§ 69.56 Attendance costs for incarcerated students.

(a) The cost of attendance for a student who is incarcerated for whom at least one-half of his or her room and board expenses is provided includes—

(1) Tuition and fees as determined under § 690.52; and

(2) An allowance of $150 for books and supplies.

(b) The cost of attendance for a student who is incarcerated and for whom less than one-half of his or her room and board expenses is provided is the same as that allowed for a student who is not incarcerated.

(Sec. 4 of Public Law 98–79)

§ 690.57 Attendance costs for students at U.S. Armed Forces Academies.

A student enrolled at the U.S. Military Academy at West Point, the U.S. Naval Academy, the U.S. Air Force Academy or the U.S. Coast Guard Academy is considered to have no cost of attendance.

(Sec. 4 of Public Law 98–79)

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Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 172
Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame; Denial of Requests for Hearing; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket Nos. 75F-0355 and 82F-0305]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration.

ACTION: Denial of requests for hearing; final rule-related.

SUMMARY: The Food and Drug Administration (FDA) is denying the requests for a hearing on certain safety issues related to the amendment to the food additive regulation concerning aspartame that provides for the safe use of the substance in carbonated beverages and carbonated beverage syrup bases. After reviewing the objections to the amendment and the requests for a hearing, FDA has concluded that the objections do not raise issues of material fact that justify granting a hearing on a food additive regulation.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-427-5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

Aspartame (*N*-*L*-α-aspartyl-*L*-phenylalanine 1-methyl ester) is the nutritive methyl ester of a dipeptide formed from phenylalanine and aspartic acid. G. D. Searle & Co., 4901 Searle Parkway, Skokie, IL 60077, originally petitioned in 1973 for approval of its use as a sweetener and flavor enhancer in dry foods. FDA approved the petition in a final regulation published in the **Federal Register** of July 26, 1974 (39 FR 27317), and codified at 21 CFR 172.804.

FDA received formal objections to this regulation and requests for a hearing to investigate certain alleged toxic effects of aspartame. FDA granted the request for a hearing and established a Public Board of Inquiry (the Board), nominated from scientists outside the agency, to hear expert testimony and evaluate the scientific issues raised in the objections. Subsequently, FDA stayed the regulation (40 FR 56907; December 5, 1975) and delayed the Board's convening while an extensive audit of the authenticity of certain toxicological studies on aspartame was conducted. Of the 15 pivotal studies, 3 were reviewed by an FDA task force and 12 by scientists from Universities Associated for Research and Education in Pathology, Inc. (UAREP), a consortium of 9 universities. Following the finding by UAREP that the animal studies were authentic, the Board convened a public hearing; it completed the hearing and issued its report in 1980 (Aspartame, Decision of the Public Board of Inquiry, Docket No. 75F-0355) (Board's decision).

In the **Federal Register** of July 24, 1981 (46 FR 38285), the Commissioner of Food and Drugs reviewed the Board's conclusions and announced his final decision that aspartame was safe within the meaning of section 409(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)). The Commissioner specifically determined that, on the basis of available data, aspartame consumption would not cause brain damage such as mental retardation, brain lesions, or endocrine dysfunction, nor would it cause brain tumors. FDA then reinstated the original regulation (46 FR 50947; October 16, 1981), approving aspartame for the following uses as a sweetener: dry sugar substitutes in free-flowing and tablet form; cold cereals; chewing gum; and dry bases for beverages, instant coffees and teas, puddings and gelatins, and dairy analog toppings (21 CFR 172.804(c)). None of the parties who originally requested a hearing on the regulation objected to or sought judicial review of the agency's final decision to reinstate the regulation approving the dry uses of aspartame.

II. Aspartame For Use In Carbonated Beverages

A. Regulation Approving Use

In the **Federal Register** of July 8, 1983 (48 FR 31376), FDA issued a final rule that amended § 172.804 by adding new paragraph (c)(6) to permit the additional use of aspartame as a sweetener in carbonated beverages and carbonated beverage syrup bases. That regulation responded to a petition filed by G. D. Searle & Co. (47 FR 46140; October 15, 1982). Before approving this new use, the agency reviewed, among other safety issues, the potential neurotoxicity of the components and decomposition products of aspartame, the stability of aspartame in carbonated beverages, and the potential impact on health of increased consumption of aspartame resulting from its additional use in carbonated beverages.

In the preamble to the final rule, FDA also considered and responded to a number of safety issues raised in comments on the carbonated beverage petition (48 FR 31376 at 31378-31381). These comments expressed particular concern about potential adverse effects of aspartame's component amino acids on the brain, and the potential for exposure to toxic levels of decomposition products, including methanol, from aspartame's use in carbonated beverages. FDA based its approval of aspartame for use in carbonated beverages on its evaluation of clinical studies which were submitted by the petitioner to supplement animal study data supplied with the dry uses petition, data from other relevant studies in the scientific literature, and data contained in comments submitted on the petition (*id.*). These data are all included in the administrative record of Docket No. 82F-0305.

