

FDA Dietary Supplement Regulations (National Nutritional Foods Association v. Food and Drug Administration)

Andrea Catania

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Perhaps, as acknowledged by Judge Friendly, "it would be wiser for Congress to allow the FTC to impose penalties for violations of its orders, subject to limited judicial review,"⁶⁷ but Congress has not yet seen fit to do so. Where Congress has designated the district court as the forum for adjudicating violations of FTC orders and for imposing the consequent civil penalties, "it must preserve to the parties their right to jury trial."⁶⁸ Thus, Judge Friendly's majority opinion in *Williams* strikes a proper accord between the seventh amendment and the Federal Trade Commission Act as currently written.

Christopher R. Belmonte

FDA DIETARY SUPPLEMENT REGULATIONS

National Nutritional Foods Association v. FDA

Section 401¹ of the Food, Drug, and Cosmetic Act² empowers the Food and Drug Administration (FDA) to promulgate a "reasonable definition and standard of identity" for any food under its "common or usual name" when such action "will promote honesty and fair dealing in the interest of consumers."³ When first proposed, the section was viewed as a tool to protect consumers against cheapened products.⁴ Identity standards for particular foods, such as a requirement that peanut butter consist of 90 percent peanuts, have been utilized to guarantee the sale of products conforming to an established minimum standard of quality.⁵ The Second Circuit, in *National Nutritional*

⁶⁷ 498 F.2d at 430.

⁶⁸ *Pernell v. Southall Realty*, 416 U.S. 363, 383 (1974) (citation omitted).

As was probably realized by Judge Oakes, *see* 498 F.2d at 441 n.8, the majority holding places the vindication of the Sixth Circuit's parallel enforcing order in the hands of a jury. *See* text accompanying note 3 *supra*. Such a result is, however, a necessary corollary to a statutory scheme which provides for the alternative remedy of a civil penalty to be adjudicated in district court. Indeed, a jury clearly would be required to vindicate a circuit court's parallel enforcing order in the event a criminal proceeding is brought under 15 U.S.C. § 54 (1970), *see* note 5 *supra*, where the sixth amendment right to trial by jury would be applicable.

¹ 21 U.S.C. § 341 (1970).

² *Id.* § 301 *et seq.*

³ *Id.* § 341.

⁴ 27 C. DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT 1073* (1938) [hereinafter cited as DUNN]. During legislative hearings, illustrations of cheapened foods included: (1) butter to which water was added to reduce fat content, *id.* at 218; (2) oysters to which water was added, *id.* at 161; (3) jams and preserves in which a higher percentage of sugar than fruit was used, *id.* at 819.

⁵ *See, e.g.,* *Corn Prods. Co. v. HEW*, 427 F.2d 511 (3d Cir.), *cert. denied*, 400 U.S. 957 (1970) (sustaining a peanut butter standard of identity requiring a minimum of 90% peanut content); *Columbia Cheese Co. v. McNutt*, 137 F.2d 576 (2d Cir. 1943), *cert. denied*, 321 U.S. 777 (1944) (upholding a cream cheese standard of at least 33% milk fat).

For an explanation of the purpose of § 401 as a means of setting a minimum standard

Foods Association v. FDA,⁶ confirmed the FDA's authority to promulgate a standard of identity for the *entire class* of dietary supplements.⁷ Moreover, the court upheld the unprecedented use of section 401 as a means of prohibiting the marketing of many dietary supplements containing ingredients which, though harmless, mislead the consumer as to the actual nutritional benefits he will derive.⁸

In *Nutritional Foods*, the FDA regulations under review required that dietary supplements be marketed only in narrowly prescribed combinations of vitamins and minerals.⁹ Mandatory and optional

for food products, see Austin, *The Federal Food Legislation of 1938 and the Food Industry*, 6 LAW & CONTEMP. PROB. 127, 132 (1939) and Baldwin & Kirlin, *Consumers Appraise the Food, Drug, and Cosmetic Act*, 6 LAW & CONTEMP. PROB. 144, 146 (1939). A summary of the standards that have been promulgated under § 401 may be found in Comment, *The Federal Food Drug and Cosmetic Act as an Experiment in Quality Control*, 20 SYRACUSE L. REV. 883 (1969).

⁶ 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 43 U.S.L.W. 3465 (Feb. 25, 1975).

⁷ 504 F.2d at 774-77. Dietary supplements include vitamins and/or minerals which are prepared and offered as tablets, capsules, wafers, or other similar uniform units; in powder, granular, flake, or liquid form; or in the physical form of conventional foods; and purport to be or are represented for special dietary use by man to supplement his diet by increasing the total dietary intake of one or more of the essential vitamins and/or minerals specified in paragraph (f) of this section.

