effective date which generally cannot be less than 30 days after the date of publication.

The regulations require an opportunity for public comment for most types of Agency regulations. Exceptions, which are listed in Section 2.10(e),[28] are narrowly drawn. And, while the Commissioner may determine for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the regulations require that when he does so the final regulation shall then provide an opportunity for the submission of comments.

Procedural Regulations

The procedural regulations also provide additional procedures that the Commissioner may use in the promulgation of proposed and final

[25] Now § 10.40(c).

[26] The regulations provide that the number of comments will not ordinarily be a factor regarding the agency's disposition of a particular matter. At the same time, the fact that large number of comments are submitted may be taken into consideration where the degree of public interest in a particular proceeding is a legitimate factor to be considered. See § 10.40(c)(1).

[27] Now § 10.40.

[28] Now § 10.40(e).

regulations. These procedures are set forth in Section 2.10(f).[29] They include, briefly, conferences and meetings, other forms of hearings which are specifically provided for in the regulations, notice in the *Federal Register,* and draft and tentative *Federal Register* documents.

The release of draft tentative and final regulations is governed by Section 2.18[30] which provides, essentially, that drafts of *Federal Register* documents may be made available publicly if made available to all members of the public. Moreover, this section requires a notice of availability to be published in the *Federal Register* when such a draft is to be made available.

As noted, the regulations provide for the use of tentative *Federal Register* documents. These are placed on public display in the Office of the Hearing Clerk and may or may not be published in the *Federal Register.* When placed on display, a tentative regulation will be subject to a notice of availability in the *Federal Register.*

Subpart A also contains provisions regarding formal rulemaking and adjudications. While such requirements are found primarily in other subparts of the procedural regulations, Section 2.12[31] authorizes formal evidentiary public hearings for the promulgation of regulations and for adjudications. Section 2.13[32] of the regulations contains requirements regarding the separation of functions in the Agency in the conduct of such hearings, and also sets forth restrictions on ex parte communications. With respect to the latter, this section incorporates those provisions of the recently enacted Government in the Sunshine Act[33] as they apply to FDA hearings. The requirements for separation of functions are divided into two parts, the first dealing with hearings that are intended for the issuance of rules under the more formal rulemaking procedures of the Administrative Procedure Act (APA) and the second with hearings that are intended to serve as adjudication.

Administrative Record

Subpart A also contains requirements by which FDA decisions can be appealed within the Agency. A basic tenet of the regulations is that the review of Agency action is limited to the administrative record, which includes all of the material which the Agency receives from interested persons, and all of the material which it generates during the rulemaking proceeding. The regulations specify the record for each particular type of administrative action. Thus, the record of

[29] Now § 10.40(f).
[30] Now § 10.80.
[31] Now § 10.50.
[32] Now § 10.55.
[33] P. L. 90-409 (September 13, 1976).

a citizen petition is codified at Section 2.7(i),[34] the record of any administrative reconsideration of action is codified at Section 2.8(k),[35] the record of an administrative stay of action is codified at Section 2.9(h),[36] and the record for a regulation promulgated pursuant to Section 2.10[37] is codified at Section 2.10(g).[38] These requirements are substantially similar and, in summary, attempt to list all documents which the Agency receives from outside parties and all documents which are generated internally to support the Commissioner's action. They include such things as the petition if one were filed, the notice of proposed rulemaking if one were prepared and published, all comments that are received, any final regulation, and transcripts or minutes of meetings held by the Agency regarding the matter.

Agency appeal is essentially limited to reconsideration under Section 2.8,[39] and the granting of a stay pursuant to Section 2.9.[40] The regulations limit reconsideration only to those matters arising under Section 2.6;[41] that is, where the matter results from a petition from an interested person. Reconsideration is intended to permit the Commissioner to reevaluate a decision, but solely on the record of the original action and not on new information. Reconsideration may be obtained following the formal submission of a petition for reconsideration. Such a petition must be submitted within 30 days after the date of the decision for which reconsideration is requested. The regulations obligate the Agency to promptly review a request for a reconsideration and to either grant or deny the petition in writing. If reconsideration is granted, the regulations provide for publication of the decision in the *Federal Register* if the Commissioner's original decision was published in the *Federal Register*. Optionally, any other determination to grant or deny reconsideration may also be published in the *Federal Register*.

Administrative Stay of Action

Section 2.9[42] of the regulations provide for the seeking of an administrative stay of action. Here, again, the requirements for the filing of a stay include the filing of a formal petition within 30 days after the day of the decision involved. I would note that neither the filing of a petition for reconsideration, nor for a stay, will automatically stay a regulation that has been issued. Moreover, while the Commissioner is obligated to promptly review a petition for stay, the

[34] Now § 10.30(i).
[35] Now § 10.33(k).
[36] Now § 10.35(h).
[37] Now § 10.40.
[38] Now § 10.40(g).
[39] Now § 10.33.
[40] Now § 10.35.
[41] Now § 10.25(a).
[42] Now § 10.35.

regulations provide for him to oppose, as a failure to exhaust administrative remedies, a request to a court to stay Agency action if that request has not been made previously to the Agency. The requirements for publication of the Commissioner's decision on the stay of action are essentially similar to those applicable to his decision on reconsideration.