B. Objections and Requests for a Hearing and a Stay

Two objections were filed to the July 8, 1983 regulation approving the use of aspartame in carbonated beverages. The objections contended that numerous safety issues had not been adequately considered by the agency before the promulgation of the regulation, and requested that the regulation be stayed pending examination of those issues in a public hearing. The two parties objecting to the regulation on the basis of unresolved safety issues were James S. Turner, 1424 16th St. NW., Washington, DC 20036, objecting on behalf of himself and the Community Nutrition Institute, 1146 19th St. NW., Washington, DC 20036; and Woodrow C. Monte, Director, Food Science and Nutritional Laboratories, Arizona State University, Tempe, AZ. In addition, Richard J. Wurtman, Massachusetts Institute of Technology, Cambridge, MA, commented on the regulation, but did not request a hearing or a stay of the regulation. Before publication of the final rule approving the use of aspartame in carbonated beverages, Dr. Wurtman wrote a series of letters to FDA in which he expressed his concern about potential adverse effects on brain function of ingesting high levels of carbohydrate and aspartame, and reported the results of some experiments conducted in his laboratory.

FDA denied the requests to stay the effectiveness of the carbonated beverage regulation (48 FR 52899; November 23, 1983), because the public interest did not require it. FDA briefly evaluated each contention of the objections, and concluded that they failed to create doubts about the safety of aspartame significant enough to stay the regulation approving the use of aspartame in carbonated beverages. In that document, FDA also confirmed July 8, 1983, as the effective date of the

regulation authorizing the use of aspartame in carbonated beverages.

C. Standard for Granting a Hearing and Character of the Objections

Section 409(f) of the act provides that any person adversely affected by a final food additive regulation may file objections, specifying with particularity the provisions of the order "deemed objectionable, stating reasonable grounds therefor," and request a public hearing based upon such objections. However, the Commissioner may deny the hearing request if the objections to the regulation do not raise genuine and significant issues of fact that can be resolved at a hearing. Specific criteria for determining whether a request for a hearing has been justified are codified at 21 CFR 12.24(b). The pertinent criteria in 21 CFR 12.24(b) for granting a hearing are:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issues can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought * * *.

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing." *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980) *reh. den.* 446 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973). An allegation that a hearing is necessary to "sharpen the issues" or "fully develop the facts" does not meet this test. *Georgia Pacific Corp.* v. *U.S. E.P.A.*, 671 F.2d 1235, 1241 (9th Cir. 1982). If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, courts are authorized to issue summary judgment without an evidentiary hearing whenever they find that there are no material issues of fact in dispute and a party is entitled to judgment as a matter of law. See Rule 56, Federal Rules of Civil Procedure. The same principle applies in administrative proceedings.

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. *Pineapple Growers Association* v. *FDA*, 673, F.2d 1083, 1085 (9th Cir. 1982) (where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing). *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959) *cert. denied*, 362 U.S. 911 (1960). FDA need not grant a hearing in each case where an objection submits additional information or posits a novel interpretation of existing information. See *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971). Stated another way, a hearing is justified only if the objections are made in good faith and if they "draw in question in a material way the underpinnings of the regulation at issue." *Pactra Industries* v. *CSPC*, 555 F.2d 677 (9th Cir. 1977). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. See *Citizens for Allegan County, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.*, v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in the earlier aspartame proceeding leading to the approval of aspartame for dry uses. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. It is illogical not to recognize that the various judicial doctrines dealing with finality can be validly applied to the administrative process. In explaining why these principles "self-evidently" ought to apply to an agency proceeding, the D.C. Circuit wrote:

The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.

Retail Clerks Union, Local 1401, R.C.I.A., v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972). See *Costle* v. *Pacific Legal Foundation, supra* at 1106. See also *Pacific Seafarers, Inc.* v. *Pacific for East Line, Inc.*, 404 F.2d 804 (D.C. Cir. 1968).

In sum, a hearing request should present sufficient credible evidence to raise a material issue of fact which has not already been the subject of an administrative hearing. As is detailed in section III below, the hearing requests of Mr. Turner and Dr. Monte either do not present sufficient credible evidence to warrant a hearing or, where credible evidence is presented, even if true, that evidence does not raise a material issue of fact. Moreover, the hearing request of Mr. Turner, who was a participant in the hearing on the dry uses of aspartame, raises substantially the same objections that he had presented in the administrative hearing on the dry uses of aspartame. Those issues were considered by the Board's decision at p. 2 and reviewed in the Commissioner's decision (46 FR 38285), and Mr. Turner did not seek judicial review or administrative reconsideration of the agency's final approval for the dry uses of aspartame. Mr. Turner has thus had a fair opportunity to present his position on these issues and an additional hearing on the same issues is unwarranted.

III. Analysis of the Objections

A. Introduction

This section examines the specific issues identified in the objections to the regulations approving the use of aspartame in carbonated beverages. This document deals with each issue, but certain of the issues are considered at greater length because they have not been covered as extensively in public documents. Similar issues have been combined for ease of discussion and analysis. The general categories are: brain damage, decomposition products, consumption levels, cancer, interpretation of data from clinical studies, quality of data, and labeling. In responding to the various issues raised by the objections, the agency incorporates by reference all materials in the administrative record (Docket Nos. 75F–0355 and 82F–0305).

B. Brain Damage

1. *Brain lesions and mental retardation.* Mr. Turner's objection has expressed concern about aspartame's potential for causing mental retardation, brain lesions, and other adverse behavorial and physiological effects, because of adverse responses to its component amino acids, phenylalanine and aspartate. The issue was raised by Mr. Turner (p. 2) at the hearing on the dry uses of aspartame and was fully

considered by the Board and the Commissioner. Thus, further hearing on this issue is unwarranted. The following discussion summarizes the agency's consideration of this brain damage issue and explains the basis for the agency's conclusion that aspartame has been shown to be safe.

Because the phenylalanine and aspartate constituents of aspartame are also constituents of normal dietary protein, any risk from aspartame ingestion would occur because of the exposure to these amino acids in excess of normal exposure from dietary sources.

