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Food·Drug·Cosmetic Law
JOURNAL

Trade Regulation Rule on Food Advertising

An Analysis

. . . . . STEPHEN A. WEITZMAN

Remarks

. . . . . J. THOMAS ROSCH

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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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TO THE READER

Trade Regulation Rule on Food Advertising. This month's issue of the *Journal* is devoted to three articles on the Trade Regulation Rule on food advertising proposed by the Federal Trade Commission and published in the *Federal Register* on November 11, 1974.

The first article, by Stephen A. Weitzman, is an in-depth analysis of the rule from different aspects. Mr. Weitzman, a partner in the law firm of Harter, Calhoun & Williams, presents the main points of the proposed rule, along with the Commission's explanations and the staff's additions.

Arranging the paper, titled "Trade Regulation Rule on Food Advertising—An Analysis," topically, Mr. Weitzman begins by comparing the definitions proposed in the rule with those found in the Federal Food, Drug and Cosmetic Act.

The proposed rule classifies the types of nutritional claims made by advertisers into six major categories, with stipulations that specific nutritional requirements (nutritional thresholds) be met before such claims can be made. In addition, these claims must be backed by affirmative disclosures relating to the product's nutritional values.

Mr. Weitzman discusses the various claims, comparing the Commission and the staff proposals, citing contrasting provisions. Examples in each category are given, including statements that would satisfy the proposed requirements. Both text and charts are used for clarification. This article can be found on page 140.

The other two articles resulted from a briefing session on the Trade Regulation Rule held by the Food and Drug Law Institute in Washington, D. C. on December 18, 1974.

The paper by J. Thomas Rosch is a speech he made at the session. Titled "Trade Regulation Rule on Food Advertising—Remarks," it contains a brief outline of the rule, a discussion of the legal underpinnings of its provisions and an analysis of matters not yet included in the rule but which will be covered in the rule-making procedure.

Mr. Rosch, Director of the Bureau of Consumer Protection in the Federal Trade Commission, also provides examples of the six major types of nutritional claims made by advertisers. In each of the claims, he explains the levels chosen as nutritional thresholds and the requirements for affirmative disclosures.

Mr. Rosch, whose article begins on page 172, discusses the court cases which have upheld the Commission's authority to set standards such as those required by the rule, citing the cases and the authority granted under the Federal Trade Commission Act.

Mr. Rosch concludes his paper by discussing other controversial issues which were not dealt with in the proposed rule but which the Commission wishes to consider before publishing its final version of the rule.

The concluding article is the text of the question and answer period held during the briefing session. The answers were provided by J. Thomas Rosch, Director of the Bureau of Consumer Protection in the Federal Trade Commission and by James H. Cohen, Deputy Assistant Director for National Advertising in the Federal Trade Commission. "Questions and Answers" begins on page 183.

Vol. 30, No. 3 March, 1975

Food·Drug·Cosmetic Law
Journal

Trade Regulation Rule on Food Advertising— An Analysis

By STEPHEN A. WEITZMAN

Mr. Weitzman Is a Partner In the Law Firm of Harter, Calhoun & Williams.

IN THE *FEDERAL REGISTER* of November 11, 1974, the Federal Trade Commission (FTC) published a proposed Trade Regulation Rule (TRR) for Food Advertising, an explanation of the Commission proposal, and a separate staff proposal. Below is an analysis of those documents.

The Commission's proposal is directed at implicit as well as explicit claims. Thus, an advertisement need not expressly state that "Food X is a good source of iron" to be subject to the provision dealing with emphatic claims; it is sufficient if it can be interpreted to make that kind of claim.

The Commission's proposals contain a common remedial thread and provide for (1) general and specific requirements for disclosure and (2) minimum compositional requirements for making certain claims.

The staff proposal includes the Commission proposal and adds requirements for "affirmative disclosure" of a nutrient profile along the lines of the Food and Drug Administration's (FDA's) nutrient-labeling program. The staff also proposes to require "mandatory disclosure" of calorie information for foods to which its affirmative-disclosure requirements do not apply.

Scope of Paper

This analysis covers the FTC's proposed Trade Regulation Rule (TRR), the Commission's explanation of the rule, and the additions proposed by the FTC staff. The material has been organized so that all information relating to the same generic topic is discussed in the same section.

The analysis appears in the following order:

(I) Scope of Application of the FTC Trade Regulation Rule

A review of the important definitions of "Advertisements" and "Foods" to which the proposed rules apply and comparison of the FTC definitions with their counterparts in the FDA regulations.

(II) Legal Underpinnings of the Proposed Rule

A short review of the legal basis for the rule. A more elaborate statement appears in the original *Federal Register* document.

(III) Identification or Designation of Food

A description of the requirements for identifying a food by its entire name.

(IV) Method and Form of Disclosure

A description of the rules on clarity of disclosure and presentation of information, including details such as type-size requirements.

(V) Required Content of Disclosures, Statements and Claims

This section includes:

(A) The rules prescribing the required amplification of any reference to a nutrient, including the percentage of the U. S. RDA (recommended daily allowance) of the nutrient present in the food.

(B) Substantiation and disclosure rules proposed by the Commission, as well as those additionally offered by the FTC staff, which specify threshold nutritional composition and disclosure requirements in connection with specified kinds of "voluntary claims."

(C) The Staff's affirmative-disclosure proposals (1) for foods required by FDA regulations to bear nutritional labeling, or which are voluntarily nutrition-labeled, and (2) for all other foods.

I. Scope of Application of the FTC Trade Regulation Rule

The jurisdiction of the FTC in regard to food products extends not only to advertising claims (implicit and explicit) but to claims in labels

and labeling. However, the proposals only apply to advertising claims [Section 437.1(h)].

Labels, Labeling, Advertising: The Federal Food, Drug and Cosmetic Act [Section 201(k) and (m)] and, in a similar manner, the Wholesome Meat Act [Section 1(o) and (p)] and the Poultry Products Act [Section 4(s)] defines "label" and "labeling" as follows:

"The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear(s) on the label shall not be considered to be complied with unless such word, statement, or other information also appear(s) on the outside container or wrapper if any there be, of the retail package of such article, or unless the information is easily legible through the outside container or wrapper.

"The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

The FTC proposal (Section 437.1) defines "advertisement" as follows:

"'Advertisement' or 'Advertising.' Any written or verbal statement, illustration, or depiction, other than a label or in the labeling, which is designed to effect the sale of any food product, or to create interest in the purchase of such product, whether the same appears in a newspaper, magazine, leaflet, circular, mailer, book insert, catalog, sales promotional material, other periodical literature (except professional or scientific journals), billboard, public transit car, or in a radio or television broadcast or in any other media. It does not include point-of-purchase advertising or any promotional material developed and/or disseminated by retail supermarket and food store establishments and wholesale food distributors the content of which refers solely to the price of an advertised food and which does not contain representations regarding nutrition, nourishment, or other nutrition claims relative to the product."

Under the FTC definition, the proposed rule would cover food advertising except for advertisements or any point-of-purchase promotional material promulgated by or for retail supermarkets, food stores and wholesale food establishments if:

(a) The contents of the advertisements relate only to price; and

(b) The advertisements contain no nutrition claims.

Additionally, the staff proposes that:

(a) "Natural" and "organic" claim rules apply to point-of-purchase advertisement; and

(b) Advertising by restaurants which contains any voluntary claim covered by Subpart B must comply fully with the rule, except that the provisions relating to affirmative disclosure would not apply to restaurant advertising.

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Food: Both the FTC proposal and the food laws define "food" as including virtually all food products.

The Federal Food, Drug and Cosmetic Act (Section 201) defines "food" as follows:

"(f) The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."

The FTC proposal defines "food" as:

"(b) 'Food.' Any article used for food or drink by humans, including chewing gum. However, it does not include:

(1) Special formula foods which are developed, intended or marketed exclusively for infants (persons not more than 12 months of age) and which provide the complete nutritional requirements of infants.

(2) Foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions and advertised only in professional journals or publications.

(3) Alcoholic beverages subject to the provisions of the Federal Alcohol Administration Act of 1935 (27 USC Section 201, *et seq.*)."

The definitions of "advertising" and "food" in the proposal contain limits on the lay definitions of these terms. The limits are really "exceptions" to the rules proposed and should more properly have been included in a separate exemption section.

Representation: The FTC proposal defines "representation" to include:

"Any direct or indirect statement, suggestion or implication in advertising, including but not limited to one which is made orally, in writing, pictorially, or by any other audio or visual means, or by any combination thereof."

II. Legal Underpinnings of the Proposed Rule*

The asserted legal underpinnings for this rule are, in my opinion, insufficient to justify the broad disclosure requirements. However, it is premature to present the legal arguments against the rule at this time.

III. Identification or Designation of Food [Section 437.2(f)]

A food shall be identified or designated in accordance with any applicable federal regulations prescribed in the Code of Federal Regulations. Non-standardized foods shall be identified or designated by their respective common or usual names, if such exist, pursuant to 21 CFR Part 102.

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* See "Trade Regulation Rule on Food Advertising—Remarks" by J. Thomas Rosch, p. 177.

(The Commission and staff proposals are identical on this point.)

This rule requires any food, whether advertised by itself or as an ingredient to be used in conjunction with the food being advertised, to be identified by its "generic designation" and not simply by its brand name or only a portion of its common name (for example: "Pasteurized Process Cheese," not merely "Cheese.") The proposed regulation incorporates the FDA requirements for identity labeling, enumerated for the most part in Volume 21, Code of Federal Regulations, Section 1.8 [21 CFR Section 1.8].

These FDA requirements specify:

(i) Use of the standardized food's name if there is a standard; or

(ii) Use of the common-or-usual name specified in a Part 102 regulation or, if there is no regulation, the name used by consumers; or

(iii) If the product is new and there is no name, use of "an appropriately descriptive term, or where the nature of the food is obvious, a fanciful name commonly used by the public for such food;"

(iv) Where a food other than a standardized food is marketed in various optional forms (whole, sliced, diced, etc.) the particular form shall be stated as part of the name, except that if the form is depicted by an appropriate vignette on the label, the particular form need not be included in the statement; (There may be a question as to the application of this section to advertisements.)

(v) Imitation foods must include "Imitation" as part of their name [21 CFR 1.8(e)].

An issue raised by the rule, though not specifically mentioned by the Commission, is whether the generic name must be used each and every time the brand name is used.

IV. Method and Form of Disclosure

A. "Clear and Conspicuous"—Definition [Section 437.1(g)(1)]

"Disclosing in a manner which can be easily understood (in the case of television and print advertising, also easily seen and read) by the casual observer, listener, or reader among members of the public and which conforms (except where otherwise provided in this Rule), for advertising in any media, in all relevant respects to the Commission's Statement of Enforcement Policy of October 21, 1970. (See Vol. 2, CCH TRADE REGULATION REPORTER, Section 7569.09.)* Each disclosure shall be presented in the same language principally employed in the

* **.09 "Clear and conspicuous" disclosure.**—The FTC issued an enforcement policy statement setting forth the standards it considers in determining whether, in fact, an affirmative disclosure in a television commercial is "clear and conspicuous." The FTC explained that in recent years it has issued various opinions, orders and trade regulation rules

(Continued on the following page.)

advertisement. (See Commission's Statement of Policy of July 24, 1973, as amended, 38 *Fed. Reg.* 21494-95.)"**

This provision is intended to ensure that the disclosures required by the proposed rule will be visible and comprehensible. Specific methods of

(Footnote continued.)
concerned with the need for affirmative disclosures in connection with various kinds of representations. In making a determination, the FTC said that it will take into consideration all the technical factors, such as the size of letters and the duration of disclosure, used in presenting the disclosure to a television audience, as well as the substance of the individual disclosure. The following standards should be met for a television disclosure to be deemed "clear and conspicuous": (a) the disclosure should be presented simultaneously in both the audio and video portions of the television advertisement; (b) the video portion of the disclosure must contain letters of sufficient size so that it can be easily seen and read on all television sets, regardless of picture tube size; (c) the video portion of the disclosure should contain letters of a color or shade that readily contrasts with the background, and the background should consist of only one color or shade; (d) no other sounds, including music, should occur during the audio portion of the disclosure; (e) the video portion of the disclosure should appear on the screen for a sufficient duration to enable it to be completely read by the viewer; and (f) the audio and video portions of the disclosure should immediately follow the specific sales representations to which they relate and should occur each time the representation is presented during the advertisement; in cases where a disclosure is required, but is not linked to a specific representation, it should appear in immediate conjunction with the major sales theme of the advertisement. Television advertisers should also consider the audience to whom the disclosure is directed in order to assure that persons (such as children) can understand the full meaning of the disclosure. If securing this understanding is impractical, then the advertisements containing such representations should not be used on television. *FTC Statement of Enforcement Policy*, October 21, 1970.

** Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

PART 14—ADMINISTRATIVE INTERPRETATIONS, GENERAL POLICY STATEMENTS AND ENFORCEMENT POLICY STATEMENTS

Foreign Language Advertising, Correction

FR Doc. 73-16085, appearing at page 20820 for the issue of Friday, August 3, 1973, is corrected to read as follows:

§ 14.9 Requirements concerning clear and conspicuous disclosures in foreign language advertising and sales materials.

The Federal Trade Commission has noted that, with increasing intensity, advertisers are making special efforts to reach foreign language-speaking consumers. As part of this special effort, advertisements, brochures and sales documents are being printed in foreign languages.

In recent years the Commission has issued various cease-and-desist orders as well as rules, guides and other statements, which require affirmative disclosures in connection with certain kinds of representations and business activities. Generally, these disclosures are required to be "clear and conspicuous." Because questions have arisen as to the meaning and application of the phrase "clear and conspicuous" with respect to foreign language advertisements and sales materials, the Commission deems it appropriate to set forth the following enforcement policy statement:

(a) Where cease-and-desist orders as well as rules, guides and other statements require "clear and conspicuous" disclosure

(Continued on the following page.)

disclosure for specific types of advertising media are set forth in Section 437.2(g) (television) and Section 437.2(h) (print media).

There is no staff disagreement with this proposal.

B. Television Advertisements [Section 437.2(g)]

Commission Proposal: Any disclosure required under the Commission rules shall be made in the *same portion* (audio or video) of the advertisement in which the *voluntary claim is made.*

Any disclosure required as part of specified kinds of voluntary claims in any advertisement shall be made in immediate conjunction with the voluntary claim which creates the requirement for such disclosure. The Commission has not defined the phrase "in immediate conjunction."