²¹ C.F.R. § 80.1(a) (1974).

⁸ 504 F.2d at 781. An assumption underlying the regulations is the high degree of consumer ignorance in the area of sound nutrition. See Findings of Fact ¶¶ 8, 11, & 22, 38 Fed. Reg. 20,734-35 (1973) [hereinafter cited as Findings of Fact]. The FDA found that [a]lthough approximately 20 percent of the users of dietary supplements of vitamins and minerals actually use those articles to supplement or balance their diet, more than 40 percent of those persons admit they have no idea which vitamins or minerals, if any, are not sufficiently supplied by their diet.

Id., ¶ 9 at 20,735.

⁹ The regulations provide:

(1) A dietary supplement . . . shall be offered . . . only in the following combinations . . . (i) All vitamins and minerals. (ii) All vitamins. (iii) All minerals. (iv) All vitamins and the mineral iron. . . .

(2) A dietary supplement may also be composed of any single vitamin or mineral listed in paragraph (f) of this section.

²¹ C.F.R. § 80.1(b)(1)-(2) (1974). Fortified foods are also covered by the standard if:

- (1) more than 50% of a nutrient's adult RDA has been added;
- (2) the addition is not just a replacement for nutrients lost in processing;
- (3) the product is represented for special dietary purposes.

Id. §§ 80.1(b)(5), 80.1(e)(5), 80.1(e)(7). A fortified food is one to which a vitamin and/or mineral is added to increase its nutritional value.

Testimony at hearings prior to the promulgation of the regulation had shown that 59 different multivitamin and/or multimineral tablets were available for sale. The number of ingredients contained in each type of supplement ranged from 9 to 57. An example of the wide range of potencies was vitamin C. "The dosage per tablet or capsule of vitamin C . . . ranged from 30 to 500 mg." *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 776 (2d Cir. 1974).

Consideration of the proposals spanned more than a decade. The original notice to revise the dietary supplement regulations was published in 1962. 27 Fed. Reg. 5815 (1962). The regulations were finally promulgated on August 2, 1973, with an effective date of January 1, 1975. 38 Fed. Reg. 20,708-18, 20,730-40 (1973). The evidentiary hearings themselves lasted 22 months and produced over 32,000 pages of testimony. *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 767-68 (2d Cir. 1974).

nutrients, each within a specified dosage range, were designated for each combination.¹⁰ As its quantitative standard, the FDA adopted the schedule of Recommended Daily Allowances (RDA)¹¹ of the National Academy of Sciences and required that the nutrients contained in most dietary supplements be within 50 to 150 percent of their RDA.¹² Barred from all combinations were ingredients devoid of nutritional value,¹³ as well as valuable nutrients for which no RDA had yet been established.¹⁴ Nonconforming supplements would be deemed misbranded¹⁵ and hence could be seized¹⁶ and their producers held criminally liable.¹⁷ Combinations containing a nutrient in excess of 150 percent of its RDA were classified as drugs,¹⁸ and thus, were subject to more stringent standards required of new drugs.¹⁹

For an account of the lengthy hearing procedures, see Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 TEXAS L. REV. 1132, 1145-51 (1972) [hereinafter cited as Hamilton].

¹⁰ Included in the list were ten mandatory and three optional vitamins, and five mandatory and three optional minerals. 21 C.F.R. § 80.1(f)(1) (1974).

¹¹ *Id.* § 80.1(f)(2). The RDA replaces the Minimum Daily Requirements (MDR) as the nutritional yardstick. The RDA's indicate what would be an adequate nutritional level for between 95 to 99% of the normal healthy population. Findings of Fact ¶ 18, *supra* note 8, at 20,735.

Under the previous regulations, the MDR served only a labeling function, *viz.*, in the case of certain vitamins and minerals the percentage of the nutrient's MDR had to be disclosed on the label. 504 F.2d at 769. The RDA's, however, also serve as the basis for the standard of identity.

¹² 504 F.2d at 791. Under the FDA standard, for example, the dosage range of vitamin B₆ for adults was one to three mg.; for vitamin E, 15 to 45 units; for vitamin C, 30 to 90 mg. 21 C.F.R. § 80.1(f)(1) (1974). Vitamins A and D were limited to 100% of their RDA since higher quantities were deemed toxic. Findings of Fact ¶ 20, *supra* note 8, at 20,735.

¹³ 21 U.S.C. § 125.2(b)(5) (1974).