Very high doses of aspartate given by gavage or injection have been associated with discrete lesions in the brains of rodents. However, when the same high levels of aspartate or aspartame are administered in the diet to rodents, plasma levels of aspartate do not reach the concentrations required to produce lesions in rodent brains (46 FR 38285 at 38287). Continuous, extremely high plasma levels of phenylalanine, the other constituent amino acid of aspartame, have been known to produce mental retardation in the fetus of phenylketonuric mothers and in infants with phenylketonuria (PKU). However, an adequate margin of safety exists between the levels of phenylalanine known to produce mental retardation and those resulting even from exaggerated exposure to aspartame in carbonated beverages.

The possibility of brain lesions and mental retardation resulting from the use of aspartame was one of the major issues raised by Mr. Turner in his objection to the regulation approving the dry uses of aspartame and was fully considered at the hearing. The Board concluded that the ingestion of aspartame at levels that would be higher than those expected from consumption of aspartame for dry uses and in carbonated beverages could not be expected to increase the incidence of mental retardation, brain damage, or dysfunction of neuroendocrine regulatory system (Board's decision at p. 39). Subsequently, the Commissioner again reviewed the available evidence regarding brain lesions in rodents associated with asparatate and mental retardation related to phenylalanine. The Commissioner concluded that an adequate margin of safety exists between the amino acid levels resulting even from exaggerated exposure to aspartame and those observed to produce brain lesions in the rodent and mental retardation in PKU-related conditions (46 FR 38285 at 38288).

This issue has already been thoroughly considered in the earlier proceeding leading to the approval of aspartame for dry uses and Mr. Turner was given a full and fair opportunity to present his views in the earlier proceeding. Moreover, Mr. Turner could have sought judicial review or administrative reconsideration of the Commissioner's decision on this point, but did not challenge it. Accordingly, he is now estopped from raising the issue without new evidence unavailable at the time of the earlier proceeding. His objection presents no new information on this issue. A hearing is not justified if no data and information are submitted to support the factual determination urged (21 CFR 12.24(b)(3)).

2. *Potential adverse behavioral effects.* The amino acids, phenylalanine, tyrosine (a metabolite of phenylalanine), and tryptophan serve as precursors in the biosynthesis of neurotransmitters in both the periphery and the brain. According to the objections (Turner, p. 4; Monte, p. 5), the data submitted by Dr. Wurtman require the agency to hold a hearing to determine whether aspartame ingestion may alter the brain levels of these precursor amino acids and, in turn, neurotransmitter function, thereby leading to potentially adverse behavioral effects.

Although theories have been postulated to correlate changes in neurotransmitter function with cognitive or affective behavior, the state-of-the-art is such that little definitive evidence is available to support such relationships.

The data submitted by Dr. Wurtman (Ref. 1) in his comments on the carbonated beverage petition demonstrate increases in the plasma amino acid concentrations of phenylalanine and tyrosine in the human and rat following administration of large doses of aspartame to fasted subjects. The same data also demonstrate increases in the concentration of phenylalanine and tyrosine in the brain of the rat. Dr. Wurtman asserts that these increases in brain tyrosine and phenylalanine might result in changes in catecholamine neurotransmitters synthesized from these precursor amino acids. Drs. Wurtman (Ref. 2) and LaChance (Ref. 3) submitted comments that also postulated that these potential changes in neurotransmitters might lead to unpredictable behavioral effects, but submitted no evidence that would demonstrate that such behavioral effects have been observed or that they might plausibly be anticipated other than on the basis of the theories presented.

In the final regulation approving the use of aspartame for use in carbonated beverages, FDA discussed the data submitted by Drs. Wurtman and LaChance and the related literature on neurochemistry and behavior, and concluded that exposure to aspartame in foods would not result in adverse behavioral effects (48 FR 31376 at 31379-31380). After FDA had approved the use of aspartame in carbonated beverages, Dr. Wurtman submitted additional data in which he measured the levels of rat brain serotonin (5-HT) and its metabolite, 5-hydroxy-indoleacetic acid (5-HIAA) (Ref. 1). An increase in 5-HT and 5-HIAA occurring after high levels of glucose intake in fasted rats was blocked by concurrent administration of a high dose of aspartame. Dr. Wurtman suggested that this inhibition or "blockage" of glucose-mediated increases in brain levels of 5-HT and 5-HIAA by very high doses of aspartame, which he observed in animal studies, might mean that consumption of aspartame by humans could interfere with their normal pattern of carbohydrate consumption. Dr. Wurtman did not provide any evidence that the observed changes in brain 5-HT and 5-HIAA levels produced a change in the eating habits, preferences, or any other behavior of the animals tested.

FDA has reviewed the data dealing with the effect of aspartame in glucose-mediated changes in brain neurotransmitters that were submitted and has concluded that they are consistent with expected results following simultaneous administration of any food containing protein with glucose. The findings represent normal physiological variations in brain neurochemicals, which are a response to a specific dietary regimen, and thus would not be expected to be associated with adverse behavioral effects.

Drs. Wurtman and Lachance have developed interesting, but untested, hypotheses. The hypotheses do not, even if true, suggest that aspartame is not safe; they suggest merely that certain chemical changes may occur as the result of ingesting aspartame. For this reason, no purpose would be served by holding a hearing, because no issue of material fact is raised by the hypotheses. Moreover, even if the hypotheses raised an issue of material fact, a hypothesis, standing alone, does not justify a hearing in the absence of data on which to base a resolution of the issue raised. No such data are identified in Dr. Wurtman's submission or in the objections. FDA, therefore, denies the request for a hearing on these issues.