Video disclosures shall be prominently displayed in the form of either a superimposition or a title, or on the screen by themselves, so as to enable them to be completely and easily seen and read on all television sets, regardless of picture tube size, that are commonly available for purchase by the consuming public.

Staff Proposal: The staff proposal repeats the Commission requirements, and mandates all required disclosures to be "in immediate conjunction with and at least as clear and conspicuous as the voluntary claim which creates the requirement for disclosure."

The staff also adds a requirement that required affirmative disclosures in television commercials which are longer than 30 seconds be displayed on the screen by themselves—not by a superimposition or a title—simultaneously with the required audio disclosure.

C. Print Advertisements [Section 437.2(h)]

1. General Requirements

Commission Proposal: The Commission proposal is technical in nature, including details on type-size requirements. Failure to meet such type-size requirements is a *per se* violation of the rule. The proposal forbids use of condensed type and also notes that adherence to the type-size specifications does not automatically preclude a finding that the disclosure is not "clear and conspicuous."

The rule requires all disclosures to be set in type on a slug at least one point larger than the point size of the type (not solid), using only normal word and letter spacing.

(Footnote continued.)
of certain information, that disclosure must be in the same language as that principally used in the advertisements and sales materials involved.

(b) Any respondent who fails to comply with this requirement may be the subject of a civil penalty proceeding for violating the terms of a Commission cease-and-desist order.

Staff Proposal: The staff proposal adds the requirement that disclosures mandated under Section 437.2(a) or (b) and Part B shall either be in immediate conjunction with and at least as clear as the claim which triggers the disclosure or shall be prominently displayed by themselves. Affirmative disclosures (Sections 1 or 2 of the staff proposal) shall always be prominently displayed by themselves.

Disclosures prominently displayed by themselves (that is, not in immediate conjunction with the voluntary claim) must be set in type on a slug at least one point larger than the point size of the type (not solid).

The staff would require billboard disclosures to be set in all capital letters.

2. Type-Size Requirements

Print Advertisements [*Section 437.1(h)(1)*]

Trim Size of Advertisement	Commission Proposal	Staff Proposal
Less than 65 sq. in.	1/16 in.	Affirmative Disclosure under Section 2: 3/32 in. All others: 1/16 in.
65 to 110 sq. in.	3/32 in.	Affirmative Disclosure under Section 2: 1/8 in. All others: 1/16 in.
110 to 180 sq. in.	1/8 in.	Affirmative Disclosure under Section 2: 5/32 in. All others: 3/32 in.
180 or more sq. in.	Type size is the same proportion as 1/8 in. to 180 sq. in.	Affirmative Disclosure under Section 2: Type size in the same proportion as 5/32 in. to 180 sq. in. All others: Type size in the same proportion as 3/32 in. to 180 sq. in.

Print Advertisements Longer than One Page

Commission Proposal	Staff Proposal
(i) Required type size is determined by the size of the largest page if the total area of the advertisement is greater than the page size.	Same
(ii) Disclosure may be on any page.	Disclosure shall appear on the page with the greatest portion of the advertisement. If the advertisement is equally distributed over more than one page then disclosure appears on the first of such pages.

3. Type-Size Requirements

Billboard Advertisements [*Section 437.1(h)(1)*]

(Not applicable to interior advertisements in a public transit vehicle)

Trim Size of Advertisement	Commission Proposal	Staff Proposal
180 to 270 sq. in.	1/4 in.	Same
270 to 1500 sq. in.	1/2 in.	Same
1500 or more sq. in.	Type size in the same proportion as 1 in. to 3000 sq. in.	Same
Minimum Size	1/2 in. for advertisements above 1500 sq. in.	Same

4. Additional Requirements for Special Types of Advertisements [Section 437.2(h)(v)]

(a) Lighted or Reflective Advertisements: Lighting on the required disclosure shall be the same as the lighting on the most prominently lit matter.

(b) Multi-Sided Displays: The required type size is determined by the area of the major display area (m. d. a.), and the disclosure must appear on the major display area.

(c) Unusual Advertising Material: Advertisers may petition for approval of alternative disclosure forms.

There is no staff disagreement with these requirements.

ISSUES*

(1) Will the proposed specifications adequately ensure that disclosures are clear, conspicuous and comprehensible to consumers?

(2) What alternative specifications, if any, would serve the purpose of the rule as well as—or better than—the proposed specifications, while further reducing the burden on advertisers?

V. Required Content of Disclosures, Statements and Claims

The Commission proposal includes disclosure rules which:

(1) Define and prescribe the required information to be included in any reference to nutrients.

(2) Prescribe the form and style of presentation of this information.

(3) Set (a) nutritional composition thresholds before certain types of voluntary claims can be made and (b) disclosure requirements for those claims.

The staff proposal would add two affirmative-disclosure requirements to the above rules. These would include:

(1) A format of nutritional disclosure similar to nutrition labelin [21 CFR 1.17(c)] in concept which would apply to the advertising of all products to which nutrition labeling applies.

(2) Mandatory disclosure of caloric information for those products to which nutrition labeling does not apply.

* All Issues listed in this document under this heading were raised by the Commission in its explanatory document. As set forth, these "issues" are biased in favor of getting responses which concede the legal and policy position asserted by the Commission and staff. Responses must be carefully prepared to include other issues raised as well as explain that one believes there is no legal wrong to be remedied, rather than unintentionally concede some assumption of the Commission.

The staff proposal would also set nutritional compositional thresholds and disclosure requirements for substantiating certain voluntary claims not dealt with by the Commission proposal.

A. Required Disclosure of Information for Claims

1. Nutrients

Commission Proposal [Section 437.2(a)]: The Commission provides a uniform manner for disclosure of nutrient information for use by consumers in evaluating claims or comparing nutritional value of foods.

Any voluntary positive statement or representation that a food contains a nutrient (protein and those vitamins and minerals listed in 21 CFR 1.17(c)(7)(iv) and 21 CFR 125.1(b)) is assumed by the Commission to imply presence of a nutrient at a significant level [ten percent or more of the U. S. RDA (the levels established in 21 CFR 125.1)] so that failure to either provide the nutrient in at least that amount or to correct the implication is misleading.

The rule provides that:

Nutrition Threshold

(a) There must be at least ten percent of the U. S. RDA of the nutrient in a serving, unless the advertisement also discloses the percentage of U. S. RDA of all of the eight primary nutrients present in the food.*

Disclosure Rules

(b) Claims must relate only to nutrients for which a U. S. RDA is established.

(c) The nutrient must be identified by its full common or usual name.

(d) The amount of nutrient present must be declared in terms of percentage of U. S. RDA per serving.

(e) No claim may be made that a food or serving thereof contains a nutrient in an amount of 50 percent or more of the U. S. RDA unless the nutrient is present naturally or such nutrient has been added in compliance with 21 CFR 1.17(a)(2); that is, required or permitted by regulation, such as a food standard, a nutritional quality guideline, etc. [Section 437.2(a)(3)].

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* Alternatively, the FDA format for disclosure of nutrients may be used [21 CFR 1.17(c)(7)(i)]. The reference to zero [Section 437.2(a)(2)] seems to be merely a caution not to omit mention of a nutrient not present and is not a technical requirement barring the use of asterisks as permitted by the FDA.

(f) Disclosure of nutrients shall be expressed as follows:

0 — 10% U. S. RDA	2% increments
10% — 50% U. S. RDA	5% increments
50% — 100% U. S. RDA	10% increments

(Same as 21 CFR 1.17(c)(7)(i) first sentence)

Staff Proposal: The staff proposal would generally limit claims about nutrients to the primary eight nutrients except that disclosure of the percentage of U. S. RDA of any of the thirteen other nutrients for which there is a U. S. RDA would be permitted when:

(a) the food contains at least ten percent of the U. S. RDA per serving of that nutrient, or

(b) disclosure of information is made as part of a FDA-type chart, or

(c) affirmative disclosure is triggered by either addition of a nutrient to a food or a claim or representation in an advertisement, label or labeling, or

(d) disclosure is caused by the reference to the name of a food, which contains the word "enriched" or "fortified."

There is no rationale given by the staff for allowing disclosure of all eight primary nutrients even if there is less than ten percent of the U. S. RDA present but not allowing disclosure of the other thirteen unless ten percent of the U. S. RDA is present. In addition, the staff does not require the U. S. RDA to be disclosed in the initial claim relating to one of the eight primary nutrients.

ISSUES

(1) Would it better serve the purposes of the proposed rule to expand the definition of "nutrients" to include nutrients for which there is no established U. S. RDA? If so, which nutrient(s)? [Section 437.1(c)].

(2) Is it appropriate to permit in advertising (television? radio? print?) representations regarding nutrients which are *not* present in nutritionally significant amounts in view of the fact that a disclosure of the complete nutrition profile of specific nutrient data on the label will be required; or should such truthful representations be prohibited in advertising (television? radio? print?) due to the possibly misleading implications of nutritional significance that might follow from any reference to the presence of such nutrients? [Section 437.2(a)].

2. Protein

Commission Proposal [Section 437.2(b)]: Protein is included in the definition of "nutrient" [Section 437.1(c)] and thus the disclosure of protein must comply with the requirements for nutrient disclosure. In addition, protein claims may only be made if the protein in a serving is at a level of ten percent or more of the U. S. RDA and the protein has a PER (protein efficiency ratio) of 20 percent or more of the PER of casein, determined according to the methods specified in 21 CFR 1.17(c)(4) [Section 437.1(i)].

Staff Proposal: The staff proposal repeats the Commission proposal.

ISSUES

(1) Are the proposed standards for protein quality and quantity sufficiently high? If not, what other standards might be established which would be sufficiently compatible with the nutrient-labeling program standards so as to neither confuse consumers nor unreasonably burden advertisers?

(2) Should the proviso contained in Section 437.2(a)(2) apply to representations regarding the quantity of protein as well as such representations relating to those vitamins and minerals considered as "nutrients"?

3. Calories

Commission Proposal [Section 437.2(d)]: The energy content of a food shall be stated in calories per serving, expressed to the nearest 2 calorie increment up to and including 20 calories; to the nearest 5 calorie increment above 20 calories and up to and including 50 calories; and to the nearest 10 calorie increment above 50 calories. Analytical methodology is provided in 21 CFR 1.17(c)(3).

Staff Proposal: There is no staff disagreement with this proposal.

B. Substantiation and Disclosure Rules for Voluntary Claims—Commission

To supplement and reinforce the general provision against false and misleading claims in advertisements, the Commission has proposed rules covering six types of affirmative claims, grouped under five headings. These rules contain two common remedial threads to eliminate potential deception. First, nutritional composition thresholds must be met before certain voluntary claims can be made; second, there are requirements for specific kinds of disclosures which must accompany various general claims.

The staff proposed rules for three additional types of claims. The claims to be regulated under the Commission proposal include claims that a food provides energy, calories, protein, vitamins or minerals; claims to be regulated under the Commission proposal include claims value of competing products. The staff proposals cover claims relating to naturalness, dietary benefit, and health.

These claims must not only be true at the time of manufacture, but must also remain true throughout the shelf life. The product must remain unaffected by normal storage conditions.

Compliance with these rules, as with the Subpart A rules, is evaluated on the basis of the quantities of the nutrients or calories actually present [Section 437.2(a)(2)]. The analytical methods for determining compliance for meat and poultry products regulated by the United States Department of Agriculture (USDA) appear in 9 CFR . . . (not yet issued) and the methods for determining compliance for all other foods appear in 21 CFR 1.17(e) [Section 437.2(c)].

These rules appear to be codifications and elaborations of the complaints and orders issued by the FTC against food advertisements over the last four years.

1. Emphatic Nutrition Claims [Section 437.3]

The Commission believes that the disclosure requirement of this section serves to help consumers differentiate between products containing different levels of a nutrient but which make the same claim. Since there is no established nutritional standard for the claim made without elaboration, consumers are led into purchasing less nutritious foods—or even non-nutritious foods.

The 35 percent threshold, set after extensive consultation with nutritionists and the FDA, serves to set a nutritional standard for this type of claim so that consumers are not misled into purchasing foods which are not as nutritious as expected.

Before any emphatic (strong) claims about a food may be made, either in terms of general or specific nutrient content, at least one nutrient must be present at a level of 35 percent or more of the U. S. RDA per stated serving. If the claim relates to a specific nutrient, that nutrient must be present at a level of 35 percent or more of the U S. RDA per stated serving.

In addition, the identity of the nutrient and the percentage of U. S. RDA per stated serving must be disclosed.

Emphatic claims include:

"lots of ....."

"full of ....."

"rich in ....."

"excellent source of ....."

"significant source of ....."

"good source of ....."

ISSUES

(1) Is the fact that a serving of a food contributes 35 percent of the U. S. RDA of the claimed nutrients a sufficient contribution to the diet to justify an emphatic claim?

(2) Is there a lower percentage contribution which is sufficient to justify an emphatic claim?

2. Nutrient Comparison Claims [Section 437.4]

(a) *Comparative Claims for the Amount of a Nutrient [Section 437.4(a)]:* Claims that "Food X contains more Vitamin A than Food Y" may imply (a) that there is a significant difference between the Vitamin A content of the foods or (b) that Food X is more nutritious overall than Food Y, when, in reality, Food X is really nutritionally inferior to Food Y. Consumers may be misled about both the absolute and comparative nutritional values of Food X.

The Commission resolves these problems by stating that comparative claims for the *amount* of any nutrient in an "advertised" food and a "compared" food (including both named and unnamed products referred to in a dangling comparative claim; such as: "Food X has more Vitamin A") shall not be made unless five nutritional thresholds are met:

(1) In a comparison which makes a superiority claim regarding the amount of a nutrient, the advertised food must be at least ten percent U. S. RDA greater per stated equalized serving. (See below on nutritional superiority claims).

(2) The same nutrients are compared and the name of the nutrient is disclosed.

(3) The U. S. RDA of each compared nutrient per stated serving is disclosed.

(4) Comparisons for protein must be for at least the same quality protein.

(5) Servings of the foods are of equal size, and the food compared is commercially available. The compared food cannot be significantly superior to the advertised food in other respects.

The disclosure requirements are:

(1) The foods serve the same dietary purpose.

(2) If a serving of the advertised food contains the same or fewer calories than an equal-sized serving of the compared food, *the compared food must not be significantly higher* (10 percent of the U. S. RDA higher) in more than two other nutrients than the advertised food.