Court review of Agency decisions is codified in Section 2.11.[43] Of course, in order to obtain court review, the action complained of must be final Agency action, and the complainant must have exhausted his administrative remedies. Section 2.11 attempts to explain what the FDA views as final Agency action. It states specifically that the Commissioner's final decision on a citizen petition submitted pursuant to Section 2.6.[44] on a petition for reconsideration submitted pursuant to Section 2.8,[45] on a petition for a stay of action submitted pursuant to Section 2.9.[46] on any advisory opinion issued pursuant to Section 2.19,[47] on any guideline issued pursuant to Section 2.20,[48] and on the issuance of any final regulation published in accordance with Section 2.10[49] are all final Agency action entitled to review in the courts. Moreover, the Agency's position is that it will not interpose standing objections in cases seeking relief from Agency action. It does consider any person to be sufficiently interested in Agency activities to challenge them in court. It will, however, under Section 2.11(g),[50] request that all petitions for judicial review on the same matter be filed in a single United States District Court, and, if petitions are filed in more than one jurisdiction, the Commissioner will request consolidation or dismissal to prevent a multiplicity of suits.

Promulgation of Agency Regulations

This essentially concludes my discussion on the promulgation of Agency regulations under the first subpart of the Agency's procedural regulations. I would like to refer briefly to other matters that Subpart A incorporates, but which do not deal directly with the promulgation of regulations. First, I would like to at least mention Section 2.16,[51] which specifies requirements for the documentation of significant decisions in the Agency's administrative files. This section essentially requires Agency employees to retain those documents which deal

[43] Now § 10.45.
[44] Now § 10.25.
[45] Now § 10.33.
[46] Now § 10.35.
[47] Now § 10.85.
[48] Now § 10.90.
[49] Now § 10.40.
[50] Now § 10.45(g).
[51] Now § 10.70.

with the making of an Agency decision so that the Agency has a complete record of the manner in which the decision was made. This file, however, should not be confused with the Agency record of the decision, which is that material which is publicly available, placed in the Hearing Clerk's Office, and to which the Agency will rely should its action be challenged.

A second requirement to be noted is that of Section 2.17,[52] which specifies procedures by which persons may obtain review of decisions of Agency employees. The section provides for such a review at the request of the employee, at the initiative of the supervisor, at the request of any interested person outside the Agency and as required by duly promulgated delegations of authority.

Representation by an Association

Finally, I would like to discuss the requirements of Section 2.23,[53] involving representation by an association. As proposed, that section would have considered all members of an association to be bound by representations made by the association in rulemaking matters, except if the member expressly excluded himself from the association position. No other section of the proposed regulation generated the amount of comment as did Section 2.23. Most of the comments urged that the requirement was impracticable in that associations could not within the time limits generally imposed, and with existing resources, poll their individual members in order to obtain their views. On the basis of this and other comments the final regulation no longer demands that individual association members be bound by the statements of associations. This will probably have its most substantial impact in the informal rulemaking provisions that are contained in Subpart A. Nonetheless, as finalized, Section 2.23 requests associations to submit membership lists to the Agency, and does maintain, with respect to the court proceedings, that the Commissioner will take appropriate legal measures to have cases brought or considered as class actions or otherwise binding upon members of organizations except those members that are specifically excluded. In addition, regardless of whether such a case is brought or considered as a class action, the Agency will view and attempt to persuade a court that the same issues have already been litigated in a subsequent suit involving the same issues.

[The End]

[52] Now § 10.75.

[53] Now § 10.105.

Meetings and Correspondence, Including FOI Considerations

By STUART M. PAPE*

Mr. Pape Is Associate Chief Counsel for Foods, Food and Drug Administration.

MY TASK is to summarize the relationship between the Food and Drug Administration's (FDA's) public information regulations and its new procedural regulations. Those two sets of regulations—which account for over 200 pages in the *Federal Register*—cannot, quite obviously, be summarized in 20 minutes. Aside from the sheer volume, there are far too many intricate and arcane provisions to permit a summary to be made at the rate of 10 *Federal Register* pages per minute.

At the outset let me say a few words generally about the public information regulations. Those regulations—published in the *Federal Register* of December 24, 1974[1] and a second final order making essentially minor amendments to the regulations published on January 14, 1977[2]—provide for disclosure of approximately 90 percent of the records in the FDA files. Although the volume of Freedom of Information Act (FOI) requests to the FDA[3]—we anticipate over 25,000 this year—has imposed a substantial burden on Agency resources, we are managing well under the increased public scrutiny that is made possible by the ready access to Agency records. In my opinion, there is no prospect that the Agency will turn back from its openness policy; if anything we

* The opinions expressed in this article are those of the author and not necessarily those of the Food and Drug Administration.

[1] 39 *F. R.* 44602.

[2] 42 *F. R.* 3094.

[3] During fiscal year 1975, FDA received approximately 5,306 requests; in fiscal year 1976, the number ballooned to nearly 20,000. This trend continues unabated today. Approximately 84 percent of the requests received by FDA are from industry (or FOI service companies acting on their behalf) and private attorneys. The remaining 14 percent come from the general public, consumers, the press, health professionals, and scientists—the groups for whose benefit the Freedom of Information Act was ostensibly enacted.

will be attempting to expand the categories of records available to the public beyond those currently disclosed.

Set upon this framework of widespread access to Agency records are the procedural regulations. Certain sections of the regulations require the preparation of records which may or may not be available to the public; provide for the submission of records to the Hearing Clerk by private persons and the FDA, records which are ordinarily available to the public, but which, under limited circumstances, may be held in confidence; and establish a mechanism for alerting the public to the existence of meetings about which minutes are almost always made and usually disclosable.

The relationship between the two sets of regulations is apparent: the procedural regulations give rise to the obligation to create or collect records; the public information regulations determine whether the records are available to the public. They almost always are.