It was felt that the longer the list of ingredients, the greater the nutritional value the consumer thinks he is getting and the more likely he is to buy the product. Findings of Fact ¶ 32, *supra* note 8, at 20,736. See *United States v. An Article of Food . . . Nuclomin*, 482 F.2d 581 (8th Cir. 1973) (listing of non-nutritional ingredients on a dietary supplement is inherently misleading); see notes 66-68 and accompanying text *infra*.

Nonessential ingredients could be marketed so long as no nutritional claims were made and the label bore a statement to the effect that their value had not been established. Conclusion of Law B with respect to § 125.2, 38 Fed. Reg. 20,716 (1973).

¹⁴ 21 C.F.R. § 125.1(c) (1974).

¹⁵ A food is deemed misbranded under § 403(g) of the Food, Drug, and Cosmetic Act [i]f it purports to be or is represented as a food for which a definition and standard of identity has been prescribed . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard

²¹ U.S.C. § 343(g) (1970).

¹⁶ *Id.* § 334(a).

¹⁷ Misbranding is a misdemeanor. *Id.* § 333(a).

¹⁸ 21 C.F.R. § 125.1(h) (1974).

¹⁹ A significant effect of such a designation is that the manufacturer must prove the efficacy and safety of his product. See 21 U.S.C. § 355 (1970).

The thrust behind the FDA's regulations was not that the dietary supplements failed to contain the nutrients represented on the label or nutrients in adequate quantities, but rather, that the many products on the market were nutritionally "irrational" and tended to mislead the public.²⁰ Accordingly, it was deemed appropriate to establish maximum as well as minimum dosages for dietary supplements, even though amounts above the maxima are generally harmless.²¹ Those consumers desiring a nutrient in excess of its RDA could, of course, consume additional tablets²² or purchase individual vitamin and mineral supplements in order to compose their own combinations.²³

A number of parties adversely affected by the FDA's actions, including manufacturers and consumers of dietary supplements, petitioned the Second Circuit for review of the final regulations promulgated.²⁴ After disposing of the jurisdictional question presented,²⁵ the court focused its attention on whether section 401 empowers the FDA to establish a quantitative standard of identity for dietary supplements.

²⁰ Findings of Fact ¶¶ 8, 11, & 12, *supra* note 8, at 20,734-35. The agency found that the promulgation of a standard of identity would reduce consumer confusion concerning the choice of dietary supplements by insuring that a "basically rational formula for all products" be adopted. *Id.* ¶ 3, *supra* note 8, at 20,734.

²¹ See generally Letter from Peter Hutt, Asst. Gen. Counsel, Food and Drug Div., to Senator Gaylord Nelson *et al.*, reprinted in 119 Cong. Rec. 13,215-20 (daily ed. July 12, 1973), for an explanation and defense of the regulations.

²² 504 F.2d at 783. For example, to get 500 mg. of vitamin C, one would have to take six 90 mg. tablets.

²³ The court conceded that, because of the greater per unit cost of lower dosages, it would likely cost the consumer more to achieve the precise combination or dosage he wishes than it now costs him without a standard of identity. *Id.* at 782-83.

²⁴ A petition to review a final FDA regulation promulgated under §§ 401 or 403(j) may be brought directly to a court of appeals where the petitioner resides or where his principal place of business is located. 21 U.S.C. § 371(f) (1970). Petitions filed in the Ninth Circuit and the District of Columbia Circuit were transferred and consolidated with those originally filed in the Second Circuit. 504 F.2d at 767 n.1.

The present case is just one instance of the persistent opposition to the FDA's regulations by some of the petitioners. In *National Nutritional Foods Ass'n v. FDA*, 491 F.2d 1141 (2d Cir. 1974), the same regulations were challenged on the basis of a procedural irregularity. The petitioners alleged bad faith on the Commissioner's part and charged that he had failed to review exceptions to the regulations or to examine the whole record before signing the administrative orders. Despite the short tenure of the newly appointed Commissioner, the Second Circuit held that there had not been a sufficient showing that he failed to consider the record adequately. *Id.* at 1146.

²⁵ The issue was whether the court had jurisdiction to review those regulations which petitioners contended were not promulgated in pursuance to §§ 401 and 403(j). See note 24 *supra*. The court held that all but one provision arguably rested in whole or in part on these statutory sections. 504 F.2d at 773. Consequently, even if the court were ultimately to reject the Government's argument as to the authority to promulgate the regulations under these sections, the court was still bound to decide the case as required by statute. *Id.* at 772. Furthermore, since the remaining provision was part of a comprehensive set of regulations, the court by analogy to pendent jurisdiction and, in the interest of conserving judicial time, could review it as well. *Id.* at 773.