(3) If a serving of the advertised food contains more calories than an equal-sized serving of the compared food, the compared food must not be significantly higher in more than two nutrients per 100 calories of the food.

Example (From Commission Explanation)

"Actual Percent of U. S. RDA Per Serving"

	Advertised Food X (Percent U. S. RDA)	Compared Food Y (Percent U. S. RDA)
Protein	4	11
Vitamin A	61	16
Vitamin C	11	31
Thiamine	23	15
Riboflavin	22	24
Niacin	30	51
Calcium	0	0
Iron	21	38
Calories	120	140

"This hypothetical example is designed only to illustrate the operation of the proposed rule. It should be noted that the percentage comparisons must be made on the basis of the actual amount at which each nutrient is contained in a serving.

"In this case, *the claim could not be made.* Although the advertised food does contain Vitamin A in an amount greater by 10 percent or more of the U. S. RDA than the same nutrient is contained in the compared food, the compared food contains three nutrients which are present in amounts greater than the amounts at which the same three nutrients are present in the advertised food. Thus, the percentage of U. S. RDA of iron in a serving of the compared food is greater by at least 10 percent than the percentage of iron in a serving of the advertised food. The same result occurs when the percentages of the U. S. RDA of Niacin and Vitamin C in the compared food are compared to the percentages of the U. S. RDA of those same nutrients in the advertised food."

This regulation does not limit the comparative nutrient claims to the primary eight nutrients. Thus, all nutrients for which there is an established U. S. RDA may have to be examined before such claims can be made.

ISSUES

(1) Should nutrient comparison claims permitted by the proposed rule be limited to foods which serve the same purpose in the diet?

(2) Should the test for permitting a comparison between the quantity of a specific nutrient in the advertised food and the amount of that nutrient in the compared food be based on an overall comparison between those nutrients contained in the compared food and the same nutrients in the advertised food; or should the quantities of each nutrient be compared with the quantity at which any nutrient is contained in the advertised food? Are there additional or alternative tests of nutritional equivalence which should be met before a nutrient comparison claim may be made?

(b) Claims that a Food is Replacement for, or as Nutritious as, Another Food [Section 437.4(b)]: Using the FDA determination that substitute foods, whether or not they resemble the foods they replace, should not be nutritionally inferior to the foods they replace, the Commission has constructed a rule prohibiting claims as to substitution or replacement except where the food is either nutritionally equivalent or properly labeled "imitation" according to FDA regulations. The Commission contends that substitution claims imply that one food is equivalent to another food in all material respects, which claim must be true from a nutritional standpoint.

If the advertised food is a food labeled "imitation," it must be clearly and conspicuously disclosed that such food is not as nutritious as the food it is intended to replace.

Nutritional equivalency is determined as follows:

(1) The advertised food must contain equal or greater amounts per equal-sized serving of all nutrients present in the compared food in amounts above two percent of the U. S. RDA (measurable amounts).

(2) The protein must be of equal quality (PER).

The disclosure rules are as follows:

(1) The identity of the compared food must be disclosed.

(2) The calories provided by equal-sized servings of the two foods must be disclosed.

(3) If the advertised food contains a higher fat content than the compared food, that fact, as well as the total fat content, must be disclosed.

ISSUES

(1) Is it appropriate to require a serving of the advertised food to contain all the nutrients contained in "measurable amounts" (that is, two percent of the U. S. RDA) in at least the same amounts as they are contained in a serving of the compared food? If not all nutrients, as to what nutrients should there be parity?

(2) Should nutrient comparisons (for purposes of satisfying the first prerequisite of making a claim under Section 437.4(b)) be between nutrients contained not at two percent but at some higher level (for example, ten percent of the U. S. RDA) in a serving of the compared food?

(3) Will disclosure of comparative caloric and fat content be meaningful to consumers in the context of these claims or should there be prerequisites to the making of such claims which require that a serving of the advertised food have as many calories as, or fewer calories than, a serving of the compared food, and that a serving of the advertised food have the same fat content as, or a lower fat content than, a serving of the compared food, without any requirement of disclosure?

(c) Claims that a Food is Nutritionally Superior [Section 437.4(c)]: The general nutritional superiority claim, "Food X is better for you" or the dangling comparative claim "Food X is better," do not relate to any specific food. This type of claim, therefore, cannot be completely true.

Such claims may not be made unless:

(1) The identity of the compared food is disclosed (this covers the dangling comparative claim).

(2) The food contains at least ten percent more of the U. S. RDA per equal-sized serving for each nutrient present in the compared food at two percent or more of the U. S. RDA.

(3) The food contains the same quality protein as the compared food.

(4) Calories of each food, per stated serving, are clearly and conspicuously disclosed.

(5) If the advertised food contains a higher fat content than the compared food, the advertisement shall disclose that fact and the

total fat content, expressed as a statement of the number of grams of fat in a serving (portion), to the nearest gram.

3. Nourishment Claims [Section 437.5]

(a) Claims that a Food is a Valuable or Significant Source of Nutrition [Section 437.5(a)]: Unqualified nourishment claims cause confusion about the relative and absolute merits of foods because the same terms are used by different advertisers to describe the merits of foods with vastly different nutritional value. The Commission has proposed objective criteria (standards) for the nutritional values of food, which must be met before words implying that a food is a valuable or significant source of nutrition can be used in advertising.

Examples of the qualified nourishment claims which trigger this section are terms such as:

"Wholesome"...

"Nourishing"...

"Nutritious"...

Such claims cannot be made unless:

(1) the food contains at least four nutrients, one of which is protein, at ten percent or more of the U. S. RDA per 100 calories;

(2) the food contains at least one nutrient at ten percent or more of the U. S. RDA per stated serving.

Terms of significance listed in the examples above may be used to modify the name of a particular nutrient, if the nutrient is present at ten percent of the U. S. RDA per stated serving. An example of this is: "Nutritious Vitamin C, 100 percent U. S. RDA per 8 oz. serving."

ISSUE

(1) Should the prerequisite for making a claim that a food is a valuable or significant source of nutrition be based on the content of four nutrients, including protein, in amounts of ten percent of the U. S. RDA per 100 calories or should it be required that those, or some of those, four nutrients be present in amounts of ten percent of the U. S. RDA per serving of the advertised food? Are there additional or alternative requirements that should be met before such a claim is allowed?

(b) Claims that a Food Provides all the Nutrients Necessary for a Sound, Complete or Balanced Diet [Section 437.5(b)]: In order to limit such claims to foods which are truly important in terms of nutritional value,

the Commission proposed that no claim be made that a serving of a food provides all nutrients necessary for a sound, complete or balanced diet unless:

(1) it contains 100 percent of the U. S. RDA for protein and all vitamins and minerals for which there is a U. S. RDA; and

(2) competent and reliable scientific tests demonstrate that such food is a total diet replacement. Such tests could include chemical and biological assay and availability tests over a long term.

(c) Claims that a Serving of an Advertised Food Alone Provides Complete or Perfect Nutrition [Section 437.5(c)]: Except for the type of claim described above in (b), an advertisement shall not represent that an advertised food or serving alone is "perfect" or "nutritionally perfect," provides "complete nutrition," or contains "all the good things you need." An advertisement shall not use any other term of similar import which in any way states, suggests or implies that consumption of only the advertised food or a serving thereof maintains health, makes an individual well-fed or in any way is a unique, special or exclusive source of nutrition or health benefits.

(d) Claims that a Food or a Serving thereof Constitutes a Nutritionally Adequate Meal [Section 437.5(d)]: An advertisement shall not represent that a food or a serving thereof constitutes a nutritionally adequate meal unless the food or serving complies with an applicable federal regulation prescribed in the Code of Federal Regulations developed to govern the making of such claims. (An example of an appropriate regulation is "Formulated Meal Replacement," proposed 21 CFR 102.21.)

4. Claims for Foods Intended to be Combined with Other Foods [Section 437.7]

This section relates to claims for foods to which principal or characterizing ingredients or components must be added. The regulation is intended to cover types of products such as (1) "meat extenders," "add meat dinners," "instant breakfast" and (2) breakfast cereals. It sets forth rules which prevent implications that an advertised food contributes nutritional value when, in reality, the combination final product derives much of the nutritional value from the added ingredient.

The proposal would:

(1) Require clear and conspicuous disclosure that a component must be added.

(2) Prohibit claims that the food by itself provides all the nutrients in a serving. However, it would allow statements that the combination provides a designated percentage of the U. S. RDA.

(3) If the added ingredient or component contributes more than 50 percent of the U. S. RDA of any nutrient named, that fact must be disclosed by a statement that most of the nutrient comes from the other food ("milk contributes most of the calcium"). The specific nutrient must be mentioned.

In addition, an advertisement for a food which is frequently, but not necessarily, combined with other foods when consumed can make nutrient claims based only on its own value (such as breakfast cereals). This regulation limits claims that a food has particular value when the nutritional benefit claimed actually comes from an added component and not the advertised food.

5. Energy, Calorie and Diet Claims [Section 437.8]

The proposed rule covers claims for a food as a source of energy, as well as claims relating to diet, weight, health and absence of sugar.

(a) Claims that a Food Provides "Energy" or "Food Energy" [Section 437.8(a)]: Food energy is supplied by calories, yet few consumers understand this. They think of energy in terms of nutrition. Accordingly, such claims are prohibited unless, in immediate conjunction with such representation:

(1) a statement is made that "food energy" or "energy" is provided by calories; and

(2) the number of calories per stated serving of the advertised food is disclosed.

This provision thus prevents consumers from inferring that the terms "energy" or "food energy" mean anything other than calories, or that a claim that a certain food is a good source of "food energy" means that it is nutritious. Part (a) of the proposed rule requires a disclosure of the fact that "energy" or "food energy" is supplied by calories each and every time an energy claim is made, as well as a disclosure of the number of calories contained in a serving of the advertised food.

(b) Claims that a Food or Nutrient, by Itself, Provides Health, General Vigor, Sustained Energy or Alertness, or that Energy from Calories Alone Will Produce Strength, Endurance, Intellectual Performance, or Prevent Fatigue [Section 437.8(b)]: Such claims are absolutely prohibited. This provision covers claims relating to general or sustained health, as opposed to claims of temporary energy benefit.

(c) Claims that a Food Enhances or Contributes to Vigor, Alertness, Energy, Strength or Endurance [Section 437.8(c)]: Such claims are prohibited unless the advertisement discloses, in immediate conjunction with the making of each representation:

(1) that such vigor, energy, alertness, strength or endurance is enhanced by and depends, in part, upon the calories in the food; and

(2) the number of calories which are contained in a stated serving of the advertised food.

(d) Claims that a Food or Meal Contributes to or is Useful in Regulating or Maintaining Caloric Intake or Body Weight or Depiction of a Food as a "Diet" or "Low Calorie" Food [Section 437.8(d)]: Such claims are prohibited unless:

(1) The food complies with FDA regulations for low-calorie foods [21 CFR 125.6]. These regulations have not yet been finalized.

(2) The advertisement discloses the number of calories in a stated serving of the food.

(e) Diet Claims for Foods Containing Artificial Sweeteners [Section 437.8(e)]: This provision applies to foods making the type of claims described in paragraph (d) which contain artificial sweeteners. Advertisements for such foods must:

(1) comply with FDA regulations for low-calorie foods;

(2) disclose the number of calories in a stated serving;

(3) disclose the number of calories contained in an equalized serving of the same food made with nutritive sweeteners:

(4) if the product contains a nutritive sweetener, in addition to the artificial sweetener, state: "This food contains sugars and should not be used by diabetics without the advice of a physician."

(f) Representations that a food is "Sugarless" [Section 437.8(f)]: Such claims cannot be made unless the food contains *no* sugars, including, but not limited to, sorbitol, mannitol, or other hexitols.

C. Substantiation and Disclosure Rules for Voluntary Claims—Staff Proposals

The substantiation rules for the five kinds of voluntary claims discussed above represent those which the Commission believes should be proposed and adopted. After considering three other types of nutrition advertising claims, the Commission withheld its approval of rules proposed by the staff but published the staff proposals in the *Federal Register* as a device for eliciting comment from all interested parties.

The staff proposals follow.

1. Natural and Organic Claims [Section 437.6]

The FTC staff considers the terms "natural" and "organic" to be confusing since these words mean different things to different people, including advertisers. Some people interpret them to mean absence of artificial ingredients while others think of certain nutritional qualities.

There are two possible approaches to the problem of "natural" and "organic" food claims. One approach (the staff proposal) would be to prohibit the use of the terms "natural" and "organic," while allowing advertisers to make specific truthful claims, such as "contains no artificial preservatives" or "contains no artificial ingredients." A second approach would be to specifically and uniformly define the terms "natural" and "organic." However, the Commission has not yet determined which alternative should be adopted.

The staff would prohibit the use of the terms "natural" or "organic" in advertising. Advertisers could, however, state that:

(1) a food contained no artificial or synthetic preservatives [Section 437.6(a)], if such is the case;

(2) a food contained no artificial or synthetic flavors, colors or ingredients [Section 437.6(a)], if such is the case;

(3) a food has not been subjected to pesticide or artificial fertilizers, if such is the case [Section 437.6(b)].

No representation implying nutritional superiority on the basis of the above factors can be made.

2. Fat, Fatty Acid and Cholesterol Content Claims [Section 437.9]

This rule is directed at handling the current debate on the impact of cholesterol and fats on health. The staff would prohibit any advertising claims regarding fat, fatty acid, or cholesterol content other than those claims allowed by the FDA regulation on fat and fatty acids [21 CFR 1.18]. Before such a claim can be made, the label and advertising must carry full nutrition labeling.

In order to make the permitted declaration about fat, the food must contain ten percent or more fat on a dry weight basis and not less than two grams of fat in an average serving.

The FDA regulation and the FTC staff proposal specifically prohibit claims indicating or implying that the product will prevent, mitigate or cure heart or artery disease or any attendant condition.

The FDA regulation also prohibits any statement relating to fatty acid or cholesterol content of a food on a label or labeling other than that specified in a prescribed format as part of the nutrition label format.

The FDA format is as follows:

(*a*) *Fatty Acid:*

(1) total fat content in terms of the percentage of total calories in the food provided by fat: "Percent of Calories from Fat: . . . . . ;"

(2) the number of grams of polyunsaturated fatty acid per serving;

(3) the number of grams of saturated fatty acid per serving;

(4) the number of grams of other types of fatty acid per serving.