Procedural Regulations

The first specific provision of the procedural regulations that I would like to discuss is Section 2.5,[4] which, among other things, governs the submission of material to the Hearing Clerk, and in part, the public availability of material so submitted. Section 2.5, as proposed,[5] contained one of the more controversal aspects of the regulations, the so-called "look-but-don't-copy-rule", which would have applied in evidentiary hearings in which confidential material, such as the full reports of safety and effectiveness data for new drug, were involved. The "look-but-don't-copy-rule" has been abandoned in the final regulations, but let me delay, briefly, the discussion of that aspect of Section 2.5, and instead focus on the aspects of Section 2.5 that have broader applicability.

The general rule established in Section 25(j)(1) can be simply stated: all material submitted to the Hearing Clerk—petitions, comments, objections and requests for hearing, material submitted at a formal evidentiary hearing or alternative form of hearing, and material placed on public display by the FDA—is available to the public under the public information regulations. This rule ordinarily presents no problems; most persons fully expect that such material will be accessible to the public.

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[4] On Tuesday, March 22, 1977 FDA recodified the procedural regulations (42 *F. R.* 15553). This recodification, the last in a series of recodifications of FDA regulations over the past few years, means that the textual citations to the regulations are outdated. The new section numbers are provided in footnotes. Section 2.5 is now Section 10.20.

[5] See 40 *F. R.* 40682.

What, however, about the situation in which someone desires to submit confidential information, or more precisely, allegedly confidential information, to the Hearing Clerk? Will simply marking it confidential suffice? No—however marked, submission of *any* document to the Hearing Clerk may be one of the quickest ways for confidential material to lose its status.

Under Section 2.5(c)(6), the Hearing Clerk will not make decisions regarding the confidentiality of submitted documents. It is assumed ordinarily, that material submitted to the Hearing Clerk is intended to be and should in fact be available to the public. Confidential documents submitted to the Hearing Clerk may, and frequently are, filed along with everything else and subsequently disclosed to the public.

Confidential Documents

Does this mean that confidential documents cannot be submitted to the FDA without losing their confidential status? No, and here the public information regulations come into play. Section 4.44 of those regulations (21 CFR section 4.44), establishes a procedure—commonly known as "presubmission review"—to obtain a determination from the FDA concerning the status of the documents under the FOI before those documents become part of the FDA files. Section 4.44[6] permits the withdrawal of the documents if the FDA determines that they are not entitled to confidentiality. A few words of caution, however. Presubmission review is available only if (1) the documents in question are not required to be submitted in compliance with the Act or the FDA's regulations, and (2) their status under FOI is not already determined in the public information regulations.[7]

In short, virtually everything in the Hearing Clerk's office is accessible to the public—except for certain material that, under the proposed procedural regulations, would have been subject to the "look-but-don't-copy-rule." This material—documents prohibited from public disclosure as a clearly unwarranted invasion of personal privacy (Section 4.63 of the public information regulations)[8] and the following types of documents submitted with objections and requests

[6] Now Section 20.44.

[7] Presubmission review under Section 4.44 is not an opportunity to obtain an "exemption" or other special treatment under the public information regulations. Rather, it is a mechanism to obtain an opinion from FDA about the status of voluntarily submitted information when the regulations are silent on the question. Ordinarily the regulations or preamble do indeed discuss the status of the information under the Freedom of Information Act.

[8] Now Section 20.63.

for hearing, or at a formal evidentiary hearing or alternative form of hearing:

(1) Safety and effectiveness data and information;

(2) A protocol for a test or study;

(3) Production sales or distribution data;

(4) Quantitative and semi-quantitative formulas; and

(5) Data and information on design or construction of products

are not placed on public display in the Hearing Clerk's office unless, of course, they are available to the public under the public information regulations, because, for example, they have previously been disclosed to the public.[9]

Material of the sort I just identified should, when submitted to the FDA, be segregated by the person submitting it from other material and clearly identified as subject to Section 2.5(j)(2)(i). In accordance with Section 2.5(j)(2)(ii), persons who do not agree that a submission is subject to Section 2.5(j)(2)(i) may request a ruling from the Assistant Commissioner for Public Affairs on the issue, and in accordance with Section 4.46 of the public information regulations (21 CFR Section 4.46)[10] may seek judicial review of that decision.

The material listed in Section 2.5(j)(2)(i)(a) and (b)—that is, safety and effectiveness data and information and protocols—may be disclosed to, for example, the parties in a hearing, under a protective order, *in camera,* and only to the extent necessary for the proper conduct of the hearing. The protective order will state which persons (parties or participants, or only counsel) may view the data, and other conditions necessary to ensure that the confidentiality of the data is maintained.

You will note that Section 2.5(j)(c) does not provide for public disclosure of the full reports of safety and effectiveness data. This does not mean, however, that the public generally has no access to any information pertaining to safety and effectiveness of new drugs and new animal drugs. Under the FDA regulations, 21 CFR Sections 314.14 and 514.11, detailed summaries of the safety and effectiveness data are available to the public as soon as a drug is approved.

[9] An FDA record that contains exempt material is available to the public to the extent that the data and information have been previously disclosed to any member of the public in a lawful manner. See Section 4.81 of the public information regulations, 21 CFR Section 4.81 (now Section 20.81).

[10] Now Section 20.46.