C. Decomposition and Reaction Products

There is a customary battery of toxicological tests in various animal

species that is required to demonstrate the safety of a direct food additive. These tests generally are familiar to sponsors of food additive petitions. To disseminate information about these tests further, the agency has developed and published a set of publicly available guidelines describing these tests "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food" ("REDBOOK" (Ref. 4)). The "REDBOOK" also sets forth certain tests beyond the customary battery of tests that the agency requires if the chemical structure of the additive or some other factor suggests particular reasons for concern.

In support of its petition for the use of aspartame for dry uses, Searle performed a complete series of traditional toxicological studies involving laboratory animals to verify the safety of aspartame during chronic exposure (Ref. 5). The design of the studies meets or exceeds that stated in the "REDBOOK" guidelines. In addition, because a consumer could be exposed to significant quantities of aspartame on a daily basis, and occasionally to high levels of aspartame, the petitioner conducted clinical studies (studies in humans) that provided ample evidence of the safety of aspartame under predicted levels of chronic ingestion or unusual situations of high, acute exposure (Refs. 6 and 7).

Before FDA approved aspartame, Searle submitted, and FDA evaluated, more than the usual tests with respect to the decomposition of this food additive. Because it is not feasible to require manufacturers to test every decomposition product, the agency routinely does not require testing of all of them unless a particular decomposition product poses a safety question, or little is known about its toxicological profile.

With respect to the toxicity of diketopiperazine (DKP), a primary decomposition product of aspartame, Searle submitted data in support of its petition for aspartame's dry uses to establish DKP's safety (Ref. 8). The agency also anticipated that a safety problem might arise in the use of aspartame in carbonated beverages if DKP, in solution, formed nitrosamines. Accordingly, Searle submitted, and FDA evaluated, studies on the likelihood of nitrosamine formation from the use of aspartame in carbonated beverages (Ref. 9).

FDA was aware of significant scientific literature on the toxicity of the following components of aspartame: phenylalanine, aspartic acid, and methanol. The agency reviewed the safety data submitted by Searle in support of its petition for dry uses derived from animal and clinical studies and consumption studies, as well as the existing body of scientific data, and concluded that the studies demonstrated the safety of these components. The Board's decision at p. 20 and p. 38 and the Commissioner both concluded that these components are safe (46 FR 38285 at 38287).

The objections now contend that FDA has failed to dispose of the possibility that decomposition and reaction products created by the addition of aspartame to carbonated beverages and carbonated beverages syrup bases may make those products unsafe (Turner, II, p. 9).

1. *Unidentified and unsafe decomposition and reaction products.* The objections present no evidence to support their contention that unidentified decomposition products or reaction products of aspartame may be harmful (Turner, p. 9; Monte, p. 8). One objection refers to an abstract of a scientific talk which discusses the reactivity of aspartame with certain flavor components of food (aldehydes and ketones) (Monte, p. 9). Reactions between food components occur too commonly to warrant specific testing for each individual class of reaction or decomposition products. Food itself undergoes a number of reactions, for example, in cooking. As the agency pointed out in the final regulation approving the use of aspartame in carbonated beverages, the similarity of the basic dipeptide structure of aspartame to normal dietary protein provides an added measure of assurance of its safety in regard to reactivity with food components and its metabolic fate (48 FR 31376 at 31382). Because the objection has presented no data to support its concern, and because the agency has no independent basis for concern, there is no basis upon which to grant a hearing. The agency will not grant a hearing on the basis of mere unsubstantiated allegations. Further, in the absence of any data, the simple charge that there may be a safety issue regarding decomposition products calls into question the agency's policy regarding the threshold for requiring scientific testing of such products. This question is one of both policy and law, i.e., the proper legal interpretation of the safety standards of the act, and thus is not a proper issue for an evidentiary hearing.

2. *Inability to account for up to 30 percent of the sweetener.* The objection states that Searle is unable to account for as much as 30 percent of the sweetener, despite having analyzed for components expected in the usual breakdown pathways, and that a more complete breakdown occurs at temperatures above 30° C (86° F) (Turner, p. 10). As detailed in the preamble to the carbonated beverage rule, the petition for this use of aspartame included the results of extensive stability studies on carbonated beverages (48 FR 31376 at 31377). These experiments were performed with beverages stored at various temperatures for periods of up to 52 weeks. Four beverage flavors were analyzed for aspartame and five decomposition products at various intervals. Essentially all of the analyses of beverages stored at 30° C for up to 40 weeks accounted for 90 to 100 percent of the original added aspartame. The contention that 30 percent of the decomposition products are unknown is misleading, because it focuses on the results at high temperatures (40° C (104° F); 55° C (131° F)) in which the results of the analysis are not as complete as those at lower temperatures. The more complete breakdown at higher temperatures is not unexpected, and, more important, is not crucial to the determination of the safety of the breakdown products. The sum of the decomposition studies submitted with the aspartame food additive petition for use in carbonated beverages provided the necessary identification of the decomposition products and evidence of their safety. The objections present no evidence in support of the implied increase in risk from greater decomposition at the higher temperature, other than the contention that the decomposition products are "unidentified" and that higher levels of free methanol would be present. After evaluating the studies and the general body of literature on the subject, FDA concluded that there was no reason to believe that the additional decomposition products would be substantially different from those formed at lower temperatures (48 FR 31376 at 31377). The objection does not justify a hearing because it presents no evidence that calls into question the safety of these decomposition products. As discussed above in section III.C.1., the allegation that all decomposition products should be presumed to be unsafe and therefore tested raises a legal and policy issue and is not appropriate for resolution at a hearing. (The toxicity of the decomposition product methanol is discussed below.)