(b) *Cholesterol:*

(1) the number of milligrams of cholesterol per serving, stated to the nearest five milligram increment;

(2) the number of milligrams of cholesterol per 100 grams of the food, to the nearest five milligram increment.

The statement "Information on fat and/or cholesterol content is provided for individuals who, on the advice of a physician, wish to modify their total dietary intake of fat and/or cholesterol" must be placed either immediately after the other information relating to fat and/or cholesterol or immediately following the complete nutrition information statement. When both fatty acid and cholesterol information are provided, these declarations may be combined into one declaration.

The Commission is not yet willing to adopt the FDA and staff approach, which is intended to prevent dissemination of "medical advice" through labels linking food consumption to the prevention of coronary disease. The staff would propose a rule consistent with the FDA policy, but the Commission is concerned that this approach may prevent the making of certain limited and accurate claims.

3. Health and Related Claims [Section 437.10]

The staff proposal incorporates under this heading the six health and nutrition claims specifically prohibited by FDA regulations [21 CFR 1.17 (i)]. In addition, the staff would prohibit the use of the term "health food," while allowing specific positive claims under the Subpart B requirements.

The six prohibited claims are:

(1) A food because of the presence or absence of vitamins and minerals is effective in the prevention, mitigation, cure, or treatment of disease.

(2) A balanced diet cannot supply adequate amounts of nutrients.

(3) The type of soil on which a food is grown may be responsible for dietary deficiencies.

(4) The processing, storage, transportation, or cooking of a food may be responsible for dietary deficiencies.

(5) A food possesses any dietary property when such property is of no significant value in human nutrition. Advertising for such items can claim no nutritional or therapeutic benefit for the foods.

(6) A natural vitamin is superior to a synthetic vitamin.

The FDA's prohibition against these claims has recently been upheld in the case of *National Nutritional Foods Association v. Weinberger,* 504 F. 2d 761 (CA—2, August 2, 1974).

D. Affirmative Disclosure Requirements—Staff Proposal

The staff proposal requires the affirmative disclosure of nutrient information about food in advertising in a manner similar to that of the FDA nutrition-labeling regulation [21 CFR 1.17]. The staff bases its proposal on the assumption that such information is exceptionally material, and that failure to provide this nutrition information to consumers is misleading, deceptive and unfair.

In addition, the staff feels that failure to disclose nutrient content is unfair in that consumers may be purchasing more expensive types of food than necessary to achieve a nutritionally balanced diet, as well as purchasing unnecessary products, such as dietary supplements. These problems contribute to an unnecessarily high average family budget for food.*

For these reasons, the staff has proposed requirements for affirmative disclosures of nutrient content. Section 1 of the proposal applies to foods with nutrient labels and is triggered by the addition of any nutrient to a food, or the dissemination of any nutrition claim or information. Section 2, covering foods without nutrient labels, would require, minimally, a disclosure of caloric content per stated serving, and, in the absence of contrary analytical data, a disclosure that the food does not contain at least ten percent of the U. S. RDA of any nutrient.

The only instances where the Commission requires affirmative disclosure of nutrition information is in conjunction with the kinds of "vol-

* See Rosch article, p. 180—181.

untary claims" described in Subpart B, and when a claim or representation is voluntarily made for a *nutrient* present below ten percent of the U. S. RDA per serving [Section 437.2(a)(2)].

The staff proposal (Section 1) would add a requirement for "comprehensive disclosure" of the nutrient content of a serving of the food in a format similar or identical to that required under the FDA regulation [21 CFR 1.17], when:

(a) *any* nutrition claim is made; or

(b) *any* nutrient is added to the food; or

(c) nutrient labeling is voluntarily applied.

Section 2 would require disclosure of the number of calories per serving and disclosure of the absence of significant nutrient content (if applicable) for all other foods.

Like the FDA nutrition-labeling rule, these staff proposals require that disclosure of nutrition information relating to a product must follow a specified format.

Legal Basis: As a legal basis for requiring affirmative disclosure, the staff cites Sections 12 and 15 of the Federal Trade Commission Act.**

1. Triggering Mechanism for Section 1—Affirmative Disclosure

Nutrition Labeling—FDA

Triggers:

21 CFR Section 1.17(a)

". . . Except as provided in paragraph (h) of this section, inclusion of any added vitamin, mineral or protein in a product or of any nutrition claim or information, *other than sodium content,* on a label or in advertising for a food subjects the label and that labeling to the requirements of this section.

(1) Solicitation of requests for nutrition information by a statement (For nutrition information write to ——•——) on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the labeling to the requirements of this section if no other nutrition claim is made on the label or in other labeling or advertising., if the reply to the request conforms to the requirements of this section, and if no vitamin, mineral, or protein is added to the food." (emphasis added)

There are two basic triggering mechanisms: (1) the addition of nutrients (fortification, enrichment, restoration, compliance with a food standard or nutritional quality guideline, addition to make a food nutri-

** An exposition of their rationale appears in Rosch article, p. 177.

tionally equivalent to a food it is designed to replace) and (2) the dissemination of a nutrition claim or information (except one relating to sodium). Nutrition claims include claims relating to vitamins, minerals, calories, protein, carbohydrate and fat.

Section 1.17(h) contains a list of exempted foods.

Solicited and Unsolicited Requests for Information: Nutrition labeling is not automatically triggered by a response to an unsolicited or solicited request for information if the response includes a disclosure meeting the required format. Such responses may otherwise have been considered labeling since labeling has been judicially construed to include such documents.

Nutrition Information to Professionals: 21 CFR 1.17(f) exempts products from nutrition labeling provided the information required in the standardized format is attached.

Nutrition Advertising—Staff Affirmative Disclosure

Triggers:

"If a food contains an added nutrient except as provided in 21 CFR 1.17(h), or if any nutrition claim or information respecting nutrition is made on the label, in labeling or in advertising, or if its label or labeling is subject to the requirements of 21 CFR 1.17, an advertisement for such food shall clearly and conspicuously disclose the following information. . ."

There are two basic triggering mechanisms: (1) the addition of nutrients (fortification, enrichment, restoration, compliance with a food standard or nutritional quality guideline, addition to make a food nutritionally equivalent to a food it is designed to replace) and (2) the dissemination of any nutrition claim or information respecting nutrition. Nutrition advertising may also be triggered by a solicitation on the label, labeling or advertising, such as "For nutrition information, write to . . ." if this is considered a nutrition claim.

Solicited and Unsolicited Requests for Information: There is no mention of the status of solicited or unsolicited responses to consumers about the nutritional value of a food. Hence, the FTC must regard these as labeling or advertisements.

Nutrition Information to Professionals: Advertisements in professional and scientific journals are excluded. See Section 437.1, Definition of Advertisement.

2. Formats for Affirmative Disclosure (Section 1)

(a) *Television Commercials—30 Seconds or Less (Section 1a)*

Video

For at least six seconds, the video portion of the advertisement must:

(a) identify at least four of the primary eight nutrients (Protein, Vitamin A, Vitamin C, Thiamine, Riboflavin, Niacin, Calcium and Iron) which are present in a serving of the food in amounts of ten percent or more of the U. S. RDA (if the food contains less than four such nutrients, each nutrient present in such amount must be listed) as well as the percentage of the U. S. RDA of each such nutrient present in a stated serving;

(b) state the number of calories contained in a stated serving.

EXAMPLE

*Vitamin D Milk**

Nutrition Information (optional heading)

Serving Size	1 Cup
Calories Per Serving	150
Percentage U. S. RDA per serving	
Protein	20
Riboflavin	25
Calcium	30

OR

Section 1(a)(1) (This is the FDA format specified in 21 CFR 1.8(d) and 1.17(c).)

For 15 seconds of the commercial, the video portion of the advertisement must show the full FDA format including the eight primary nutrients. If a nutrient is present at less than two percent of the U. S. RDA, the nutrient must be declared as zero (asterisks cannot be used).

EXAMPLE

Nutrition Information Per Serving

Serving Size	1 Cup
Servings Per Container	4
Calories	150
Protein	8 Grams
Carbohydrate	11 Grams
Fat	8 Grams

* The source of the technical data on milk was the Milk Industry Foundation.

Percentage of U. S.
Recommended Daily Allowances (U. S. RDA)

Protein	20	Vitamin D	25	
Vitamin A	4	Vitamin B6	4	
Vitamin C	4	Vitamin B12	15	
Thiamine	6	Phosphorus	20	Optional
Riboflavin	25	Magnesium	8	
Niacin	0	Zinc	4	
Calcium	30	Pantothenic acid	6	
Iron	0			

AND

Section 1(a)(3)

Audio: The audio portion must state "Read the food label for more nutrition information."

Section 1(a)(2)

Products without Significant Amounts of any Nutrient: Apart from these requirements, advertisements for foods which do not contain at least one nutrient in an amount of ten percent or more of the U. S. RDA per serving must either:

(1) disclose (video) the full FDA format for 15 seconds;

OR

(2) disclose simultaneously in the audio and video: "This food does not contain ten percent or more of the U. S. RDA of any vitamin, mineral or protein."

(b) Television Commercials—Greater than 30 Seconds (Section 16b)

(1) For at least 12 seconds, the video portion of the advertisement must either:

(a) disclose the identity and percentage of the U. S. RDA of any of the eight primary nutrients present in a serving at or above ten percent of the U. S. RDA;

(b) disclose the number of calories per stated serving;

OR

Display the full FDA nutrition-labeling format on the screen for at least 15 seconds.

(2) The audio portion must:

(a) state at least four of the nutrients disclosed in the video portion, with percentage of U. S. RDA per stated serving;

(b) state calories per stated serving;

(c) state "Read the food label for more nutrition information."

Furthermore, advertisements for foods which do not contain at least one nutrient in an amount of ten percent or more of the U. S. RDA per serving must either:

(1) show the full FDA nutrition format for 15 seconds;

OR

(2) disclose simultaneously in both audio and video portions: "This food does not contain 10% or more of the U. S. RDA of any vitamin, mineral or protein."

(*c*) *Print Advertising (Section 1c)*

The advertisement must disclose either:

(1) the identity and percentage (even if zero) of the U. S. RDA per stated serving of each of the primary eight nutrients;

(2) serving size;

(3) calories per stated serving;

OR

the entire FDA nutrition labeling chart.

A staff addition to Section 437.2(h) would require listing nutrients in descending order, in parallel columns; listing the nutrients and the percentage of the U. S. RDA; and would add a required heading "NUTRITION INFORMATION PER SERVING."

EXAMPLE

[For VIT. D MILK 3.25% Fat, 8.25% SNF (Solids)]

(This exact format is required by the staff addition to Section 437.2(h))

NUTRITION INFORMATION PER SERVING (Mandatory)

Serving Size	1 Cup
Calories per Serving	150
Percentage of U. S. Recommended Daily Allowances (U. S. RDA)	
Calcium	30
Riboflavin	25
Protein	20
Thiamine	6
Vitamin A	4
Vitamin C	4
Niacin	0
Iron	0

OR

NUTRITION INFORMATION

Per Serving

Serving Size	1 Cup
Servings per container	8
Calories	150
Protein	8 Grams
Carbohydrate	11 Grams
Fat	8 Grams

Percentages of U. S.
Recommended Daily Allowances (U. S. RDA)

Protein	20
Vitamin A	4
Vitamin C	4
Thiamine	6
Riboflavin	25
Niacin	*
Calcium	30
Iron	*
Vitamin D	25
Vitamin B6	4
Vitamin B12	15
Phosphorus	20
Magnesium	8
Zinc	4
Pantothenic acid	6

* Contains less than 2% of the U. S. RDA of these nutrients.

(d) Radio and Billboard Advertising (Section 1d & e)

The advertisement must state: "Read the food label for nutrition information."

This requirement does not apply to advertising in public transit vehicles.

3. Affirmative Disclosure for Foods Not Subject to Nutrition Labeling or Nutrition Advertising (Section 2)

While the FDA's nutrition-labeling regulation has no disclosure requirements for foods which do not contain added nutrients and for which no nutrition claim or information is disseminated, the FTC staff would require limited mandatory nutrition disclosure for all foods.

Even if a food advertisement is not subject to Section 1 requirements for disclosure, any advertisement for the food must disclose:

(a) The number of calories per stated serving; and

(b) Unless it is demonstrated that relevant analytical data for the advertised food, or, in the absence of such data, that relevant analytical data for the specific kind of advertised food indicate that a serving of food contains at least one nutrient in an amount of ten percent or more of the U. S. RDA, the following statement: "This food does not contain 10% or more of the U. S. RDA of any vitamin, mineral or protein."

EXAMPLE

NUTRITION INFORMATION PER SERVING

210 calories per 6 oz. serving. This food does not contain 10% or more of the U. S. RDA of any vitamin, mineral or protein.

Such disclosure would then subject the food to mandatory nutrition labeling.

Both the FDA regulation and the staff proposal create an exception from nutrition labeling for generic advertisements.

The FDA provision states: "An advertisement which does not mention the name of a distributor of a food or his brand, would not trigger required nutrition disclosure even though nutrition claims are made."

The staff proposal generally states that an advertisement which does not mention the distributor of a food or his brand(s) for fresh meat, fish or fowl; or a fresh vegetable; or a fresh fruit; or fresh potatoes, may clearly and conspicuously disclose the common or usual name (without any designation of the percentage of the U. S. RDA per serving) of any of the primary eight nutrients which, according to relevant analytical data for the specific kind of advertised food, is found in such food in an amount of ten percent or more of the U. S. RDA per serving. Such advertisement is not required to disclose the number of calories per stated serving.

[The End]

Trade Regulation Rule on Food Advertising—Remarks

By J. THOMAS ROSCH*

Mr. Rosch Is Director of the Bureau of Consumer Protection in the Federal Trade Commission. His Remarks Were Presented Before the Food and Drug Law Institute's Briefing Session on the Federal Trade Commission's Proposed Trade Regulation Rule on Food Advertising. The Session Was Held in Washington, D. C. on December 18, 1974.

I PLAN TO DO THREE THINGS TODAY. The first is to "walk you through" the provisions of the Trade Regulation Rule which have been proposed by the Federal Trade Commission (FTC). The second is to discuss the legal underpinnings of those provisions. And the third is to review the matters about which the Commission has issued no proposals to date but which it has indicated that it intends to address in the current rule-making proceedings.

Proposed Rule Provisions

The Commission has issued proposed rule provisions covering six types of affirmative claims, and I will discuss them in order.