At the outset, the Second Circuit rejected the contention that section 403(j),²⁶ which specifically requires full disclosure on the label of the value of ingredients in supplements, precludes the application of section 401 to dietary supplements.²⁷ In the court's view, section 403(j) represented one method, but by no means the exclusive method, of consumer protection with respect to vitamin and mineral supplements.²⁸ Further, it was reasonable for the FDA to conclude that truthful labeling would not alone provide adequate protection.²⁹ Thus, section 403(j) did not act as a bar to the use of section 401 in this instance.

Petitioners also contended that the FDA had exceeded its authority in fixing a standard for "dietary supplements" since such terminology denoted an entire class of foods and not a "common or usual name" of a specific food.³⁰ Judge Friendly, writing for the court, rejected this argument, noting that the section provides that a standard of identity shall be prescribed "under its common or usual name *so far as practicable*."³¹ Based solely on this statutory language, the court felt that Congress had intended the section to be applicable to "a food or a class of foods under something other than its common or usual name."³²

²⁶ Pursuant to § 403(j), food is misbranded

[i]f it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be . . . necessary in order fully to inform purchasers as to its value for such uses.

²⁷ 21 U.S.C. § 343(j) (1970).

²⁸ 504 F.2d at 774-75.

²⁹ *Id.*

³⁰ *Id.* at 777. In addition to the standard of identity, the FDA regulations included two basic labeling provisions. The label was to indicate the percentage of U.S. RDA for each nutrient. 21 C.F.R. § 125.3(a) (1974). Also, specific statements concerning the efficacy of the various ingredients and the quality of the American diet were disallowed. The labeling could not claim or imply that: (1) the dietary supplement could effectively prevent or cure any disease or symptom; (2) ordinary foods cannot supply sufficient amounts of nutrients; (3) the soil in which food is grown may reduce the nutritional quality of a food; (4) storage, transportation, processing, or cooking of foods may be responsible for nutritional deficiency; (5) certain foods not shown to be essential to human nutrition have nutritional benefit; and (6) natural vitamins are superior to added or synthetic ones. *Id.* § 125.2(b)(1)-(6).

The court concluded that labeling provisions alone might be inadequate in eliminating consumer confusion since

[t]he subject matter is simply too recondite and the offerings of products too diverse for a label alone to be "clear enough so that, in the words of the prophet Isaiah, 'wayfaring men, though fools, shall not err therein'"

³¹ 504 F.2d at 777, quoting *General Motors Corp. v. FTC*, 114 F.2d 33, 36 (2d Cir. 1940).

³² Petitioners compared dietary supplements to the broad category of cheese, and a specific vitamin to a particular type of cheese. It was argued that while the FDA may have authority to establish a standard for vitamin A, just as it would for Swiss cheese, it could not establish one for dietary supplements as a class any more than it could for cheese as a class. Brief for Petitioner Nutritional Foods Ass'n at 15.

³¹ 504 F.2d at 779, quoting 21 U.S.C. § 341 (1970) (emphasis added by the court).

³² *Id.* Under § 401, the FDA in "prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted" shall "designate

Furthermore, it reasoned that despite the variation among competing products, the term "dietary supplement" has become "common and usual" for the total range of products.³³ A product composed of nutrients, by its very nature, "purports to be" a "dietary supplement," thereby making standardization possible.³⁴

Having determined that the FDA had the authority to promulgate a standard of identity for dietary supplements, the court next considered whether the regulation could extend so far as to effectively ban wholesome, safe, and accurately labeled products from the marketplace.³⁵ Petitioners alleged that such an effect would violate the congressional intent underlying section 401.³⁶ To support their contentions, they noted that both the Senate³⁷ and House³⁸ reports indicated that wholesome, yet substandard or nonconforming products, could be marketed, albeit under a different name. Responding to these arguments, the court ruled that section 401 was not merely adopted to guard against unwholesomeness,³⁹ but was also designed to "promote honesty and fair dealing in the interest of the consumer."⁴⁰ As Judge Friendly noted:

Advertising a potency in excess of the upper limits is bound to make consumers think they are getting a superior product when,

the optional ingredients which shall be named on the label . . ." 21 U.S.C. § 341 (1970) (emphasis added). The Government reasoned that if the FDA has the power to require the listing of optional ingredients on a label of a standardized class of foods, it must also have the authority to promulgate a standard for such class. Brief for Respondent at 24.