Disclosure Rule

The disclosure rule for documents submitted in a hearing is designed to balance the objective of enhancing the utility and fairness of public hearings by making the relevant information available to the public against the competing constraints imposed by various statutory provisions, notably 21 U. S. C. 331(j) and 18 U. S. C. 1905.

Enough said about Section 2.5(j)(2)—the controversy surrounding it far exceeds the frequency in which the provision will come into play. Two sections of the procedural regulations—Section 2.15 and Section 2.22,[11] pertaining to meetings and correspondence and the public calendar, respectively—have much greater impact on the day-to-day activities of Agency personnel and private persons.

Section 2.15 recognizes two types of meetings, those requested by private persons and those initiated by the FDA, and provides slightly different rules for each. A meeting in this context includes any oral discussion, whether in person or by telephone (21 CFR Section 2.3(A)(24)).[12]

Section 2.15(d) acknowledges the right of private persons to request and obtain a private meeting with the FDA to discuss any matter of interest. Neither the FDA nor any other person may, according to Section 2.15(d)(1), require the attendance at such a meeting of any person who is not an employee of the Executive Branch of the Federal Government. Of course, by mutual agreement, any person can attend such a meeting. Section 2.15(d)(2) provides that the FDA, and not the person requesting the meeting, will determine which Agency employees shall attend. The person requesting the meeting may request, but not require or preclude the attendance of any specific FDA employee. Finally, any person who wishes to attend a meeting, but who under Section 2.15(d) is not permitted to, or cannot because the "meeting" is a telephone call, may seek and obtain a separate meeting to discuss the same or any other matter (Section 2.15(d)(4)).

The ground rules for meetings initiated by the FDA are a bit different. A meeting initiated by the FDA which involves a small number of persons—one or two manufacturers, or a trade association—may be a private meeting. An FDA-initiated meeting involving a large number of persons—10 manufacturers—is an open meeting conducted in accordance with Section 2.15(b). The "number of persons" criteria is not, as some have assumed, a hard and fast rule. Rather

[11] Now Sections 10.65 and 10.100.

[12] Now Section 10.3(A)(24).

it is a readily usable "rule-of-thumb" for determining when an FDA-initiated meeting should be open to the public. It should also be noted that the "number of persons" rule-of-thumb may be used by the Commissioner in deciding whether other meetings, including those requested by private persons, should be open to avoid the implication of undue influence on an Agency decision or to otherwise further the purposes of the Act.

Section 2.15(c) now requires—and, this has been Agency practice by informal rule for several years—that all meetings, including telephone conversations with any person outside the Department of Health, Education, and Welfare, including any person in the executive or legislative branches of the federal government relating to a pending court case, administrative hearing, or other regulatory matter to which the FDA is a party, must, unless the substance of the conversation involves nothing more than a brief description of the matter, be summarized in a written memorandum which is then filed in the appropriate administrative file or files. (Section 2.15(c).)

The regulations also provide for the receipt by the FDA of written summaries of meetings prepared by any person who attends a meeting. Those summaries will be included in the same administrative file as the memorandum prepared by the FDA.

Public Information Regulations

At this point, the public information regulations come into play. Section 4.104 (21 CFR 4.104)[13] provides generally that all written summaries are available to the public. This general rule is limited by the application of the statutory exemptions in the FOI, 5 U. S. C. Section 552. Thus, for example, a meeting between a pharmaceutical manufacturer and the FDA concerning a pending new drug application (NDA), the existence of which has not been previously disclosed or acknowledged, would be summarized in a written memorandum that would be filed in the NDA file. The memorandum would not, however, be available to the public under Section 314.14 of the new drug regulations until the drug is approved. After approval, the memoranda of oral discussions in an NDA file are available to the public (21 CFR Section 314.14(e)(7)).

In the event that a summary of a meeting prepared by a private person has been submitted to the FDA, it too will be released in response to an FOI request.

[13] Now Section 20.104.

The public information regulations also provide that all correspondence to and from members of the public is available to the public on request, subject again to any overriding exemption, for example, the correspondence relates to a pending NDA (21 CFR Section 4.103).[14]

The requirement that memoranda of meetings and correspondence be disclosed to the public plays an important role in maintaining public credibility in the FDA and in permitting public scrutiny of and participation in the FDA regulatory activities. When Sections 4.103 and 4.104 were issued in December 24, 1974, there were dire predictions by some that the flow of information to the FDA and communication with companies subject to the FDA jurisdiction would virtually dry up. In my opinion, this prediction has not come true; I see no decrease in the number or type of contacts between the FDA and private persons. This is not to say that some persons are not more cautious in telling the FDA something, or that some persons do not make the first order of business in a meeting an inquiry into whether a memorandum will be made and if so, how detailed will it be.

A few observations, however: first, the making of a written summary of a meeting is the rule, subject only to the narrow exemption that a brief description of a matter does not require that a memorandum be written. This rule applies to all FDA employees. Second, the amount of detail in any memorandum will vary depending further on the particular circumstances. There obviously can be no hard and fast rule about the amount of detail to be included in a memorandum. A memorandum that stated simply "I met with John Smith about a matter of interest" would not approach the objective of a fair and complete memorialization of the discussion. Beyond that, the question of the amount of detail is left to each employee's discretion, judgment, and common sense.

Public Calendars

Let us assume that a meeting has occurred and that a memorandum has been made, is there a way to discover its existence, or is it left to chance? A partial answer, at least, is found in Section 2.22 of the procedural regulations, dealing with public calendars.

There are two types of public calendars maintained by the FDA: the prospective calendar listing, insofar as possible, the public meetings, conferences, hearings, seminars, and other public proceedings

[14] Now Section 20.103.

of the FDA for the following four weeks. This calendar is on public display in several FDA offices.