3. *Methanol ingestion from decomposed aspartame.* Both objections argued that aspartame's decomposition can result in exposure to adverse levels

of methanol, "a known poison," (Monte, p. 2) and that the metabolism of methanol in the body yields formaldehyde, "a known carcinogen" (Turner, p. 12) (see section III.E. below). The agency evaluated the safety issues related to the ingestion of methanol derived from aspartame in its evaluation of aspartame for dry uses and concluded that the levels of methanol resulting from the use of aspartame in carbonated beverages did not pose any safety issues because they were well below levels of exposure expected to produce toxicity (Ref. 10).

Dr. Monte's objection argued (1) that "free" methanol produced by the decomposition of aspartame in carbonated beverages is more toxic than "dietary" methanol formed by the metabolism of aspartame in the gastrointestinal tract because of the differences in metabolism and a more complete amount of absorption of "free" rather than "dietary" methanol; and (2) that the amount of "free" methanol absorbed as a result of aspartame consumption is of sufficient quantity to produce a "significant and rapid rise in methyl alcohol and formate levels in the plasma" (Monte, p. 4). The objections allege that these levels are of toxicological concern under acute or chronic use conditions, but they neither submitted nor referred to available data in support of that allegation.

a. *Free Methanol Is Not More Toxic Than Methanol Produced by the Metabolism of Aspartame in the Gastrointestinal Tract.* The objection proffered a hypothesis that the decomposition of aspartame to methanol or to any of its secondary metabolities prior to consumption poses additional safety questions regarding the continued use of aspartame in carbonated beverages, but provided no evidence to support that position (Monte, p. 3). FDA analyzed the methanol safety issue before the agency approved aspartame for dry uses and again in its evaluation of the petition for use in carbonated beverages (Ref. 10). The objection has presented no evidence of any kind to alter FDA's original evaluation. FDA cannot accept as a basis for conducting a hearing unsubstantiated hypotheses concerning issues the agency already satisfactorily resolved.

Metabolic studies performed in monkeys and submitted by Searle in support of its petition for aspartame for dry uses demonstrate that the overall metabolic disposition of the methanol moiety from aspartame is similar to that of methanol administered alone to monkeys (Ref 11). The methyl moiety appears to be rapidly and completely cleaved from aspartame in the gastrointestinal tract, and this methyl group is oxidized in essentially the same manner as "free" methanol. The only detectable difference in the pharmacokinetic properties between "free" methanol and "dietary" methanol derived from the hydrolysis of aspartame is a faster rate of absorption of the "free" methanol within the first hour. "Free" methanol is readily absorbed from the stomach whereas aspartame must pass into the small intestine before hydrolysis and absorption of the methanol can occur. This small difference in the rate of methanol absorption is not significant because the metabolism of methanol is slow and because the overall amount of methanol ultimately absorbed as a result of consumption of a given quantity of aspartame-sweetened beverage is the same.

Thus, there is no scientific basis for differentiating the "free" from the "dietary" methanol in analyzing the toxicological profile of aspartame. The agency evaluated the metabolism data early in its evaluation of the data in support of the dry use petition, and assumed that methanol was completely hydrolyzed from aspartame in the gastrointestinal tract (Ref. 11). Exposure to methanol from aspartame can be calculated on a one-to-one molar basis independent of the decomposition rate in carbonated beverages, which can vary with storage conditions. Therefore, an estimate of methanol exposure following ingestion of aspartame is provided by taking 10 percent of the weight of the aspartame dose. The objection submits no data that supports its position or discredit the agency's conclusions based on the earlier studies performed by Searle. Thus, there is no basis for granting the hearing request.

b. *The Amount of Free Methanol Absorbed from Aspartame Does Not Produce a Significant and Rapid Rise in Plasma Methyl Alcohol and Formate Levels.* One objection (Turner, p. 11) contended that FDA had incorrectly concluded that the level of dietary exposure to methanol is not of "prime importance" in assessing the safety of aspartame (48 FR 31376 at 31380). The objection did not, however, present evidence showing at what concentration methanol is toxic or that the consumption of aspartame would result in the consumption of toxic levels of methanol.

The agency does not believe that methanol exposure equivalent to 10 percent of the aspartame dose is of sufficient quantity to be of toxicological concern under acute or chronic use conditions. A study (Ref. 12) submitted by Searle in support of its petition for the dry uses of aspartame showed no detectable levels of methanol in the blood of human subjects following the ingestion of aspartame at 34 milligrams per kilogram (mg/kg) body weight (the 99th percentile level of projected ingestion across all age groups). Assuming complete hydrolysis after ingestion, this 34 mg/kg dose of aspartame is equivalent to a dose of 3.4 mg/kg body weight of methanol. The agency reviewed this study and others dealing with methanol toxicity prior to approving aspartame for dry uses and cited the data in the preamble to the final regulation approving the use of aspartame in carbonated beverages (48 FR 31376 at 31380).