In Senate reports on the scope of § 401, examples of foods that would be subject to standardization included "edible oils," S. REP. No. 493, 73d Cong., 2d Sess. (1934), and "spices," S. REP. No. 361, 74th Cong., 1st Sess. (1935), both being classes of food. See DUNN, *supra* note 4, at 119, 246.

³³ 504 F.2d at 779.

³⁴ *Id.* at 780.

³⁵ Under the regulations, common products, such as vitamin B complex and vitamin C in a dosage exceeding 90 mg., could not be sold.

³⁶ See Brief for Petitioner, Archon Pure Prods. Corp. at 24-26; Brief for Petitioner, National Nutritional Foods Ass'n at 17-18.

³⁷ The Senate Committee Report on S.5, an intermediate version of the 1938 Act, stated:

It should be noted that the operation of this provision [§ 401] will in no way interfere with the marketing of any food which is wholesome but which does not meet the definition or standard, or for which no definition and standard has been provided; but if an article is sold under a name for which a definition and standard has been provided, it must conform to the regulation.

S. REP. No. 361, 74th Cong., 1st Sess. (1935), in DUNN, *supra* note 4, at 246.

³⁸ The House report read:

Under this a single reasonable standard of quality can be prescribed for any food and if the product falls below this standard it must be labeled as substandard [but can still be marketed].

H.R. REP. No. 2139, 75th Cong., 3d Sess. 5 (1938), in DUNN, *supra* note 4, at 819.

³⁹ It should be noted that the legislative comments were directed at the proper identification of cheapened products and did not contemplate a situation where the plethora of products itself would confuse and mislead the purchasing public. *Id.* at 781.

⁴⁰ 504 F.2d at 782.

in the FDA's view, they are not; furthermore . . . the problem would not be fully obviated by prescribing a label statement that the potencies exceeded the RDA's by particular amounts.⁴¹

Although conceding that accurate labeling would sufficiently protect the sophisticated purchaser,⁴² the court found it "far from irrational" for the agency to determine that such labeling would not safeguard the ordinary buyer.⁴³ Judge Friendly further commented that striking a proper balance among the interests of these consumers lay with the agency, not the reviewing court.⁴⁴

In reaching its decision, the Second Circuit relied principally upon the Supreme Court decision in *Federal Security Administrator v. Quaker Oats Co.*⁴⁵ For ten years, Quaker Oats had been marketing a product labeled "farina enriched with vitamin D." Subsequently, the standard of identity established for farina excluded vitamin D, though the vitamin could be included as an optional ingredient in "enriched farina."⁴⁶ In effect, Quaker Oats could not market its product as "farina," since it included an additional ingredient; nor could it market it as "enriched farina," since it did not contain all the nutrients required for the enriched product.⁴⁷ In sustaining the standard, the Court stated:

The statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition . . .⁴⁸

Furthermore, the Court noted the FDA's wide discretion in determining what ingredients should be included, concluding that the existence of reasonable alternatives would not constitute a valid objection to agency action.⁴⁹

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ 318 U.S. 218 (1943).

⁴⁶ *Id.* at 220.

⁴⁷ *Id.* at 224.

⁴⁸ *Id.* at 232, cited in *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 778 (1974).

Chief Justice Stone stated that the FDA was justified in so protecting consumers: [T]he evidence of the desire of consumers to purchase vitamin enriched foods, their general ignorance of the composition and value of the vitamin content of those foods, and their consequent inability to guard against the purchase of products of inferior or unsuitable vitamin content sufficiently supports the Administrator's conclusions . . . [that, in the absence of appropriate standards of identity, consumer confusion would ensue].

Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218, 229 (1943).

⁴⁹ 318 U.S. at 233.

The Second Circuit also relied on two appellate decisions: *United States v. 20 Cases*

In accepting *Quaker Oats* as controlling, Judge Friendly refused to view *62 Cases of Jam v. United States*⁵⁰ as a retreat from the broad scope previously enunciated.⁵¹ In *62 Cases of Jam* the Supreme Court held that if properly labeled an imitation, a product resembling jam but containing less fruit than standardized jam was not misbranded.⁵² The Second Circuit discerned that *62 Cases of Jam* does not preclude the use of section 401 to ban a wholesome product from the market. It holds only that a properly labeled imitation can be sold since it does not purport to be the standardized product, a view unchallenged in *Nutritional Foods*.⁵³

The court next considered whether the particular standard promulgated by the FDA was reasonable,⁵⁴ concluding that the agency had failed to establish the reasonableness of some aspects.⁵⁵ The FDA was directed to consider applications for permitting vitamin B complex