Of greater importance and utility is the retrospective calendar. This calendar, which is prepared and made publicly available each week, lists all meetings between persons outside the Executive Branch of the federal government and certain designated FDA officials, including the commissioner, deputy, associate, and assistant commissioners, bureau directors and the chief counsel. Telephone conversations are listed on the retrospective calendar on an optional basis. The calendar listing includes the date, persons involved, and subject matter of the meeting. Meetings whose existence might prejudice law enforcement activities, invade privacy, or disclose trade secrets are not listed. The retrospective public calendar will show those meetings for which a memorandum is available—usually by means of an asterisk. The retrospective calendar is also on public display in several Agency offices.

Availability of Memoranda

Thus, the existence of meetings and the availability of memoranda summarizing those meetings, when the meeting involved a top official of the FDA, can be readily ascertained. The existence of meetings involving other FDA employees cannot, however, be systematically determined. Summaries of those meetings, however, will frequently be filed in places to which the public has ready access—for example, in the Hearing Clerk's office. And, of course, if the existence of a meeting and, therefore, a summary of the discussion becomes known, the memorandum will ordinarily be available to the public under the public information regulations.

I would now like to turn my attention briefly to Section 2.24,[15] which deals with settlement proposals. That Section provides, very simply, that any person may, at any time, propose settlement of any issues involved in administrative proceedings involving FDA, for example, a formal evidentiary hearing. The Section also provides that all participants in the hearing are to have an opportunity to consider any proposed settlement and that unaccepted settlements and related matters—unagreed to stipulations, for example—are not admissible in evidence in FDA proceedings. These provisions are not, in my judgment, controversial.

[15] Now Section 10.110.

What is of interest and subject to some dispute, is whether proposed settlements and responses to them are available to the public under the public information regulations, and, if so, when.

The public information regulations do not give an explicit answer and the arguments for and against disclosing settlement proposals have merit. On the one hand, it is argued, disclosure will inhibit persons from making settlement proposals, thus defeating the objective of Section 2.24. Proponents of disclosure argue that the public should be in a position to be made aware of settlement proposals and that the matters that the FDA deals with involve interests broader than those of just the parties in an administrative proceeding. The proponents of disclosure have, based on my experience, prevailed on this issue and settlement proposals are routinely filed with the Hearing Clerk when sent or received by the FDA. Aside from the public policy aspect of disclosure, this result would appear to be required by the FOI, for it is difficult to see how one of the nine statutory exemptions can be reasonably applied. Disclosure of settlement proposals in the FDA administrative proceedings may make the parties a bit uncomfortable, but it does not, in my judgment, seriously interfere with the valuable process of settlement discussions.

Finally, I would like briefly to discuss Section 2.153,[16] which relates to formal evidentiary hearings under Subpart B[17] of the procedural regulations. That section requires that before a notice of hearing is published in the *Federal Register,* the Director of the Bureau responsible for the hearing must submit to the Hearing Clerk the relevant portions of the administrative record and all documents in his files containing factual data and information, whether favorable or unfavorable to his position which relate to the issues involved in the hearing. The other participants in the hearing are required to file the equivalent documents from their files within 60 days of publication of the notice.

Submission of Documents

It is important to note that the submission of documents required by Section 2.153 does not extend to documents reflecting internal FDA deliberations—for example, a memorandum expressing the views of an Agency employee about the approvability of a particular product, even though those documents may be contained in an administrative file related to the hearing. The Section 2.153 requirement does not extend

[16] Now Section 12.85.

[17] Now Part 12 of Subchapter A of Title 21 of the Code of Federal Regulations.

to documents that are the work product of Agency attorneys representing the Bureau involved in the hearing—for example, memoranda of interviews with potential witnesses, or those that are subject to the attorney-client privilege, such as requests for legal opinions, even though they might contain factual data and information.

These exceptions to the submission requirement in Section 2.153 are based, among other things on the fact that these types of documents are exempt from disclosure under the FOI and FDA's public information regulations, pursuant to the fifth exemption for inter- and intra-Agency memoranda (5 U. S. C. Section 552(b)(5)).

These types of documents are also not properly subject to the submission requirement in Section 2.153 because they will not ordinarily relate to the issues at the hearing. For example, a hearing on the safety and effectiveness of a new drug involves just that issue: does the available data establish the safety and effectiveness of the product? It would not be an appropriate subject for the hearing to delve into the Agency decisional process or the advice given by FDA attorneys to the bureaus or Commissioner. In short, the submission requirement in Section 2.153 is intended to facilitate evaluation of all factual material; it is not an occasion to explore what are no doubt interesting, but nonetheless irrelevant aspects of Agency activities, at least in the context of an administrative hearing. And, the requirements are not intended to be, and do not in fact, provide a mechanism to circumvent the authority of the Commissioner to deny access to certain internal Agency documents under the public information regulations.

It should be quite clear that I have barely skimmed the surface of the relationship between the procedural regulations and the public information regulations. Generally speaking, the two sets of regulations complement and re-enforce each other. Together they contribute substantially to making the FDA a very open Agency. **[The End]**

A View From the Bench

By JUDGE DANIEL J. DAVIDSON

Judge Davidson Is Administrative Law Judge for the Food and Drug Administration.

WHEN I FIRST LOOKED AT the then proposed Rules and Regulations under Subpart B,[1] it seemed to me that the Food and Drug Administration (FDA) was giving its reluctant consent to the holding of formal evidentiary hearings—something like, "If we're forced to hold hearings, let's make the rules so tough that we can't lose."