Before doing so, however, I think a couple of general observations may be useful.

First, affirmative claims may be made implicitly as well as explicitly, and the various provisions of the proposed rule cover both kinds of claims. In other words, an advertisement need not expressly state that "Food X is a good source of iron" to be subject to the provision dealing with

* The remarks in this address represent only the views of a member of the Federal Trade Commission staff. They are not intended to be, and should not be construed as, representative of official Commission policy.

emphatic claims; it is sufficient if the advertisement can be interpreted as making that kind of claim.

Second, there is a common remedial thread running through most of the six proposals. In most cases, the Commission proposes to eliminate potential deception by two means. The first is to set up nutritional thresholds which must be crossed before various claims can be made. The second is to require the various general claims to be accompanied by more specific disclosures—disclosures which, for the most part, are extremely short, sweet and to the point.

Simple Claims

(1) The first matter covered by the proposed rule is the simple claim that a food contains a nutrient; for example, "Food X contains iron." The problem here is that the claim may be literally true—Food X may contain traces of iron—but the clear implication of the claim—that Food X contains a significant amount of iron—may be false. Consumers thus may be led to foods that are actually non-nutritious.

This problem is addressed by Section 437.2(a)(2) of the proposed rule. In this case, the nutritional threshold which must be crossed is ten percent of the recommended daily allowance (U. S. RDA) of the nutrient mentioned; that is: a serving of Food X must contain at least ten percent of the U. S. RDA of iron, which is the nutrient level which the Food and Drug Administration (FDA) would require to be present to support a claim that the nutrient is present in a significant amount. The affirmative disclosure requirement would simply require disclosure of the amount of the U. S. RDA of iron per serving or, alternatively, would permit reproduction of the label information required under the FDA's labeling program.

Emphatic Claims

(2) The second subject covered is the matter of *emphatic* claims; for example, "Food X is a *good* source of iron." As matters now stand, two advertisers may make precisely the same claim for foods which contain completely different amounts of the same nutrient. Since there is no established nutritional standard for the claims and since the claims are made without elaboration, the net result is that consumers may be led to less nutritious foods—or even non-nutritious foods—by these kinds of claims.

This problem area is treated in Section 437.3 of the proposed rule. The nutritional threshold in this instance is 35 percent of the U. S. RDA

of the nutrient for which the emphatic claim is made. In other words, a serving of Food X would have to contain at least 35 percent of the U. S. RDA of iron, a level which was the product of extensive consultation with nutritionists and with the FDA. And all that must be disclosed is the amount of the U. S. RDA of iron actually present in a serving of Food X.

Comparison Claims

(3) The third subject covered in the proposed rule is the matter of nutrient *comparison* claims. There are several kinds of these claims.

The first is a specific nutrient claim, such as "Food X is higher in iron than Food Y." Again, this may be literally true, but the claim may carry several possibly false implications; for example, that Food X contains a significant amount of iron or that Food X is more nutritious overall than Food Y. Thus, consumers may be misled about both the absolute and the relative nutritional values of Food X.

The proposed remedy for these problems appears in Section 437.4(a). In this instance there are four principal nutritional thresholds.

Nutritional Thresholds

The first is the ten percent U. S. RDA threshold. A serving of Food X must have at least ten percent more of the U. S. RDA of iron than a serving of Food Y and, thus, must itself have at least ten percent of the U. S. RDA of iron. This eliminates the possibility of comparative nutrient claims being made for foods which contain no significant amount of any nutrient.

Second, the compared food (Food Y) cannot be significantly superior to the advertised food (Food X)—using the ten percent U. S. RDA figure as a measure of significance—in more than two other nutrients. This helps eliminate the possibility that consumers will be led to nutritionally inferior foods.

Third, for the same reason, when the advertised food contains more calories than the compared food, the nutrient-caloric ratio of the compared food (Food Y) cannot be significantly superior to that of the advertised food (Food X).

And fourth, the protein—if any—in the advertised food must be of the same quality as that in compared food.

With respect to affirmative disclosure, all that is required is disclosure of the amount of U. S. RDA per serving of the nutrient or nutrients in the compared products (Food X and Food Y).

Substitute Claim

A second type of nutrient comparison claim covered by Section 437.4 is the "substitute" or "replacement" claim; for example, "Food X is a substitute for Food Y." This kind of claim carries with it the implication that Food X is equivalent to Food Y in all material respects, which may or may not be true from a nutritional standpoint.

The proposed solution, once again, consists of nutritional thresholds and affirmative disclosure. In this instance, a serving of Food X must be at least equivalent to Food Y in terms of number, quality and percentage of U. S. RDA of nutrients present in a serving of Food Y before such a "substitute" or "replacement" claim can be made. And the ad must disclose the number of calories per serving of Food X and Food Y and, also, the fat content of Food X if it is higher than that of Food Y.

Superiority Claim

The third kind of nutrient comparison claim covered by Section 437.4 is the general nutritional superiority claim; for example, "Food X is better for you" or the dangling comparative claim that "Food X is better." The problem with the specific claim is that it is unqualified from a nutritional standpoint. The problem with the dangling comparative claim is that it is entirely open-ended so that nutritional superiority is being claimed over all foods. This is a claim which cannot be true for any food.

Advertisements of this sort must pass two nutritional tests. One is that each nutrient in the compared food (Food Y) must be present in the advertised food (Food X) at a significantly higher level; ten percent of U. S. RDA per serving is again the standard of significance. The second is that Food X must contain protein of at least the same quality as any protein in Food Y. All that would be required in the way of affirmative disclosure is the number of calories present in equal-sized servings of Food X and Food Y unless Food X has a higher fat content than Food Y. In that event, that fact and the fat content of Food X would also have to be disclosed.

Nourishment Claims

(4) The fourth subject covered by the proposed rule is the unqualified *nourishment* claim, the express or implied claim that Food X is, with-

out qualification, "nourishing" or "wholesome." The problem here is much the same as it is with respect to emphatic nutrition claims. Several advertisers whose foods are vastly different in terms of nutritional value may make this kind of superlative claim because there are currently no standards for such claims. As a result, consumers may be misled about the relative and absolute merits of the advertised food in this respect.

Section 437.5 attempts to eliminate this problem by establishing strict standards for use of these claims. If such a claim is made for Food X, it must contain at least one nutrient at a significant level—once again using ten percent as the level of significance—and a serving of Food X must contain at least four nutrients whose ratio to the calories in Food X is at least 10 U. S. RDA per 100 calories. If the advertisement for Food X goes further and claims expressly or implicitly that Food X provides *all* of the nutrients necessary for a complete or sound diet or that it is nutritionally perfect, Food X must satisfy stringent existing FDA standards for such claims. In short, under Section 437.5 these claims would be confined to foods which are truly important in terms of nutritional value.

Claims for Combined Foods

(5) The fifth matter covered by the proposed rule, more specifically, by Section 437.7, is what must be said when nutritional claims are made for foods intended to be *combined* with other foods. There are essentially two types of these foods.

The first is a product like meat extenders which *must* be combined with other foods in order to be edible. Section 437.7 permits nutritional claims to be made about the combination, but it requires the disclosure of the need for combination and also requires disclosure that most of the nutrients referred to are provided by the added food when that is the case.

The second type of combination food is a product like cereal which is frequently, but not necessarily, combined with other foods. Section 437.7 would require that any nutritional representations made be based solely on the advertised food, not on the combination.

Diet Claims

(6) Finally, the proposed rule covers various kinds of energy, calorie and diet claims.

The principal problem in this area is the rather loose use of the word "energy." Food energy is supplied by calories. Yet few consumers understand this; they think energy is synonymous with nutrition.

Accordingly, Section 437.8 of the proposed rule provides that each time an advertiser claims that "Food X provides energy," the ad must disclose that energy is supplied by calories and it must disclose the number of calories present in Food X. The rule would ban completely general health claims attributable to food energy or calories; for example, a claim that Food X by itself will produce health or general vigor or that the energy from the calories in Food X will by itself provide strength or prevent fatigue.

The second problem treated by Section 437.8 involves the indiscriminate use of diet claims; claims, for example, that Food X is "low in calories," is "dietetic" or "contains artificial sweeteners." Once again, consumers can easily be misled by these claims because of the lack of standards and the lack of explanation about what is meant.

Under the proposed rule, Food X would have to comply with the FDA's existing requirements for diet foods, and the number of calories per serving would have to be disclosed. If Food X contains an artificial sweetener, its advertisement must also disclose the number of calories contained in an equal-sized serving of Food X made with nutritive sweeteners. If Food X also contains a nutritive sweetener, a warning for diabetics must be disclosed.

Finally, Section 437.8 insists that "sugarless" or "sugar free" claims be scrupulously accurate—banning their use for foods containing any sugar whatsoever.

Underpinnings of Proposed Rule Provisions

That covers the provisions of the proposed rule. Let me turn briefly to their underpinnings.

You will notice that all of the provisions deal with affirmative food advertising claims, a subject which is explicitly dealt with in Sections 12 and 15 of the Federal Trade Commission Act. Section 12 expressly prohibits affirmative food advertising claims which are false or misleading.[1] Section 15 defines a "false advertisement" so as to include the omission of facts in food advertising which are "material" in light of the affirmative claims that are made.[2]

These statutory provisions specifically dealing with food advertising are buttressed by Section 5 of the Act, which broadly condemns all "unfair or deceptive acts or practices in commerce."[3] The Commission has stated

[1] 52 Stat. 114 (1938); 15 U. S. C. 52.
[2] 52 Stat. 116 (1938); 15 U. S. C. 55.
[3] 52 Stat. 111 (1938); 15 U. S. C. 45.

on several occasions that Section 5 imposes a very high duty of care on the advertiser whose advertising has an impact on health,[4] as affirmative nutritional claims has.

Taken together, Sections 5, 12 and 15 proscribe the making of all affirmative nutritional claims which, for whatever reason—lack of uniform standards, lack of adequate disclosure or inherent deceptiveness—have the tendency or capacity to mislead consumers.

Broad Discretion

The Commission's power to remedy such law violations by trade regulation rule was confirmed by the D. C. Court of Appeals in the *National Petroleum Refiners* case.[5] And the Supreme Court has several times held that the Commission has broad discretion in fashioning remedial relief to eliminate law violations.[6] It is necessary only that the remedy bear a "reasonable relation to the unlawful practices found to exist."[7] Thus, the Commission unquestionably has the power to remedy by rule the tendency and capacity of nutritional claims to mislead consumers.

To be more specific, if uniform standards are needed, the Commission can establish such standards. Previously, it has established preconditions to the making of claims by rule.[8] It did so only last year in its trade regulation rule on misbranding of belts.

Preconditions

If fuller disclosure is needed, the Commission can require that such disclosures be made as a precondition to the making of the claims. The courts have frequently affirmed the power of the Commission to order disclosure as a condition of making claims which would otherwise be deceptive.[9] For example, in *J. B. Williams v. FTC,* the Sixth Circuit

[4] See, for example, *Rodale Press, Inc.*, 71 F. T. C. 1184, 1239, 1241 (1967), vacated and remanded on other grounds, *Rodale Press v. FTC*, 407 F. 2d 1252 (CA of D. C. 1968); Trade Regulation Rule for the Prevention of Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking and Accompanying Statement of Basis and Purpose of Rule 93-94 (1964), 29 *Fed. Reg.* 8354-8355.

[5] *National Petroleum Refiners Assn. v. FTC*, 482 F. 2d 672, 698 (CA of D. C. 1973), cert. den., 415 U. S. 951 (1974).

[6] *FTC v. National Lead Corp.*, 352 U. S. 419 (1957); *FTC v. Ruberoid Co.*, 343 U. S. 470 (1952); *Jacob Siegel Co. v. FTC*, 327 U. S. 608 (1946).

[7] *FTC v. National Lead Corp.*, 352 U. S. 419 (1957).

[8] See Trade Regulation Rule: Misbranding and Deception as to Leather Content of Waist Belts, 16 CFR 409 (1973).

[9] *J. B. Williams v. FTC*, 381 F. 2d 884 (CA-6 1967); *Keele Hair and Scalp Specialists, Inc. v. FTC*, 275 F. 2d 18 (CA-5 1960); see also *P. Lorillard Co. v. FTC*, 186 F. 2d 52, 58 (CA-4 1950).

Court of Appeals affirmed a Commission order requiring the advertiser of Geritol to include extensive qualifications on its claims for the efficacy of that product.

Or if absolute prohibition is required, the Commission can promulgate rules containing such bans. It has always been considered to have the power to prohibit claims that are deceptive or unfair.[10] And it has in fact prohibited such claims by rule in the past.[11]

In sum, all three of the remedies which appear in these proposed rule provisions—standards, affirmative disclosure, and, in a few instances, flat prohibitions—enjoy extensive support in Commission and/or court law.

Other Matters to be Covered in Rule-Making Proceeding

Now let me turn to the other matters which will be covered in this very comprehensive rule-making proceeding. There are four of them.

(1) The first is the advertising of so-called "natural" and "organic" foods. The trouble, in this case, is that these words mean different things to different people. To some, they simply imply the absence of artificial coloring or flavoring. To others, the words "natural" or "organic" connote foods that have been grown in a certain way or which have certain nutritional characteristics. Thus, these terms inevitably have a tendency and capacity to confuse and mislead. One possible remedy, of course, is to completely ban the use of these terms, and that alternative is being considered. Rather than adopting that alternative, however, the Commission is soliciting suggestions for possible uniform or minimal definitions of the terms "natural" or "organic." This alternative might permit continued use of the terms in advertising but would eliminate their potential for misleading consumers.

(2) The second matter which will be considered in the proceedings is the advertising of so-called "health" foods. Like the term "natural" food, the term "health" food means different things to different people, including advertisers. In the rule-making proceeding, the Commission will determine whether a definition for this term can be developed or whether an outright ban is the only way to eliminate the capacity of this term to mislead and confuse.

[10] *Sears, Roebuck & Co. v. FTC*, 258 Fed. 307 (CA-7 1919); see also "Developments in the Law—Deceptive Advertising," 80 *Harv. L. Rev.* 1005, 1019-27 (1967).

[11] See, for example, Incandescent Lamp (Light Bulb) Industry, 16 CFR 409 (1973); Power Output Claims for Amplifiers Utilized in Home Entertainment Products, 39 *Fed. Reg.* 1538 (May 3, 1974).