. . . "Buitoni 20% Protein Spaghetti," 228 F.2d 912 (3d Cir. 1956), *aff'g on opinion below*, 130 F. Supp. 715 (D. Del. 1954); *Libby, McNeill & Libby v. United States*, 148 F.2d 71 (2d Cir. 1945), *aff'g sub nom. United States v. 306 Cases . . . Tomato Catsup With Preservative*, 55 F. Supp. 725 (E.D.N.Y. 1944). The manufacturers in both cases contended that their products had independent identities from the food being standardized; thus, their products did not have to conform to the standards. The additional nonconforming ingredient in each respective product was safe. Nevertheless, it was held that the companies had to reformulate their products if they were to be sold as spaghetti and catsup, respectively. 130 F. Supp. at 720; 148 F.2d at 72-73.

⁵⁰ 340 U.S. 593 (1951).

⁵¹ 504 F.2d at 778-79.

⁵² 340 U.S. at 600-01. Under § 403(c) of the Food, Drug, and Cosmetic Act, a food is deemed misbranded

[i]f it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

21 U.S.C. § 343(c) (1970).

⁵³ 504 F.2d at 778-79. *See United States v. 856 Cases . . . Demi*, 254 F. Supp. 57 (N.D.N.Y. 1966), wherein the court rejected the Government's attempt to condemn, as misbranded, an imitation margarine that did not meet the standard of identity for margarine. *But cf. United States v. 30 Cases . . . Leader Brand Strawberry Fruit Spread*, 93 F. Supp. 764 (S.D. Iowa 1950) where a product resembling jam but labeled a fruit spread, was deemed mislabeled for not meeting the standard promulgated for jam.

The Second Circuit noted, however, that the possibility of marketing imitation dietary supplements to avoid the impact of §§ 401 and 403 is a totally unrealistic alternative for manufacturers. As the court recognized, use of the word "imitation" would be "commercial death in an industry where naturalness is next to godliness." 504 F.2d at 779 n.18.

⁵⁴ In considering reasonableness, the court was guided by the rule that administrative findings "as to facts, if supported by substantial evidence, shall be conclusive." 21 U.S.C. § 371(f)(3) (1970). Substantiality is determined in light of the total record. *Universal Camera Corp. v. NLRB*, 340 U.S. 474 (1951); *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218 (1943).

⁵⁵ 504 F.2d at 792. Petitioners had strenuously objected to the use of the RDA's as the standard establishing the maximum dosages. It was argued that the RDA's only represented an adequate standard for 95-99% of the healthy population. *Id.* at 791. As the court noted, quantitative limits were essential to carry out the purposes of the standardization. *Id.* at 790. Despite conflicting expert testimony, the court did not view the adoption of RDA's as the maximum standard unreasonable per se. *Id.* at 792.

supplements and vitamin C in larger dosages than originally proposed.⁵⁶ For this purpose, the court stayed the enforcement of the regulations until June 30, 1975, or until six months after the judgments become final, whichever is later.⁵⁷ In addition to reviewing such applications, the agency was directed to reopen the record to allow for the reasonable cross-examination of a key witness on the validity of adopting the National Academy of Sciences' RDA as the standard for maximum dosages.⁵⁸

The court also held that the FDA did not have the authority to classify dietary supplements exceeding the maximum limits as drugs,⁵⁹ or to ban from the standard, essential ingredients for which no RDA had been established.⁶⁰ Furthermore, though the regulations provided for revisions in accord with changes in nutritional knowledge,⁶¹ the upper limits were to be responsive solely to changes in the RDA. The court held that future revisions should not be so restricted. Instead, the maxima should be based on whether the limit promotes "honesty and fair dealing," by balancing the freedom infringed with the confusion that may be created by increasing the maxima.⁶²

⁵⁶ *Id.* at 785. The court-directed method for evaluating the application was to balance the potential increase in confusion caused by an increased variety of nutrients on the market against such factors as: (1) the consumer demand for the product and the degree to which nutritional experts believe that the product is not irrational for a substantial number of persons; (2) the extent to which labeling alone would reduce consumer confusion; (3) the dependability of the National Academy of Sciences' RDA for the particular nutrient at issue. *Id.* at 785-86.

⁵⁷ *Id.* at 785.

⁵⁸ *Id.* at 798-99. In an attempt to limit friendly cross-examination, the hearing examiner had ruled that since the witness involved was opposed to part of the regulations, he could not be cross-examined by other opponents. The witness had been instrumental in the formulation of the RDA's. The Second Circuit noted that the validity of the RDA's was a central issue and observed that the National Health Federation, which requested the cross-examination, and the American Medical Association, which had called the witness, did not have common interests. *Id.* at 795-99. See Hamilton, *supra* note 9, at 1167-70, generally supporting the examiner's effort to limit friendly cross-examination.