Now that I have seen the rules in operation, I can assure you that this was not the case—it was more like, "Since we must offer these (expletive deleted) formal hearings, let's make the rules so confusing the parties will be forced to opt for one of our alternative procedures."

All kidding aside, I am sure you realize the difficult task facing the Agency, as well as the problems encountered in the past with respect to formal hearings. Virtually everyone remembers the unduly protracted peanut butter and vitamin mineral hearings. The feeling that the FDA has generally been reluctant to hold formal hearings is a direct result of what happened in those cases, and the Subpart B rules attempt to avoid some of these problems for the future. I see my role in this process as one of conducting an orderly hearing for the purpose of obtaining a fair and complete picture of the relevant facts necessary for an impartial, initial decision based on those facts. To this end, the rules must be subject to a continuing process of modifications as experience dictates. Therefore, you can expect to see additional changes in the rules as we gain more experience. The important thing to remember is that the Subpart B rules merely

[1] Subpart B was initially codified at 21 CFR S 2.100 to 2.191 on November 23, 1976 (41 *F.R.* 51706). It was reorganized and recodified on March 22, 1977 as Part 12. The new section numbers are provided in the footnotes. Subpart B is now Part 12.

represent a point of departure, and that rules for administrative proceedings should, and generally will, be construed by the Administrative Law Judge with a view toward having an orderly, fair and impartial hearing.

Authority of Presiding Officer

With this in mind, I will now try to briefly take you through the regulations in the order you might encounter them in the conduct of an actual case. I will highlight the points where the adopted rules differ significantly from those originally proposed and also indicate those modifications which I routinely impose under Section 2.142(m),[2] which deals with the *Authority of presiding officer.* Incidentally, I consider that section to be the most important of all the rules because it permits the Administrative Law Judge to waive, suspend, or modify any of the other rules of Subpart B, as long as no one is prejudiced thereby.

Normally, you would expect the term "parties" to be broad enough to include the different interests in any legal proceeding. However, this is not the case under Subpart B hearings, because "parties" are defined as only those who file objections and requests for a hearing under Section 2.112,[3] in response to a "notice of opportunity for a hearing. Remember, the Agency first publishes a "Notice of Opportunity for Hearing" and then the "Notice of Hearing." Those who wait to enter the proceeding for the first time after the notice of hearing." Remember, the Agency first publishes a "Notice of Oppordo not have the same rights as parties.

Nonparty participants do not have the right to submit written interrogatories or to conduct cross-examination unless the presiding officer specifically finds that their interests would not otherwise be adequately protected. By understanding the distinction and the ramifications thereof, you will be better able to decide the extent of your own participation requirements.

The rule represents a means whereby some degree of control may be exercised over the time required to complete a hearing by limiting the rights of nonparties, particularly with respect to cross-examination. I do not usually consider the cross-examination process to be unusually troublesome, because I require that an orderly and concise procedure be followed by the questioner. Repeatedly prolonged delays or irrelevant questions which may reasonably be interpreted as indicating a lack of proper preparation or intentional delaying tactics, are

[2] Now § 12.70(m).
[3] Now § 12.22.
[4] Now § 12.89.

grounds for the early termination of cross-examination. Nevertheless, the Agency apparently is concerned because the rule states that nonparties will not have all the rights of parties unless permitted by the presiding officer.

Fair Hearing and Complete Record

I would permit exceptions to the rule, only if convinced that it would aid in obtaining a fair hearing and a complete record. The time consumed by the extension of these rights to nonparties would also be considered. In other words, the number of nonparty participants for which an exception might have to be made and the effect thereof on the overall time required to conclude the hearing would have definite bearing on whether it should be permitted. What is important is that as a nonparty participant, you may be faced with a situation where you will not be permitted to cross-examine. Now that you have the distinction between "party" and "nonparty" firmly in mind, I will endeavor, for the remainder of this talk, to refer to all interests simply as "participants."

Assuming that you have filed objections and requested a hearing, you may now be faced with Section 2.115,[5] *Denial of formal evidentiary public hearing in whole or in part.* The denial of a hearing request constitutes final Agency action, and a total denial is a finding that there is no need for a hearing. If you disagree, judicial review is available. A partial denial is another matter.

Partial denial of a hearing request concerning certain issues is designed to prevent hearings from being side-tracked or unduly delayed through inclusion of those possibly related issues which do not necessarily require determination before a particular Agency action may be concluded. The question is, "Is the denial of those issues final when pursuant to Section 2.118(b),[6] *Notice of hearing; stay of action,* the presiding officer may revise the 'statement of issues'?" If an issue on which a hearing was denied is subject to consideration by the presiding officer, the denial was obviously not the final Agency action.

The authority of the presiding officer to review issues is necessary to protect against Agency oversights as well as any possible unfairness which might result from a one-sided approach to the framing of the issues. My inclination to modify would be limited along these lines. Nevertheless, the uncertainty as to what constitutes final Agency action could cause you problems with respect to the timing of requests for judicial review of a partial denial of a request for hearing. Should you immediately pursue a court appeal

[5] Now § 12.28.

[6] Now § 12.35(b).

prior to the conclusion of the administrative hearing on related issues, or await final Agency determination on those related issues? Will awaiting final Agency action mean you waived your right of judicial review on those issues denied a hearing?