Even following administration of an abuse dose of aspartame of 200 mg/kg body weight (equivalent to 20 mg/kg body weight of methanol or drinking more than 13 quarts of aspartame-sweetened orange soda) in a clinical study conducted by Searle, the mean peak blood methanol concentration reached only 26 mg per liter. The hearing request contains no evidence to suggest that even this level of methanol, consumed in free form, is toxic. Thus even if all aspartame in soft drinks decomposed prior to their consumption, the agency has no reason to believe any danger of methanol poisoning would exist. FDA remains convinced that the studies submitted by Searle in support of the dry use, and reviewed by FDA prior to the dry uses approval and again in its evaluation of the carbonated beverage petition, adequately support the agency's conclusion that there was "no cause for concern from the levels of dietary methanol resulting from the highest projected levels of aspartame consumption" (48 FR 31376 at 31381).

The agency has recently become aware, however, of clinical data that further buttress the agency's determination. Although FDA did not rely on these studies in approving the carbonated beverage petition, nor is it necessary to rely on the studies here, the agency believes that they present pertinent information that is consistent with that contained in the Searle data. This document discusses them to some extent. FDA has placed copies of the reports in the administrative record for Docket No. 82F-0305. Among these studies are some that indicate that the toxic effects of methanol are due to formate accumulation and not to formaldehyde or methanol itself (Refs. 13, 14, and 15). Formate is the oxidation product of formaldehyde which is itself formed from the metabolism of

methanol. In the Searle clinical study using abuse doses of aspartame equivalent to 20 mg/kg body weight of methanol, no significant increases were observed in plasma concentrations of formate, suggesting that the rate of formate production does not exceed its rate of urinary excretion. In fact, studies in human subjects given oral dosages of methanol of 71 to 84 mg/kg body weight showed no toxic effects with blood levels of methanol reaching 47 to 76 mg per liter 2 to 3 hours afterwards (Ref. 16). From estimates based on blood levels in methanol poisonings, it appears that the ingestion of methanol on the order of 200 to 500 mg/kg body weight is required to produce a significant accumulation of formate in the blood which may produce visual and central nervous system toxicity (Refs. 17 and 18).

The toxic doses of methanol (200 to 500 mg/kg body weight) are approximately one hundred times that ingested when aspartame is consumed at the 99th percentile level of projected chronic ingestion (10 percent of 34 mg/kg body weight aspartame, or 3.4 mg/kg body weight methanol). Moreover, orange soda, which may contain the highest concentration of aspartame in carbonated beverages (335 mg aspartame per 12 fluid ounces or 930 mg per liter), results in a lower methanol level (93 mg per liter) than that found in the average fruit juice (140 mg per liter) (Ref. 19). Under the most conservative assumption, the complete hydrolysis of aspartame to methanol, an adequate margin of safety exists for the use of aspartame in carbonated beverages. The consumption of aspartame would not result in toxicologically significant methanol and formate levels.

Finally, it is well known that much food contains significant quantities of methanol. In fruit juices, the average content of methanol is 140 mg per liter and grain alcohols (such as gin and whiskey) contain as much as 1,000 mg per liter (Ref. 19). Moreover, fresh fruits and vegetables also contain compounds that are metabolized in the body to methanol (Refs. 20 and 21). Normal metabolic processes such as purine and pyrimidine biosynthesis and amino acid metabolism require methyl groups from compounds like methanol (Ref. 22). It also appears that either methanol or formaldehyde may serve as precursors for the methyl groups in choline synthesis (Ref. 23).

The agency has concluded that, because the objection has failed to present evidence establishing at what level methanol is toxic and whether consumption of carbonated beverages containing aspartame would exceed that level, no hearing is required to reevaluate the significance of exposure to methanol from aspartame consumption. The objection submitted no data and the agency is aware of none in support of the objection's position. FDA will not grant a hearing on the basis of a mere allegation.

4. *Nitrosamines formation from DKP and toxicity of DKP.* The objections allege that the agency has "mischaracterized" and "failed to consider" data dealing with potential toxicity from DKP (Turner, p. 10) and has failed to assess the "potential danger" of nitrosamine formation by intestinal bacteria after prolonged exposure to DKP (Monte, p. 7).

a. *Nitrosation of DKP.* FDA reviewed studies conducted by Searle aimed at evaluating the nitrosation potential of aspartame and DKP before the original approval of aspartame in 1974. These studies attempted to form, under ideal conditions, the nitrosamines of aspartame and DKP and demonstrated that stable nitrosamine derivatives were difficult to form at a level detectable with the then current analytical methodology (Ref. 24). The study also demonstrated that nitrosamine derivatives of aspartame or DKP intermediates, formed under ideal laboratory conditions, were extremely unstable under physiological or aqueous conditions. Given these results, FDA concluded that it was most unlikely that any nitrosamines could remain in the gastrointestinal tract or in an aqueous solution, such as soft drinks, containing aspartame or DKP (Ref. 25).

The objections further contend that the agency has been remiss in not reexamining the nitrosamine issue, employing more sensitive, modern analytical methodology. In support of this contention, one objection (Monte, p. 7) cites a recent publication describing the low level detection at parts per billion levels of structurally unrelated nitrosamines in malt beverages. The objection offered no evidence that the formation of nitrosamines in malt beverages has any possible relevance to structurally dissimilar nitrosamine formation in soft drinks containing aspartame. Nor did the objection present any evidence to rebut the data submitted by the petitioner that these compounds cannot be readily formed in aspartame. The agency therefore concludes that no hearing is required because the objection did not provide any evidence to refute the previous safety determination on nitrosamine formation. Thus, the objection states an allegation, but raises no issue of fact on which to base a hearing.

b. *Toxicity of DKP.* An additional issue raised by the objection was that FDA had "mischaracterized" the results from Lederer's study on DKP and that the agency had "failed to consider adequately the concern" for fetal toxicity (Turner, p. 10). The teratology and reproduction studies conducted by the petitioner in support of its petition for dry uses of aspartame rebut that position (Ref. 25). Moreover, the agency notes that Dr. Lederer acknowledged, prior to the publication of the carbonated beverage rule, that "the conclusions of my work are concordant with those of the U.S.A." (Ref. 26; see also the discussion at 48 FR 31376 at 31380). Consequently, the agency also finds that the objections raise no material issue of fact with regard to potential embryotoxicity, but make an unsupported allegation. FDA will not hold a hearing based on a mere allegation.