Cholesterol Advertising

(3) The third additional matter which will be considered in the proceedings is how to handle the current debate in advertising about cholesterol and its impact on health. The FDA has prohibited advertisers from debating this issue, or from describing the debate, on food labels. In the rule-making proceeding, the Commission will determine whether the same approach should be taken in food advertising or whether it is in the public interest, and possible without deception or unfairness, to permit information respecting this matter to be included in advertising.

(4) And the final additional matter which will be considered in the proceedings is whether all food advertisers should be obliged to disclose the nutritional value—or lack thereof—of foods they advertise. I do not know whether the Commission will ultimately require such disclosures to be made. There are a couple of things I do know, however, which bear upon this matter.

Legal Implications

The first thing is that nutrition information is exceptionally *material* information and this materiality has distinct legal implications.

It is material in the fundamental sense that it is valuable to consumers from a health standpoint. The Ten-State Nutrition Survey,[12] conducted by the Department of Health, Education and Welfare (HEW) in 1968, and the First Health and Nutrition Examination Survey (HANES),[13] conducted by HEW in 1971 and 1972, produced substantial evidence that a significant part of this country's population was malnourished or had a high risk of developing nutritional problems.[14] The Ten-State Nutritional Survey also showed that a significant part of the male population—particularly the white male population—in this country was obese.

These studies were conducted several years ago. But, if anything, the need for accurate nutrient and caloric information is probably greater today than it was then. With the amount of food that can be purchased for a dollar shrinking, there is an even greater likelihood of nutrient deficiency and of excessive caloric intake.

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[12] U. S. Department of Health, Education, and Welfare, Health Services and Mental Health Administration, *Ten-State Nutrition Survey 1968-1970.* DHEW Publication No. (HSM) 72-8134.

[13] U. S. Department of Health, Education, and Welfare, Public Health Service, *Preliminary Findings of the First Health and Nutrition Examination Survey, United States, 1971-1972.* DHEW Publication No. (HRA) 74-1219-1.

[14] Ten-State Survey, "Highlights", *supra* note 1, at 8.

So I repeat that nutrition information is exceptionally material information in the sense that it is needed in the interest of good health.

Purchase Decisions

It is also material in the sense that many consumers can and will use it to make purchase decisions. In 1970, *Chain Store Age* magazine exposed consumers to a selection of products, some of which had full disclosure of their nutrient and caloric content. The study found perceptible shifts in consumer preferences toward the brands with full-disclosure labels. In some cases, shifts of over ten percent occurred.[15]

About a year after this study, the FDA contracted with the Consumer Research Institute (CRI) to research consumer understanding and use of nutrition labeling. CRI found, among other things, that: "2. In situations where a product or brand has a real nutritional advantage over its competitors, there was a major change in that product's share of the market."[16]

These studies, and others like them,[17] establish an additional aspect of the materiality of nutritional information; that is, that shoppers can and will use it in making purchase decisions.

The legal implications of the materiality of this information flow in the first instance from the text of Sections 12 and 15 of the Act. Section 15 treats as a "false advertisement" (within the meaning of Section 12) the omission of facts which are "material with respect to the consequences which may result from the use of the commodity to which the advertisement relates. . . ." If, as the HEW studies suggest, the omission of nutritional information can result in nutritional deficiencies and obesity, it is certainly "material with respect to the consequences which may result from use" of an advertised food.

Material Information

The more general language of Section 5 furnishes an additional string to this bow. In several recent trade regulation rules proceedings, the Commission has treated silence which harms the interests of consumers as a violation of Section 5. In the recent Care Labeling Rule proceeding, for example, the Commission stated that in the case

[15] 37 *Fed. Reg.* at 6494 (1972).
[16] 37 *Fed. Reg.* at 6495 (1972).
[17] 37 *Fed. Reg.* at 6495 (1972).

of a necessary like clothing, it was "unfair" within the meaning of Section 5 to omit from clothing labels care instructions—and limitations—which would permit consumers to make product comparisons on that basis.[18] Food, like clothing, is plainly a "necessary." And, nutritional information is material to purchasers of food products just as care information is material to purchasers of garments.

To sum up on this point, then, one of the things about which I feel certain is that a very respectable legal argument can be made that the Commission has the authority to insure that consumers get this exceptionally material information in advertising regardless of whether affirmative claims are made.

Another thing about which I feel certain is that the Commission, as presently constituted, is extremely concerned about this matter. It said so in its statement. It specifically solicited suggestions as to the form which such affirmative disclosures should take. And the Chairman has publicly reaffirmed that the matter is "a live issue."

These circumstances, it seems to me, make it inadvisable for food advertisers to simply sit on the sidelines and boo. What the Commission has done here is give the industry a golden opportunity to help shape whatever rule does issue. This kind of notice and opportunity is, to my knowledge, unprecedented. The question which you as an industry, and as individuals, must answer is whether to let it pass. I suggest to you that you should not. **[The End]**

[18] Trade Regulation Rule: Care Labeling of Textile Wearing Apparel 22-23 (1972), 36 *Fed. Reg.* 23889.

Questions and Answers

The Following Is the Text of the Question and Answer Session of the Food and Drug Law Institute's Briefing Session on the Federal Trade Commission's Proposed Trade Regulation Rule on Food Advertising. The Session Was Held in Washington, D. C. on December 18, 1974. The Answers Were Provided by J. Thomas Rosch and James H. Cohen. Mr. Rosch Is Director of the Bureau of Consumer Protection in the Federal Trade Commission. Mr. Cohen Is Deputy Assistant Director for National Advertising in the Federal Trade Commission.

Q: Do the Part B regulations modify any of the existing complaints and orders and consent decrees on advertising of foods?

A: No, the trade regulation rule does not modify an outstanding consent order or an outstanding order. I think what the questioner meant to ask, however, was whether the regulations differ in any respect from what the Commission has said in its orders that an advertiser's obligation may be. With respect to some past Commission decisions or orders, I think the answer to that quite candidly is yes. I think that in the past the Commission has suggested that an advertiser need not fully qualify some general nutrition claims as he would have to qualify them under these proposed rules. Now the next question which arises is why? Why is the Commission proposing to do something by rule which it may have indicated recently that it would not require in a case? I think that the answer to that lies in the fact that we are dealing with a rule and not a case. There is a significant difference when you are talking about a case—which is concerned with the obligations of one advertiser and his agency and the competitive impact which flows from putting one advertiser and his agency under order when others in the industry are not under such proscriptions. I think you have a completely different situation in a case setting than you have when you put the entire industry under such obligations so that you do not have the same kind of competitive impact. I think, accordingly, these are two different situations and that accounts in part for the differences.

Q: Is the underlying information supporting the regulation available? How can it be obtained?

A: The underlying information supporting the regulation will be put on the public record by the staff.

Q: Prior to the time of filing comments?

A: Prior to the time of the expiration of the period for filing comments—some, yes. I can't recall what our timetable is for that, but at least some of the general background materials, like ads and materials cited in the staff statement, will be available for examination before the expiration date for submitting written comments.

Q: In view of that, don't you think you ought to extend the time for filing comments?

A: At some juncture there will be an opportunity to reply to what the staff has to say. I don't know whether it would be during this comment period but, at some juncture, there would be that opportunity.

Q: Why does the regulation not apply to labeling?

A: There is a practical, if not a legal, division of efforts and responsibilities between the FDA and the FTC. They have labeling and we have advertising.

Q: Does the FTC seek to exercise sort of a remote control over labeling by reference to the FDA rules? If so, is it necessary or desirable?

A: All I can say on that score is that that's not the purpose of the regulation. The purpose of the regulation is confined to advertising and its impact. Our concern is to eliminate any tendency or capacity for deception or unfairness in advertising.

Q: Do flavor regulations apply to advertisements which must identify nutrients?

A: I'm not sure I understand the question—perhaps the questioner would make it clear.

Q: I have a question on your identity requirements on common or usual names by the FDA flavor-labeling documents. Also, what are your identity requirements incorporated in the definition section of Section 437.2, in that area where you say a food has to be identified by its full name?

A: Well, we are just going to go along with the FDA on the common or usual name designation of the nutrient. Specifically there is nothing on flavoring in these regulations.

Q: Would the definition of advertising in Section 437.1 include a leaflet or press release distributed by a trade association relating to food products of a class manufactured by members of the association which does not offer any product for sale, does not identify any product by brand name or name a manufacturer, but does contain statements or representations designed to create interest in the food products of the class?

A: I don't want to give a blanket answer to that question without studying it a little more closely. The situation which is conjured up in my mind by the question would not be covered. That is to say, I don't believe that a general trade association press release about a whole class of products would be covered.

Q: There have been some ads you may have seen promoting orange juice—things of that nature as a class—that is what the question is about.

A: That's covered.

Q: I think you might want to give some consideration to that definition of advertising. I'm sure it's things you really don't intend; for example, as it's written, I think it covers nonadvertising. It would cover editorial material; for instance, a food column in a newspaper or magazine. I'm sure you don't intend that, but if you read the language it would embrace it literally.

A: Well, we'll take a look at it. This is precisely what this dialogue is for.

Q: Just to repeat this one once more—is a wire hanger that says "eat apples, they're delicious" covered? That's all it says and it's put out by a trade association.

A: No.

Q: Is anything in the store point of sale—that is, labeling under the Food & Drug Act?

A: We do have an exception for "labeling."

A: We have an exception for labeling but point-of-purchase advertising would be covered under these regulations.

Q: Do trade association journals and house organs come within the professional and scientific journal exception?

A: That would have to be a case-by-case determination. That's a legitimate question and I don't want to give a blanket answer to it. I think there may be some circumstances in which they might be and there may be others which they might not be.

Q: May we have an example of a food that falls within the proviso in Section 437.2(a)(2)?

A: "Food X contains Vitamin A" and it does not contain Vitamin A in an amount of ten percent U. S. RDA (recommended daily allowance) per serving or higher.

Q: I'd like to know what it means when it says "where a food or a serving thereof is not required to contain a nutrient at a certain percentage. That's presumably an exception to the general rule stated in paragraph 2 of Section 437.2.

A: I think we're talking about two situations in this particular provision. One is the situation where X says that X product contains iron and it does contain iron at a ten percent or higher level. The other is the situation where X makes precisely the same claim—Food X contains iron—but it does not contain iron at a ten percent or higher level. Now in the second situation it can still make the claim but if it makes the claim it has to reproduce the label information which would be required under the FDA's labeling program.

Q: My question was the meaning of the words "where the food is not required to contain a nutrient." Required by what?

A: An example would be the nourishment claims covered by Section 437.5. They require that before any claims may be made that the food is nourishing or wholesome or the like, it must contain 35 percent of the U. S. RDA.

Q: So this language refers to the requirements of this proposed regulation, not to requirements under a food standard, FDA standards or FDA nutritional guideline. It's limited to the requirements of this proposed rule.

A: That is the intention of the draft.

Q: Please discuss further the "point-of-purchase" exemption.

A: That is not an exemption as such. There is an exemption for labeling and for retailer advertisements which are limited to price but there is not a point-of-purchase exemption as such.

Q: Is the FTC's principal concern to regulate food advertising directed to consumers, rather than the food industry itself? If so, will ads for foods that are marketed solely to institutional buyers, such as restaurants or cafeterias participating in the School Lunch Program, be exempt from the proposed rules? Does the reference to "professional" journals in Section 437.1(a) include food technology publications and other trade periodicals in which institutional foods are advertised?

A: They are not exempt under the current provisions and the reason for that is that it is very difficult to segregate those advertisements which reach the consuming public from those which do not. Some thought could perhaps be given—after appropriate comments—to drawing such a distinction. Our concern is with the information which consumers get and not so much with the information which professional dietitians receive.

Q: Does the reference to "professional" journals in Section 437.1(a) include food technology publications and other trade periodicals in which institutional foods are advertised?

A: That's a case-by-case type of situation. In some circumstances they might be and in others they might not.

Q: You have me a little confused about the point-of-purchase exception. You said there was none. This document, under the definition of advertising, says the proposed rule covers all food advertising with the two exceptions, one of which is point-of-purchase.

A: I'm looking at the discussion of this, and at the analysis and statement of issues section on page 7 thereof. The explanation is erroneous. The language of the rule controls and there will be a correction of the explanation published shortly in the *Federal Register.*

Q: May I ask whether this point-of-purchase proposal doesn't directly impinge on the FDA's authority since the FDA specifically declares that point-of-purchase material is labeling? They have held this view every time I've talked with their counsel about it. They hold that anything in the retail store in the nature of a sign relating to food is labeling under their Act. So wouldn't this cause a situ-

ation where you have two completely different rules applying to exactly the same thing?

A: I think this is a situation where our rule might in fact be applying to something which the FDA could regulate. As I said before, the division of labor is practical rather than legal. I think that the Commission's powers flowing from Sections 12 and 15 particularly and also from Section 5 would enable it to get into the labeling area, insofar as labeling constituted advertising. So I'm not troubled with the notion that we might be entrenching upon an area which is within the regulatory regime of the FDA. With respect to whether or not there are inconsistent provisions, I don't think that they will be inconsistent. It's just that ours would prevail. We've got a situation here where, so far as I know, the FDA has nothing that's inconsistent as such with our regulation.

A: To further amplify on that, we have gone over these regulations very carefully with the FDA. In fact, these regulations have been developed to a large extent hand-in-hand with the FDA. They are aware of our interpretation on this. I think it's important to make clear that the kind of advertising that we are talking about in point-of-purchase is advertising which contains nutrition claims. There is point-of-purchase advertising which refers only to price and which does not make any kind of nutrition claims. Those advertisements would not be covered by the terms of this rule.

Q: Will the proposed correction include the third exception for professional and scientific journals and will it also clarify what professional and scientific journals are?

A: The correction will not do that. This is something which, to my knowledge, has been raised for the first time today and this is precisely what the comment period is for.

Q: Why is advertising disclosure necessary, since the data is on the label for those who want it? Why not confine your approach to elimination of deception, as opposed to affirmative disclosure or perhaps even establishing thresholds for claims without affirmative disclosure?

A: That is a perfectly legitimate question, particularly in light of my reference to care labeling where the information is simply required to be on the labels. I think that we are dealing here with a situation which differs from garment labeling in two very significant respects. The first is the materiality of the information. As I've indicated before, the materiality of the information in this particular case is twofold. It's not just that consumers may want this information and that it may have an impact on their purchase decisions; it is also material in that it may have an impact on their health. So that the materiality of this information is multi-dimensional. It is, in that sense, more material than perhaps any other information with respect to any other kind of necessary product that I can think of.