Administrative Finality

Based on an actual experience under similar circumstances, the Commissioner, at the request of the participants, gave assurances that administrative finality of the partial denial of a hearing as to some issues would not be raised as a defense in court following the hearing on the rest of the issues. The Agency is, therefore, aware of this problem and, hopefully, is in the process of making appropriate revisions. In the meantime, if you are faced with a partial denial of a hearing request, I suggest that, to be on the safe side, you protect yourself by seeking a stay of the administrative finality of such partial denial pursuant to Section 2.9 of Subpart A,[7] regardless of whatever other action you take.

I have mentioned the notice of hearing, the issuance of which generally signals the start of my involvement in the proceeding. Participants must file their notices of participation within 30 days after the issuance of the notice of hearing.

Draft Proposal

Incidentally, a change from the draft proposal distinguishes between participants (written notice of participation required by Section 2.131)[8] and representatives of participants (appearances required by Section 2.130).[9] Previously, appearances covered both and was the subject of some possible confusion. Also, Section 2.135,[10] *Advice on public participation in formal evidentiary public hearings,* was added in order to aid members of the public seeking advice on such matters as what, when, and where to file appearances and notices of participation.

Section 2.153(a),[11] *Disclosure of data and information by the participants,* requires the responsible bureau to file with the hearing clerk, prior to the publication of the notice of hearing, detailed information concerning its position in the case and the evidence to be relied on in the upcoming hearing. All participants in the hearing are required by paragraph (b) of this section to file similar data on their own behalf within 60 days after the notice of hearing.

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[7] Now § 10.35 of Part 10.
[8] Now § 12.45.
[9] Now § 12.40.
[10] Now § 12.50.
[11] Now § 12.85(a).

Section 2.153(b)[12] also permits the 60-day period for the submission of data and position by the participants to be extended or shortened by order of the presiding officer. While the provision for altering the 60 days has obvious merits, it created somewhat of a problem because there is no forum and no information available upon which the presiding officer could make such a determination. Accordingly, the adopted rules do not designate a time for the prehearing conference to be held. The earliest possible date would be 30 days, which is immediately after the expiration of the time for filing notices of participation. Pursuant to Section 2.158,[13] *Prehearing conference procedure,* all participants are required to be represented at the prehearing conference, and requests for changes in the 60-day period for the submission of data pursuant to Section 2.153(b) may properly be considered on the record at such prehearing conference.

Prehearing Conference

I am sure you are all aware that the prehearing conference is an extremely important part of any proceeding because it actually governs the course of the upcoming hearing with respect to procedural scheduling, and the designation of issues and material facts in dispute. Because considerable cooperation by the participants is necessary, the prehearing conference, from the viewpoint of the presiding officer, can be a gratifying experience, or it can be an extremely frustrating one. I evaluate prehearing conferences in inverse proportion to the number of rulings I am required to make which do not reflect the agreement of the participants. If the participants can agree on a particular procedure to facilitate the hearing process, I will normally accept their approach. Thus far, my prehearing conference experiences at the FDA have generally been more gratifying than I had expected.

At this juncture, I should also point out that I make a distinction between the administrative record which includes virtually everything submitted, and the evidentiary record, upon which I base my initial decision. The distinction is rather obvious. Only those portions of the record which are received in evidence, subject to the appropriate evidentiary tests of admissibility, can properly be considered in reaching a determination of the issues. This evidentiary record includes oral testimony and written documents formally received in evidence, plus those matters incorporated by reference and

[12] Now § 12.85(b).

[13] Now § 12.92.

covered by official notice. The mere submission of data to the hearing clerk does not constitute evidence.

Arguments of Admissibility

This brings us to the next modification which I routinely include. Section 2.160,[14] *Receipt of evidence,* specifically paragraph (c) (2) thereof, requires the receipt of all written evidence even if it is irrelevant or immaterial, and, in the words of that section, "even if it is of no probative value." The purpose of this provision is to avoid the possible delays caused by arguments over admissibility. However, I consider this approach to be counterproductive because, in addition to cluttering up the record, experience teaches us that receipt of irrelevant evidence usually requires the introduction of irrelevant and unnecessary rebuttal, not to mention the possible cross-examination thereon. If the participants know precisely what has been received in evidence, then their task for rebuttal is simplified considerably. I therefore waive this rule to the extent necessary to provide for the exclusion of irrelevant and immaterial evidence.

In Section 2.160(d)(2) of the proposal, the rules allowed a participant to argue that exclusion of certain oral testimony was improper and to offer for the record argument as to the facts which would have been presented if the testimony were allowed. This argument is called an "offer of proof." This provision has been deleted from the adopted rules because such arguments do not constitute evidence and could not properly be received as such. They are more appropriately included in arguments on brief than in the transcript of the proceeding. In the unusual situation where an "offer of proof" includes facts which are subsequently determined to have been erroneously excluded, such facts could only be relied on in reaching a decision after an opportunity for rebuttal by opposing participants. This is necessary since there was no opportunity for cross-examination or rebuttal concerning any matters contained in an "offer of proof" because such matters do not constitute evidence.

Interlocutory Appeals

Since we are now fairly well along in the regulations, I think it is appropriate to mention another of my routine modifications. This one concerns Section 2.163,[15] which deals with interlocutory appeals. The right to such appeals is automatic in connection with rulings under certain sections of the regulations; otherwise, a finding of necessity by the presiding officer is required under paragraph (b) of Section

[14] Now § 12.94.

[15] Now § 12.97.