⁵⁹ 504 F.2d at 789. The FDA had argued that there was no normal nutritional need for nutrients in quantities in excess of 150% of their RDA. Therefore, such amounts could only serve a therapeutic purpose. The court noted, however, that a significant number of people have a nutritional need for potencies exceeding the upper limits. "In light of this, it cannot be said even as an objective matter that a given bottle of pills, each containing more than the upper limit of one or more nutrients, is not being used for nutritional purposes." *Id.*

Furthermore, the court noted that the seller's intent is a critical element in defining a drug. While objective evidence may "pierce" a "manufacturer's subjective claims of intent," more evidence than the uselessness of potencies in excess of the upper limits is required. *Id.*

⁶⁰ *Id.* at 786-87. The court concluded that it was unreasonable to allow the separate sale of nonessential ingredients and yet ban the sale of dietary supplements not on the approved list of vitamins and minerals. Further, "the failure of the FDA, after twelve years of proceedings, to fix U.S. RDA's for . . . [these nutrients] cannot in itself render the provision 'reasonable'." *Id.*

⁶¹ 21 C.F.R. § 80.1(b)(4) (1974).

⁶² 504 F.2d at 784-85. Of the labeling provisions, see note 29 *supra*, all were sustained

In view of the unique character of dietary supplements and the broad scope of the Food, Drug, and Cosmetic Act,⁶³ *Nutritional Foods* represents a proper expansion of the scope of section 401. *Quaker Oats* required only that a product represented as the standardized food meet that standard. In contrast, pursuant to the FDA's dietary supplement regulations, a food offered to increase a person's dietary intake of one or more essential nutrients is deemed a dietary supplement and must therefore conform to the standard regardless of the representations made on the label.⁶⁴ As the court reasoned, to allow the continued marketing of nonconforming combinations or dosages by avoidance of the term "dietary supplement" would, in this instance, undermine the purpose of section 401.⁶⁵

Other circuits confronting the problem of consumer ignorance in the nutrition field have also paid deference to the FDA's contentions. In *United States v. An Article of Food . . . Nuclomin*,⁶⁶ a dietary supplement was marketed which included ingredients that were not essential to nutrition. The label itself stated that no need for these ingredients had been established.⁶⁷ Nonetheless, the Eighth Circuit held that the listing of such ingredients misrepresented the product's nutritional value and that accurate labeling information could not compensate for the inherent misrepresentation.⁶⁸ Further, in *United States v. Vitasafe Co.*,⁶⁹ the Third Circuit held that a product which listed non-

except the section prohibiting the implication that a balanced diet cannot supply adequate amounts of nutrients. The court found that women of child-bearing age and children were more likely to need iron supplements than the average adult male. As to these persons, an otherwise balanced diet would not supply the needed nutrients. Thus, the court held that the FDA had to either produce more cogent evidence to support its labeling requirement or revise the section. 504 F.2d at 802, 806.

⁶³ In rendering its decision, the Second Circuit was guided by the principles enunciated in *United States v. Dotterweich*, 320 U.S. 277 (1943), wherein it was stated:

The purposes of this legislation [Food and Drugs Act of 1906; Food, Drug, and Cosmetic Act of 1938] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

Id. at 280, cited in *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 774 (2d Cir. 1974).

⁶⁴ 504 F.2d at 781. See *United States v. 30 Cases . . . Leader Brand Strawberry Spread*, 93 F. Supp. 764 (S.D. Iowa 1950); *United States v. 69 Cases . . . Southland Fountain Fruit*, 89 F. Supp. 992 (E.D. Tenn. 1949), both involving products which resembled jam. Though the products were accurately labeled, the respective courts held that they purported to be the standardized jam or preserve by their appearance, and condemned them for failing to comply with the standard.

⁶⁵ 504 F.2d at 781.

⁶⁶ 482 F.2d 581 (8th Cir. 1973).

⁶⁷ *Id.* at 583.

⁶⁸ *Id.* at 586.

⁶⁹ 345 F.2d 864 (3d Cir. 1965), modifying 226 F. Supp. 266, 276-77 (D.N.J. 1964), cert. denied, 382 U.S. 918 (1965). In *Vitasafe*, unlike the *Article of Food* situation, no attempt through labeling was made to reveal the nonessential character of the ingredients listed.

essential ingredients falsely conveyed the impression that the inclusion of such items enhanced the product's quality.