D. Consumption Levels

Mr. Turner's objection alleges that in concluding that aspartame was safe for carbonated beverage use, the agency improperly estimated consumption levels of aspartame because (1) FDA failed to include additional individuals likely to consume carbonated beverages; (2) FDA based consumption levels on understated or nonexistent calculations; (3) the use patterns on consumption in the petition were not correct; (4) FDA did not consider the consumption of products containing aspartame at the three main meals; (5) FDA did not include consumption of aspartame in hot weather in the estimate; (6) FDA used the "gross national population consumption formula" to calculate consumption; (7) intake greater than the previous acceptable daily intake is unsafe (Turner, pp. 19–23).

Various consumption estimates, including estimates of aspartame exposure resulting from the consumption of carbonated beverages containing aspartame, were exhaustively considered by the Board's decision at p. 14 to p. 22 and by the Commissioner in his final decision approving aspartame for dry uses (46 FR 38285 at 38289–38290). Mr. Turner argued in the earlier proceeding that the consumption levels were underestimated and the Board and the Commissioner considered but rejected these arguments. Thus, Mr. Turner has been given a full opportunity to present his views on consumption.

FDA believes further that the objection demonstrates a basic misunderstanding of how the agency

calculates the estimated daily intake (EDI) of food additives, and how these dietary exposure estimates relate to the acceptable daily intake (ADI) of the additive. The agency is therefore discussing the important principles used to develop consumption estimates.

The EDI is a measure of chronic dietary exposure of the additive from all food sources in which it is used; it is the day-in and day-out estimated intake over a particular span of an individual's lifetime. The ADI is the amount of a compound that can be safely consumed each day on a chronic basis; it is derived primarily from chronic toxicological studies in animals. Levels of consumption may occasionally rise above or fall below the EDI. Daily carbonated beverage consumption, for example, may be greater in hot weather. The important safety issue is whether the EDI exceeds the ADI. Both of these figures may change as chronic consumption patterns change. The EDI will increase as the use of the additive is extended to other food categories, and the ADI may be revised as more toxicological information is evaluated. For example, prior to the approval of the use of aspartame in carbonated beverages, the agency increased the ADI from 20 to 50 mg/kg body weight, because additional toxicological data from clinical studies submitted by the petitioner demonstrated that the new level was safe (Ref. 10).

The allegations that FDA failed to include additional individuals likely to consume carbonated beverages, that carbonated beverage consumption was understated or that consumption calculations do not exist are simply untrue. Searle and FDA calculated the maximum EDI of aspartame during the proceedings leading to the approval of aspartame for dry use and again during the evaluation of the carbonated beverage petition using three different methods. FDA reviewed each of these estimates (46 FR 38285 at 38289; 48 FR 31376 at 31377). Each of the EDI exposure estimates, including the 34 mg/kg body weight estimate ultimately accepted by the Commissioner (46 FR 38285 at 38290), explicitly included aspartame intake from carbonated beverages or was even broader in scope. (See 46 FR 38289–38290 for a complete discussion of consumption levels.) One estimate assumed that aspartame replaced all sucrose in the diet of an average male, and another assumed that aspartame replaced all carbohydrate in that diet.

The objection alleges that the patterns of consumption in the petition were not correct but submitted no data to show that actual use patterns differ from those calculated by Searle and FDA. FDA calculates dietary exposure estimates of new direct food additives by applying data on food consumption, as established by surveys, and data on the concentration of the additive in foods. The data submitted by Searle dealt with all aspects of aspartame consumption including consumption with other foods, such as the three main meals. In its petition for carbonated beverage approval, Searle included a new calculation that relied on the most recent survey data compiled by the Market Research Corp. of America (MRCA). MRCA survey data are compiled from dietary records kept throughout the year by 4,000 U.S. households. Estimates using MRCA data are based on the foods actually eaten by people in various age brackets and include data from both average and heavy users in particular food categories. Prior to approving aspartame for use in carbonated beverages, the agency reviewed the Searle calculation and computed its own values for aspartame exposure from all foods (Ref. 27). The agency's evaluation specifically recorded the percentage increases in estimated aspartame exposure resulting from carbonated drink consumption, and concurred with the petitioner's method of calculation, but restated the exposure estimate to reflect "eaters only." This estimate of EDI is based on those people who actually consume the product and maximizes EDI figures for any particular age group, because it does not average in the nonconsumer in the survey population.