The second respect in which this differs from the care labeling situation is that here we're dealing with advertising which exceeds by several hundred million dollars the amount of advertising of any other industry in the United States. Under those circumstances, there is at least the possibility or the potential for the advertising, simply by the virtue of its bulk or mass, to overshadow and thus undercut the efficacy of any kind of label disclosures. It's those two factors which, for me, separate this from the care-labeling situation and which make it impossible to deal with label information in isolation without regard to advertising.

A: I might amplify on that. I think the statement of basis and purpose also indicates a number of other important reasons why we think that nutrition information should be in advertising even though it is in labeling in some instances. The first point is that not all foods carry nutrient labels. There are a number of foods which simply do not have nutrition information on the label. Second, we think the advertising has the tendency or capacity in effect to obscure the importance and value of that nutrition information on the label. Therefore, it's important that the nutrition information in advertising complement the data which is provided

on the label. And, third, many persons simply make up their minds about food purchases after they have watched the television set or read a magazine. Frequently, the consumers are making their choices before they get to the supermarket and one of the legal underpinnings of this rule is that nutrition information can affect purchase decisions.

Q: Under proposed Section 437.4 the claim "food X contains more iron than food Y" would be prohibited where, depending on the amount of calories in a serving of the two foods, the compared food contains higher levels of other nutrients, not explicitly compared in the ad. Why, if full disclosure accompanies such an explicit comparison which focuses on a single nutrient, would the general nutrient content of the compared food be considered "material" in a legal, as well as practical, sense?

A: I think that the answer to that is that although the claim may be true insofar as its precise language is concerned, it carries with it the implication that food X is superior to food Y from a nutritional standpoint and that may or may not be true. It's to ensure that the implicit claim is made only in circumstances where the implicit claim is true.

Q: May I ask two questions? Take the example "milk is a better source of calcium than other foods." First, even though you could conjure up a comparative that might have better nutrient quantities, theoretically that claim would be prohibited; and, second, the proposal seems to read to prohibit all dangling claims of that kind—even if they are true.

A: It does that because logically there could be only one food that could make that kind of claim and I'm not sure what that food would be.

Q: FDA's regulation (21 CFR Section 1.17) provides that a food that is represented as a "significant source" of a nutrient must contain at least ten percent of the U. S. RDA per serving for that nutrient. FTC's proposed Section 437.3 would count a "significant source of —" as an "emphatic claim" requiring 35 percent of the U. S. RDA. Aren't these provisions inconsistent, and if so, can they be harmonized?

A: The answer to that is they are not inconsistent. When the FDA is using the word "significant" they are using it in a statutory, regulatory context as a term of art. We are using it as a term which can be disseminated to consumers and thus could perhaps be misunderstood. If "significant" were used in an advertisement and in a context where it could be taken to be an emphatic claim, it would be covered by the 35 percent requirement.

Q: How can the housewife make a decision without comparing other foods? She has to compare labels. How does the FTC staff proposal help?

A: Well, what we are concerned with or, at least partially concerned with, is the housewife who makes her decision on the basis of what she sees on television or reads in the newspaper. In that particular instance she's not comparing foods, except in the roughest fashion. This information will give her a basis for making a determination whether or not the food has any nutritional value and, also, with respect to those nutrients which she's particularly concerned about, whether or not the food contains those nutrients.

Q: Why is 35 percent better than 25 percent or 20 percent?

A: That's a good question and it is certainly one that will be reexamined after the comments and the hearings are held. Thirty-five percent, as I indicated in my opening remarks, was something which we settled upon after extensive conferences with both nutritionists and the FDA and it was our best estimate of what a significant percentage from a nutritional standpoint would be.

Q: Would advertising a soft drink as "refreshing" be a representation under Section 437.8(c) as contributing to a person's vigor, energy, alertness, strength or endurance?

A: It might. It would depend on how it was interpreted by the public.

Q: How are you going to determine how it's interpreted by the public?

A: With respect to implicit claims, I think we are probably back where we

were in the beginning and this provision does not advance the ball much in that respect. The Commission has its own expertise and there's a body of law which allows the Commission to use its own expertise in interpreting implicit claims. And beyond that, the Commission has recently been willing to look to surveys which bear on how ads are being interpreted by consumers. The staff increasingly has been putting in that kind of evidence, too.

Q: Section 437.8(e) cites Section 125.-1(i). Where is Section 125.1(i) found?

A: Somebody ought to acquaint the questioner with the mysteries of the *Federal Register*. It is a miscitation.

Q: What are you referring to, then, if it stops at (h)?

A: It is the section in the FDA regulation under health claims. That one lists the various provisions which are, in fact, included in the so-called staff proposal on health foods on page 39862. You'll notice there is also a reference made to 21 CFR 1.17(i). The citation will be checked to make sure that it is correct; and if not, it will be corrected.

Q: Some have said "those lawyers at the FTC don't like advertising, don't understand it, and just want to destroy advertising." What are your comments on this? What is your personal view of the role and value of advertising?

A: I recognize that advertising has a very legitimate function in this society as a method of selling goods and services. What we are concerned about at the FTC is, first of all, that it not be used in a fashion which can confuse or mislead consumers and, second, its competitive impact. I will elaborate just a minute on both of these. As I've indicated before, this may be a situation where there is not any deliberate intent on the part of anybody to deceive, confuse or mislead. Instead, it may be a situation where the lack of uniform standards and the lack of elaboration and the existing public misunderstanding of some terms inevitably lead to confusion and misleading. With respect to the competitive aspect, I do think we have to take that into account. Back in the 18th Century when the basic tenets of our free enterprise system were being defined, there were markets in which all material information about the product was freely available to the consumer. If you look back at 18th Century Williamsburg—you bought your shoes from the cobbler, you knew him very well and you probably saw him making them. The philosophers assumed that free market forces would operate properly because, among other things, all material information would be available to consumers in the marketplace so that they would be able to pick and choose on the basis of merits of those products. It is virtually impossible to recreate those conditions today or to implement those assumptions today. However, as the Chairman has indicated in some of his speeches, we have to be aware of the fact that the more information about material matters is absent from the marketplace, the more the marketplace can stray from true competition. Consequently, I think we have to be concerned that essential information is available at the marketplace and, if it takes some pump-priming to do it, I see no problem with that.

Q: I would like to go back to the "refreshing" soft drink. I think, but I don't know, that the questioner was using the adjective that comes from the energy claims category and you said that possibly refreshing soft drinks would be considered as preventing or relieving fatigue. Does that mean a sugar-free soft drink could not be advertised as being refreshing?

A: If the public is interpreting the claim simply as an energy claim, then it could be made but it would have to be made with disclosure about what energy comes from (namely, from calories) and about the calorie content. If, on the other hand, the public is interpreting the claim broadly and is interpreting it to mean something that would fall within a total, prohibited class of claims, those claims would be proscribed. It would depend on how the public is interpreting it.

Q: Does this apply to any other beverage containing caffeine? Sure, the energy is coming from calories but the coffee is waking you up.

A: I really don't know how to respond to that. Are you asking whether those claims are permissible? It depends entirely on how the public is interpreting it.

Q: Do you, in fact, do research to determine how the public did react to a particular ad?

A: Before somebody would be sued under this rule, perhaps. But, as I said before, the Commission has its own expertise in interpreting ads.

Q: The whole universe—I don't think you are recognizing market segmentation. It's a tough problem. I don't think there is any problem that goes to the total universe.

A: No, and I think the Commission's law takes that into account, and it does not require the total universe to understand a claim in that fashion.

Q: Does the FTC plan to file an inflationary impact statement to accompany this proposal?

A: Obviously costs will be one of the things that will be examined in connection with it. I don't know that it will file an inflationary impact statement as such, but the costs and, certainly, all comments that indicate the manufacturer plans to pass those costs to the consumer will be considered by the Commission.

Q: Is there any chance that some parts of the TRR (trade regulation rule) will be issued in final form before the entire regulation is finalized in all aspects?

A: There is no reason to believe at this juncture that the issues about which concrete proposals do not exist will not be handled at the hearings along with those for which concrete proposals do exist. As a matter of fact, it's my understanding that they will be.

Q: If construed literally, will not Section 437.2(a) prohibit a representation or disclosure concerning protein (which is not listed in 21 CFR 1.17(c)(7)(iv) or in 21 CFR 125.1(b))?

A: I'm not sure I understand the question, but protein is a nutrient for which there is an established U. S. RDA and under Section 437.2 if protein were present at ten percent or greater, then a claim could be made. If it were present at less than ten percent, then the proviso in Section 437.2 would apply.

Q: In Section 437.2(a) it talks about advertisements that contain a representation concerning a nutrient or a disclosure of a nutrient or that make such representations or disclosures only from among the nutrients listed in these two sections of the FDA regulations. Protein is not listed in those two; don't you intend to include protein?

A: Absolutely. The reference to nutrients in Section 437.2(a)(2) is definitely intended to include protein and those vitamins and minerals referred to in the two sections of the FDA regulations.

Q: Well, why don't you make the reference cross-reference the word "nutrients" in Section 437.2(a)(1) to Section 437.1(c) rather than to two sections of the FDA regulations that technically do not include protein in the list?

A: That sounds like a good suggestion.

Q: With respect to protein, the FDA regulations use protein-efficiency ration and the proposal uses protein-efficiency ratio. What's the difference?

A: I think the word ration is a typographical error. PER stands for protein efficiency ratio.

Q: Coming back to emphatic claims, I notice that the FTC equates some quite different words as meaning the same thing; that is, "loaded with," "lots of," "excellent" and "good." Now from a nutritionist standpoint the term "fair" or "good" certainly does not equate with "excellent" or "lots of" and I'm wondering if consideration has been given to assigning some different numbers, as Canada does, to the terms "fair," "good," "very good," "excellent;" for instance, 25 percent of the U. S. RDA, 50 percent, 75 percent or 100 percent. I'm questioning whether or not you have solid nutritional backing for the view that 35 percent of the U. S. RDA equates with "lots of" or "excellent" in view of the fact that there are many natural foods where a small portion provides 100 percent or more of a nutrient. For example, a me-

dium carrot or sweet potato is over 100 percent of the U. S. RDA in Vitamin A. Yet, the 35 percent figure would allow somebody to equate a small amount of Vitamin A with the term "excellent." So, what I'm suggesting is that consideration should be given to numbers.

A: Well, that is certainly one of the things that is going to be considered on the basis of the comments that come in. The 35 percent figure was the product of trying to determine what figure would be viable from a nutritional standpoint and what would be viable from a communication standpoint. But if the public does see some ranking in the use of certain terms, I should think some ranking might be appropriate.

Q: Broadcast media are universal in perception and, hence, are used more broadly for food-information advertising. Advertisers' dollars for the past 25 years attest to this—other reasons gladly supplied. Please describe your concept of a 30 second or 10 second commercial covering opening comments.

A: I guess the question is: "Can this be done in the context of a 30 second or a 10 second commercial?" The answer is that I think it can be done in the context of a 30 second commercial but I'm not sure that it can be done in the context of a 10 second commercial. It might be that you couldn't, practically, make the kinds of affirmative general nutrition claims, in a 10 second ad, with the elaboration required by the rule in that context.

Q: Can you then have a series of commercials explaining the context?

A: That hasn't been addressed by the staff, so I would hesitate to say.

Q: Then how would one measure the differences in a commercial at a certain rating level of audiences versus another on a competitive basis as one advertiser?

A: That's precisely why I have some doubts that a truncated message is viable. The point here is that the Commission is concerned that a general claim standing alone without any elaboration may have the tendency or capacity to deceive or mislead. If you can't make anything but a general claim in a ten second spot, then you can't make it.

Q: Do you have a survey on deception on this?

A: No.

Q: This is just someone's opinion then?

A: Yes, it is not just the staff's opinion. You have to remember that the Commission itself has issued these six proposals so, in that respect, it is exercising its expertise on a *prima facie* basis. It has been guided to some extent by marketing people who have been consulted in connection with development of the proposals.

Q: What if a manufacturer makes the label format available to every consumer, by mail and in print media—does he have to expend six seconds of every thirty seconds—or twelve of every sixty seconds —for the same disclosure?

A: I think I have answered that basically in two different questions. The answer is yes; at least that is our current thinking and for the reasons I've indicated.

Q: The so-called staff proposal is preceded by a disclaimer that neither the Bureau Director nor the Assistant Director for National Advertising "proposes." (1) Would it be more accurate to characterize the proposal as one by certain persons on the staff, rather than by the staff? (2) If so, how many, or what persons? (3) How about the rest of the staff?

A: I subscribe to the staff statement of fact, law and policy, the bottom line of which is that affirmative disclosure with respect to the nutritional value of all foods, whether or not affirmative claims are made, is appropriate. I subscribe to that principle. I do not subscribe to the form of affirmative disclosure which was attached to that statement. The only people who did not subscribe to the issuance, as a proposal, of that form of affirmative disclosure at the staff level were Richard Herzog, who is the Assistant Director for National Advertising, and I.

Q: The Commission has no science staff. Whom did you consult? Are these people or groups considered advisory groups? And will you make their comments to the Commission available?

A: They will be appearing in the hearings. It has to be emphasized that at this juncture the Commission really has settled upon absolutely nothing and it will make its final determinations upon the basis of what comments it receives, both in writing and at the hearings.

Q: Will the FTC accept views of the American Medical Association and the National Academy of Sciences as to lack of validity of the term "organic"?

A: I would think it would put weight upon them. Whether it would consider them as controlling or dispositive is another matter.

Q: The staff proposal requires, in effect, nutrition education in proportion to advertising budgets. Is this good? Shall we eat 100 percent vitamins at all meals?

A: I understand the gist of that question. I can just give you my viewpoint. I don't think that the federal government has any business telling anyone what they should eat and, quite frankly, I don't think the FTC is in the education business. We are in the business, however, of making certain that the consumers get the information which eliminates the potential for deception or unfairness and we are in the business of making market forces work.

Q: Why is the proposal based on a single nutrient, rather than several nutrients; that is, is not a food containing three or four nutrients having 15 percent or 20 percent U. S. RDA's superior to another similar food with a single nutrient of 35 percent U. S. RDA?

A: It may or may not be, depending on the caloric-nutrient ratio. What we were trying to do was to come up with some sort of ranking based on consumer understanding. We felt that the individual nutrient claim in which you specified one nutrient and said that "food X was better than food Y" with respect to that single nutrient was less inclusive, less far-reaching than a more general claim. We were trying to confine affirmative disclosure to what was necessary to eliminate any public misunderstanding. Perhaps we could have required more disclosure but we felt that was enough.