At least one circuit, however, has taken a more limited view of the FDA's power. The Fifth Circuit has stated that the development of sound nutritional practices is best left to consumer education and should not be a matter subject to the enforcement procedures of the Food, Drug, and Cosmetic Act.⁷⁰ However, this decision rested on the failure of the FDA to provide sufficient information to support its allegations.⁷¹ This contrasts sharply with the substantial amount of evidence supporting the need for a quantitative standard of identity for dietary supplements.⁷²

Despite the apparent propriety of the result in *Nutritional Foods*, two areas of difficulty remain in the wake of the Second Circuit's decision. The guidelines enunciated by the court for a review of proposed revisions in the maxima⁷³ fail to account for a major source of consumer ignorance. In its evaluation, the FDA is to consider, *inter alia*, the consumer demand for a particular vitamin or mineral.⁷⁴ Yet, demand for any product may be created by the manufacturer's advertising. Thus, if the advertising is sufficiently persuasive to create an "informed" demand, the product might still be marketed though the FDA might otherwise deem it nutritionally irrational. Secondly, the agency is required to assess the dependability of a particular RDA when it evaluates future applications for changes in the maxima.⁷⁵ However, conflicting expert opinion exists as to what constitutes sound nutrition.⁷⁶ Thus, each new revision may generate renewed litigation.

It remains to be seen to what extent the FDA will actually limit the variety of dietary supplements. In addition to the court-ordered revisions, there has been congressional discontent over the zealotry with which the agency attacked the nutrient problem.⁷⁷ A proposed

See Goodrich, *Food Standardization: Past, Present and Future*, 24 FOOD DRUG COSM. L.J. 464, 471-72 (1969), illustrating how consumers pay more for dietary supplements with higher dosages, although the quality of such products is not any greater than those meeting the U.S. RDA's.

⁷⁰ *United States v. 119 Cases of New Dextra Brand Fortified Cane Sugar*, 334 F.2d 238 (5th Cir. 1964).

⁷¹ *Id.* at 238. *See also* *Cream Wipt Food Prods. Co. v. Federal Security Administrator*, 187 F.2d 789 (3d Cir. 1951), wherein the court invalidated a standard of identity upon the Government's failure to prove allegations of deceptive nutritional labeling.

⁷² 504 F.2d at 775-76.

⁷³ *See* note 56 *supra*.

⁷⁴ 504 F.2d at 785.

⁷⁵ *Id.* at 785-86.

⁷⁶ *See generally*, O. GARRISON, *THE DIGITOCRATS' ATTACK ON HEALTH FOODS AND VITAMINS* (1970); L. PAULING, *VITAMIN C AND THE COMMON COLD* (1970); WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, FINAL REP. (1969).

⁷⁷ In his remarks before the Subcommittee on Health of the Senate Labor and Public

amendment to the Food, Drug, and Cosmetic Act would prohibit the FDA from issuing standards of identity which exclude noninjurious combinations or potencies from dietary supplements.⁷⁸ Although this amendment was not passed in the last session, the FDA might take cognizance of congressional sentiment and dilute the present standards. Thus, while the Second Circuit has authorized the FDA to take strong steps in regulating dietary supplements, whether the FDA can utilize this tool effectively must await future developments.

Andrea Catania

Welfare Committee, Senator Proxmire, one of the 45 co-sponsors of an amendment to the Food, Drug, and Cosmetic Act, expressed a common criticism of the supplement regulations:

[T]hat skepticism, that reliance on common sense, that refusal to rubber stamp the so-called experts who happen to occupy key or official positions, is one of the great hallmarks of American democracy. . . . This is precisely why in the case of vitamins, when the officially enthroned experts in the FDA are challenged by eminent outside experts in a field as primitive and controversial and unsettled and developing as vitamins and nutrition[,] [o]ne, it is desirable to view "official" policy with skepticism, and, two, to leave as much freedom and discretion to public choice as is not harmful to public health.

Hearings on S. 2801 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 93d Cong., 2d Sess. 11 (1974).

See generally Murphy, *Remarks Made at the Symposium on Food Standards*, 24 *FOOD DRUG COSM. L.J.* 390 (1969) (criticism of increased food controls); Comment, *The Federal Food Drug and Cosmetic Act as an Experiment in Quality Control*, 20 *SYRACUSE L. REV.* 883 (1969) (thesis that standardization has led to concentration in the food industry).

78 S. 2801, 93d Cong., 1st Sess. § 410 (1973), reported in 119 *CONG. REC.* 22,579 (daily ed. Dec. 12, 1973).