2.163 before an appeal may be taken. Paragraph (c) apparently contemplates the filing of a brief with the Commissioner in order to pursue an interlocutory appeal. While there are certain circumstances which would warrant such an approach, this is not always the case, particularly where a hearing is actually in session. I therefore modify paragraph (c) to limit written appeals to those questions requiring detailed consideration by the Commissioner. In all other cases, the appeal is taken immediately and orally to the Commissioner. Arrangements have been made for such a procedure, just to make sure that it does not come as a complete surprise to the Commissioner when you come knocking on his door.

I believe this brings us to the point in the hearing where all of the evidence is in and the matter is almost ready for a decision. Before it is, however, we come to Section 2.162,[16] *Briefs and arguments.* Paragraph (b) of this section clearly indicates that oral argument at this stage of the proceeding is discretionary with the presiding officer. However, there is no such discretion as to briefs. The rule merely states that a schedule for the filing of briefs will be announced and that briefs will include certain things. That is not to say that all participants must file briefs. I do not think such a provision could be enforced even if this were the intent. Nevertheless, the right to file a brief is granted regardless of any need therefor.

This is one feature of the rules I have considered modifying in the interest of saving time in those instances where I do not feel the need of briefs in order to resolve the issues. However, I have not yet seen a situation where the saving of perhaps 30 or 40 days would justify precluding briefs, particularly where the participants want to submit them.

Initial Decision

We now come to another of the significant changes in the rules as adopted, Section 2.180,[17] *Initial decision.* Previously, the presiding officer would prepare his report and certify the record to the Commissioner. The Commissioner would then issue a tentative decision, incorporating therein as much or as little of the presiding officer's report as he deemed appropriate. Following exceptions thereto, the Commissioner would issue his final order.

The adopted Section 2.180, together with Section 2.181 and Section 2.182,[18] provide for a streamlined appeal procedure which is similar to the practices followed at other administrative agencies,

[16] Now § 12.96.
[17] Now § 12.120.
[18] Now §§ 12.125 and 12.130.

and which gives immediate public disclosure of the findings and conclusions of the presiding officer which are subject to exceptions and subsequent replies to exceptions prior to review by the Commissioner. The procedure also provides for automatic effectiveness of the initial decision in the absence of appeal by the participants, or notice of review by the Commissioner. Such a procedure is provided for under Section 557 of the Administrative Procedure Act (APA) and does away with the necessity of a final order in those situations where the controversy is resolved by the initial decision, as unlikely a prospect as that may appear.

The initial decision is in no way binding on the Commissioner who is free to completely disregard it if he feels it is incorrect. The procedure merely gives the participants immediate access to the findings and conclusions of the presiding officer before those findings are subject to Agency review.

Impartiality

The APA contains certain safeguards, including the prohibition of *ex parte* communications, which are designed to insure the impartiality of those presiding at hearings and making decisions in proceedings which fall under the APA. The maintenance of this impartiality is one of the most important tasks of an Administrative Law Judge. This is particularly true at agencies such as the FDA, where the Agency takes an active adversary role in virtually every formal evidentiary hearing. The Administrative Law Judge is usually physically located at the Agency and is subject to possible contact with Agency personnel on a daily basis. Therefore, in addition to complete independence and impartiality in the conduct of the hearings and in the decision-making process, the Administrative Law Judge must also avoid being involved in any activity which might (even erroneously) be construed as indicating partiality or the appearance thereof.

I want to publicly assure you that those APA safeguards I referred to are taken very seriously. I have had complete cooperation at all levels of FDA officialdom in adopting procedures for running my office in such a way as to avoid *ex parte* communications or any undue influence from within. Opportunities for *ex parte* contact are minimized by the maintenance of a separate and distinct office which is in no way related to or under the jurisdiction of any of the operating bureaus.

Outside Interests

The same approach is applied equally to the FDA and outside interests in proceedings before me. I will not hold informal conferences outside the hearing room and I do not give advance rulings or extra record indications of how I might react to certain requests. Surprising as it might seem, many of the telephone calls received by my office involve questions of this nature, such as: What happens if we do not show up at the prehearing conference? Will the time for filing be extended? How would the Judge react to such and such? I cannot blame those who want and need such information for trying, but I hope everyone understands that the less extra record contact I have with participants and their representatives, the less chance there is that I will be jeopardizing my position by even the appearance of partiality or undue influence through *ex parte* communications.

I only mention these problems because I am aware of the fact that the Subpart B regulations are a far cry from a do-it-yourself guide to FDA formal evidentiary hearing procedures, and hearing participants can be expected to need help. Most of what I have discussed here only serves to reinforce this view. If, or maybe I should say when, you find yourself in need of clarification or a special interpretation of these rules, informal assistance may be obtained pursuant to Section 2.135.[19] However, I will personally be available for assistance only on a formal basis, either on the record at a hearing or by motion filed pursuant to Section 2.165,[20] which covers motions "with respect to any matter relating to the proceeding."

Actual Proceedings

Finally, I want to emphasize that the FDA is aware of the fact that additional changes and clarifications of Subpart B will be needed. They will be based largely on the experience gained in actual proceedings, and from public requests for clarifications. In all probability, the need for clarification of these regulations will always be present because no set of procedural rules can be expected to foresee every eventuality. Those of us who are required to function under such rules must remember that they represent only a beginning. Subpart B regulations will be subject to continuing changes in the interest of obtaining a formal hearing process which is designed to avoid unnecessary delays, while, at the same time, insuring fairness and the consideration of the rights of all participants. **[The End]**

[19] Now § 12.50.

[20] Now § 12.99.

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