Q: Why do we need thiamine or riboflavin? How does merely knowing a U.S. RDA percentage have any greater an impact on purchase decisions than references to good taste? Should we all arm ourselves with calculators when entering the store? How misinformed will the consumer be when he or she finds the nutritional value of foods lost via cooking?

A: I think I have, to some extent, answered these questions. I don't know the answer as to why we need thiamine or riboflavin. I'm told by nutritionists that we do. How does merely knowing a U. S. RDA percentage have any greater impact than good taste on purchase decisions? I think the answer to that is that it probably doesn't. Indeed, good taste is probably at least as important or more important to consumers; but the point is that nutrition information is important to a significant number of consumers. With respect to arming yourselves with calculators when entering the store, I really don't know how to answer that. I was hopeful that one thing I made clear in my opening remarks was with respect to the disclosures that are required under the six provisions published by the Commission. These disclosures are not going to require anybody to use calculators. As far as a detailed affirmative-disclosure scheme is concerned, I've also tried to make it clear that, for my part, I don't think we should be doing that either.

Q: I have a question on the last part of that with regard to cooking and loss of nutrients. I understand that the FDA requires information for after cooking whereas the FTC proposal would require information in its raw state. If the nutrients are lost from cooking, what nutritional information has been acquired by our purchaser upon hearing whatever information has been disclosed in an advertisement?

A: Neither the FDA nor our nutritionists felt that the cooking process affected nutrient content sufficiently to create deficiencies. I should add, however, with respect to meats, that is not the Department of Agriculture's views.

The disclosures which they are contemplating there refer to both pre-cooked and post-cooked meats. I think what's more important than that controversy is to get some uniform terminology on the marketplace. What we need is a standard, one way or the other.

Q: Isn't there a very real danger that this regulation and the FDA's labeling requirements will result in inferring (implicitly or explicitly) that only foods containing the specified nutrients are good? As a case in point, bulk foods, according to researchers, are shown to play a major role in digestive processes and cancer of the colon.

A: It's been our judgment that there is not the danger that these requirements will result in implying that only foods containing the specified nutrients are good.

Q: You referenced a study supporting the impact of nutrient information on product labels. Is there any data to support the apparent assumption that similar information received by way of the radio will have a like impact?

A: Not that I am personally aware of.

Q: The FTC's proposed rules governing substitute and comparison claims require that the advertised food contain protein "of the same quality" as the compared food. FDA's Section 1.17 and the National Research Council (NRC) both recognize that, within certain limits, protein of a lower quality (i.e. PER) may be consumed in larger quantities to achieve a percentage of the U. S. RDA equal to that provided by a smaller quantity of higher quality protein. Was this considered in developing the FTC proposal, and, if so, why were the FDA and the NRC positions rejected?

A: It was considered and will be further considered in the hearings. This was a communications issue more than a nutritional issue. The educators and communications experts with whom we consulted suggested that when a claim is made that an advertised food is a substitute or replacement, consumers consider it to be as good in all respects, including protein or particularly in protein. Nonetheless, we would want to give consideration to this point in the hearings.

Q: Are the signs "Health Food Store," "Nutrition Center," etc. banned?

A: The answer to both is no. Let me tell you why. "Health food store" is not banned because the use of the term health is one of the things as to which the Commission has not issued a proposal to date, although it is also one of the things considered in the proceedings. It is possible that the use of the word "health" in connection with the advertising of certain foods would be banned. But in neither event, I should think, would the use of the word "health" and the use of the word "nutrition" not in connection with a product or a line of products be affected by these rules. So the answer to that is no.

Q: Who says you can't cross-examine the regulators?

A: I thought that's what you have just been doing.

Q: Do carbohydrate claims, such as "Low Carbohydrate" require further elaboration under (1) the Commission's proposal or (2) the staff proposal?

A: Carbohydrate claims are not specifically covered under the terms of these regulations. It is not considered to be a "nutrient" under the specific terms of these regulations; but perhaps it should be so considered.

Q: Why? Under the FDA's regulations they are considered nutrition claims. Why is there a difference?

A: There may not be and maybe it's one thing we should consider further in the hearings but the nutritionists with whom we have consulted have suggested that when you are talking about the nutritional value of the food, you're talking about the 20 nutrients, including protein, which are listed in 21 CFR 1.17.

Q: The staff proposal does cover carbohydrates. The Commission's doesn't. The staff disclosures are triggered, I believe, by a nutrition claim, much the same as the FDA triggers. So the staff does cover carbohydrates in that disclosure.

A: Well, to the extent that a claim relating to carbohydrate is considered to be a nutrition claim, that's covered in the Commission proposal as well. However, the disclosures required under the Commission proposal do not include mention of carbohydrates.

Q: There is no required affirmative disclosure as I see it in the Commission proposal. If you say your product is simply "low in carbohydrates," there seems to be no provision for any further modification such as a disclosure of the percentage of U. S. RDA of carbohydrates, if that were applicable.

A: That's correct and I'm not sure I see that in the staff proposal.

Q: Under the staff proposal, a carbohydrate claim would trigger a nutrition-labeling format as an alternative to the staff's format on nutrient disclosure.

A: Are you talking about the partial staff affirmative-disclosure proposal?

Q: Yes, under Section 1, if you made a nutrition claim (if a low carbohydrate claim were considered to be a nutrition claim), then you have to have all the charts and the elaboration in the advertising. So that all the information that you would be disclosing would have nothing to do with carbohydrates, even though a carbohydrate claim triggered the disclosures?

A: That's correct.

Q: Is the same thing true with regard to "fat" or "low fat" claims in the Commission's proposal?

A: Yes.

Q: Where, under Subpart B, would that claim be affected under the Commission proposal, and not the staff's?

A: It is my understanding that it would be a comparison claim. More specifically, I think it would be an open-ended nutrient comparison claim. It may be that the definition of nutrients should be clarified in Section 437.1(c) to make it clear that calories, fats, fatty acid, cholesterol and carbohydrates are considered nutrients, as I believe they are by the FDA.

Q: Then the same would go for a claim of "low carbohydrate"?

A: That's right. My view is that it would have to cross an appropriate threshold in order to make those claims. But there would be no affirmative disclosure with respect to carbohydrate.

Q: May I then ask what happens where you have a standard of identity promulgated by the FDA where the term "low fat" is part of the name of the food?

A: If the standard is part of the name of the food, we do not intend to prohibit that kind of representation although certain provisions of the proposal may apply to a claim such as "low fat." I would suggest that you comment on that particular aspect of the proposal.

Q: In the area of compliance—would you consider use of table reference data aside from use in Section 2 of the staff proposal?

A: Are you talking about Section 2 of the staff proposal?

Q: Section 2 of the partial staff proposal seems to allow for table data on calories for foods on which there aren't any nutrition labels.

A: With reference to the second part of that particular section which relates to a disclosure that it doesn't contain ten percent or more of the U. S. RDA, in that instance the required disclosure would have to be made unless either the advertiser had the data or there were some existing relevant data, such as Handbook 8.

Q: Calories concern me more particularly. I'm assuming that you are talking about advertising a chocolate candy bar or some snack food where the vitamins present may be minimal. Where you're determining calories from table data, it may be more important if you're talking about fruits and vegetables, etc. for which nutrition labeling might not apply. You're going to need table data because of the variation in the food supply.

A: In that case we would expect data of the kind incorporated in Handbook 8 to be utilized.

Q: Would you consider varying from the FDA and the USDA on table data or advertising references because you're talking about a 13 week or 26 week commercial, during which time the nutrition label conceivably could change? How is somebody going to amend their advertising distributed over the broadcast networks or the individual statements during that period, in effect forcing changes in commercials? This gets to be a compliance problem. Also, I don't know, but different manufacturers may find that regions of the country have different values and they have three or four different plants which may have, in that region, different nutrition labels and yet they are broadcasting advertising nationally. With milk, people suppose the American Dairy Association is advertising that milk contains Vitamin D, thereby triggering the proposal. You're covering more than one kind of milk and more than one kind of fat content.

A: If I understand your question, I think you are right in suggesting that it's going to have to be a matter of discretion. We are not going to require advertisers who are running a campaign to change their advertising campaign in midstream in order to comply with differing standards that may be developed in different areas. It's just a matter of requiring compliance in a fair way.

Q: Can explicit provision be put into the documents to cover these kinds of situations which are more comforting and reassuring than "we are going to be reasonable"?

A: We can certainly consider it.

Q: Re Section 437.5, why is it allowable to use an adjective such as "nutritious" as applied to a nutrient (for instance vitamin C) when by definition any nutrient utilized by humans is required for life, and therefore is "nutritious" if in suitable form or combination?

A: The question isn't quite clear. Would the questioner like to clarify the question?

Q: Well, in the regulations, it specifically refers to allowing the use of the term "nutritious vitamin C" which to a nutritionist is a monstrosity, because obviously any vitamin is nutritious. In other words, this is meaningless advertising. What I'm asking is: "Does the FTC want the use of confusing and meaningless terms?" For instance, "important vitamins"—what vitamin isn't important?—yet a lot of advertisers use this term. I'd like to know what an unimportant vitamin is. I've never heard of one.

A: Well, the intent of the section was simply to prohibit a general claim such as "nutritious" or "wholesome" when a food did not meet the particular standards. At the same time, we didn't want to prohibit advertisers from making a representation which was truthful about what the food contained. We simply wanted to suggest there that a general unqualified claim like "nutritious" would not be permitted unless all of the tests were met.

Q: The USDA is in the process of developing nutritional-labeling rules for meat and poultry. The USDA has developed rules for advertising and promotional allowances in the meat and poultry industries. This FTC proposal seems intended to cover meat and poultry. Who actually has responsibility and authority?

A: They are talking about labeling at the USDA and we are talking about advertising. I think we clearly have the authority under Sections 12 and 15. As to whether they also have it (I suspect they also have it), I think their regulations are talking about labeling right now, not advertising.

Q: They have advertising under the Act.

A: I know they have jurisdiction, but so does the FTC under Sections 12 and 15. I think it's overlapping jurisdiction and I think that the issue then is whether or not there's any potential for conflict here from both agencies exercising their jurisdiction. I was suggesting that I really didn't see it right now because I thought they were confining their activities to labeling and ours are concerned purely with advertising.

Q: Have you worked with the USDA on these regulations?

A: Yes we have, although we have worked more closely with the FDA than with the Department of Agriculture.

Q: Would you be in a position to make some comments categorizing the hearings which have been referred to several times and indicate, insofar as you can, their probable timing in relation to filing and other matters?

A: Very generally, if the comment period closes on February 5, then I would expect that the hearings would begin sometime in the late spring or early summer—May or June possibly. That's about the best target I can give you.

Q: Many of the traditional or natural foods regarded by nutritionists as highly nutritious do not contain 35 percent of the U. S. RDA for any nutrient. For example milk, which is perhaps the single most significant dietary source of calcium for many persons, does not ordinarily contain more than 30 percent of the U. S. RDA for calcium. On the other hand, fabricated foods may readily be formulated to meet the emphatic claim requirements. Because of this, do you not expect that your proposed rules may permit more emphatic claims to be made for fabricated as opposed to traditional or natural foods? If so, won't their policy tend to favor advertising for such foods?

A: With respect to milk, I thought that milk got in. But if you say it's below the 35 percent level, then so be it —the 35 percent figure will be reviewed with that in mind. With respect to the fortification horse race, I am aware of the debate between those who think that fortified foods are inferior to natural foods with the same nutrients. I'm also aware of the fact that the FDA is in the middle of that debate right now and in the process of resolving the debate. To my knowledge, it has not been resolved against fortified foods so I'm not really that troubled by fortification right now. It may well prohibit the making of emphatic claims for some foods which are natural foods as opposed to the highly processed ones but we have no indication (nor does the FDA) that a naturally occurring nutrient is any better (nutritionally superior) to an artificially contained nutrient which is there through enrichment or fortification.

Q: Here are two related questions. Why do the formats vary from Section 1.17 FDA formats? The FDA's nutrition-label format permits the use of an asterisk referring to a statement "contains no significant amounts of ....." Why doesn't the FTC allow this (1) in the Commission proposal and (2) in the staff proposal?

A: Well, the first question must refer to the staff proposal because there aren't any formats in the Commission proposal, except in the very first one which I indicated simply calls for reproduction of the FDA's labeling requirements as an alternative. I don't see that there's going to be any conflict there. I don't know what the answer is with respect to the staff proposal. I sort of dropped out of that debate.

It's simply a communications issue as to how consumers would best be able to understand the disclosure of a variety of nutrients and percentages. Unlike the nutrient-label regulation, the partial staff affirmative-disclosure proposal would call for, at most, the disclosure of only four nutrients and our communication experts indicated that presenting them in descending order at the level at which they were contained was most appropriate. In terms of the asterisk, it was a communications issue related to what would most be understood effectively through the medium of television.

As far as the Commission proposal is concerned, the reason that the asterisk system is not permitted is because the asterisk simply signifies that no significant amounts of any nutrient are contained in the food and the Commission proposals relate to affirmative claims and not to a situation where the food contains no significant amount of any nutrient.

Q: Does a solicitation by a company which says "write us for nutrition information" trigger the staff's Section 1 Rule?

A: Of course not.

Q: Does that not include the FDA exemptions in Section 1.17(a)?

A: I think we've made it clear that what we're talking about is information with respect to products.

Q: The FDA had to write a specific exemption in their interpretation.

A: If you think that that is necessary in order to get that across, I would certainly make it clear in the comments. There has been no intention at all to include that.

Q: Some products, for instance fresh fruits and vegetables, are highly variable in nutrient content. The FTC seems to adopt the FDA's requirement for 20 percent tolerance. Should not this be reviewed? In other words, the point I'm making here is there are many products where a 20 percent tolerance is completely inadequate because the variation may be, in many cases, up to 100 percent and there's nothing can be done about it. That is, that it's a natural, purely natural variation which occurs in the same product from the same area, even from the same field.

A: We were aware of that problem. Perhaps something should be done about it, but we didn't know what and we were willing to live with the fact that those tolerances would occur. If any data can be presented at the hearings or by comments on that matter, they will be considered. **[The End]**

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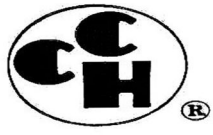

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