On an occasional day, for example in hot weather, intake levels of aspartame may exceed the ADI. However, this occasional excess would not result in chronic intake above the ADI. Whether it is safe to ingest levels of a substance on some days in excess of the established ADI depends on how acutely toxic the additive is. Clinical tests of aspartame at doses of 200 mg/kg body weight, which exceeds the ADI, were performed and submitted by Searle in support of its petition (Ref. 6). In these studies, the acute effect of the ingestion of single doses of 200 mg/kg of aspartame on blood levels of amino acids and methanol were found to be well below toxicological levels of concern (48 FR 31376 at 31381). Thus, Mr. Turner's observation that the consumption of six cans of beverage containing aspartame on a hot day will result in exposure that exceeds the ADI is not a credible basis for alleging that the agency has "understated" consumption levels (Turner, p. 21). The consumption by a 20 kg child of six 12-ounce cans of orange beverage sweetened with aspartame would result in an exposure of 100 mg/kg of aspartame, which is well below the 200 mg/kg dose administered in Searle's clinical study without any sign of acute toxicity (Ref. 6) and even further below the levels of toxicological concern. (Six 12-ounce cans of orange beverage sweetened with aspartame (.93 mg per milliliter) would contain approximately 2,008 mg of aspartame.) Accordingly, the objection fails to present credible evidence raising a material issue of fact. The objection is also based on a demonstrably false premise.

As discussed above, the agency has estimated that the highest likely chronic consumption of aspartame per day would be 34 mg/kg body weight. The objection contended that aspartame consumption will not always occur in a "throughout the day" pattern, but would occur principally in large doses, that is, at meals when individuals are most likely to consume food and aspartame-containing beverages at the same time (Turner, p. 20). The agency does not regard the possible consumption of aspartame in a single large dose as posing any safety problem whatsoever. During the evaluation of the petition for the dry uses of aspartame, the agency analyzed the toxicity from acute exposure to aspartame. FDA relied upon a study in which high single doses of up to 200 mg of aspartame per kg of body weight were given to human subjects (Ref. 6). With respect to acute toxicity, the pattern of aspartame ingestion over the day is not important as long as the total amount ingested per day does not exceed the 200 mg/kg level shown to be safe.

Finally, FDA is not familiar with the term "gross national population consumption formula" mentioned in the objection and is unable to determine its relevance to the issue of aspartame consumption (Turner, p. 22). Presumably, the objection is suggesting that FDA should adopt an entirely new policy regarding estimates for food additive consumption instead of its current policy, which is described above and is used in estimating the projected consumption of food additives. The current policy and possible alternatives to it are not at issue in this proceeding, nor are they proper issues for a formal evidentiary public hearing. Moreover, the objection presents no evidence describing this proposed new consumption formula, or establishing its validity.

FDA is denying the request for a hearing on the consumption issue for a

number of reasons. First, Mr. Turner was a party to the earlier proceeding in which consumption estimates were an important issue. He raised essentially the same consumption issue there. The Board's decision at p. 14 to p. 22 and the Commissioner's decision (46 FR 38285 at 38307) each discussed the matter and ruled against Mr. Turner's objection. Mr. Turner could have sought judicial or administrative review of the earlier decision. He did not do so. He cannot now complain, because he has had a full and fair opportunity to present his views and be heard. Moreover, his objections present no data in support of his position.

E. Carcinogenicity Potential of Aspartame and its Metabolites

1. *Aspartame's potential for causing brain tumors.* Mr. Turner objects to the approval of aspartame for use in carbonated beverages because "the Commissioner and the agency have not adequately dealt with the recommendation of the Public Board of Inquiry that approval of aspartame be withheld pending results from further oncogenic studies with the additive" (Turner, p. 15). Interpretation of the results of the chronic rat feeding studies designed to determine aspartame's potential for causing brain tumors was one of the major scientific issues before the Board, and consequently one of the most comprehensively deliberated issues bearing on aspartame's safety. The Board found that the results of these tests were not sufficiently conclusive and recommended that approval of aspartame be withheld pending results from further oncogenic studies with the additive (Board's decision at p. 49). The Commissioner disagreed with the Board's findings and concluded that there was a reasonable certainty that aspartame does not cause brain tumors in rats (46 FR 38285 at 38295). Mr. Turner was a party to that earlier proceeding and made the same objection to the regulation approving dry uses of aspartame. He recieved a formal hearing on that objection. Mr. Turner now contends that the Board's findings, rather than the Commissioner's findings, were correct. Mr. Turner's current objection did not, however, submit any new data on this issue.

In his final decision (46 FR 38285 at 38295), the Commissioner explained why he disagreed with the Board's findings that more studies were needed on the carcinogenic potential of aspartame. This decision is supported by the record which included not only the three chronic studies before the Board but also negative results observed in a subsequent animal study not available to the Board (Ref. 28).

The administrative record shows that the approval of aspartame in supported by a complete series of toxicological tests in animals. These studies have been thoroughly reviewed by FDA scientists. Based on that review and for the reasons stated in the Commissioner's decision, the agency reaffirms the conclusion that there is a reasonable certainty that aspartame does not cause brain tumors in rats.

Mr. Turner had a fair opportunity to present his arguments and have them fully considered in the proceeding leading to the approval of aspartame for dry uses. He had an opportunity to challenge the Commissioner's decision in the Court of Appeals. He chose not to do so, and is thus estopped from relitigating the issue in the absence of new evidence. He has presented no new evidence in support of his position here, and thus has raised no material issue of fact that justifies a further hearing in this proceeding.

2. *Uterine polyps in rats.* Mr. Turner's objection states that "* * * neither the Commissioner nor the agency has recognized 'precancerous polyps' in the approval of aspartame for use in carbonated beverages" (Turner, p. 34). The polyps in question originated in the uteri of rats chronically administered the diketopiperazine-derivative of aspartame (DKP) for 2 years (Ref. 29). The study data in question were submitted to the agency in support of Searle's original food additive petition for aspartame. Subsequently, as a result of FDA's concern over the issue, the agency referred the raw data to four independent teams of pathologists at FDA, the Massachusetts Institute of Technology, the Armed Forces Institute of Pathology, and G.D. Searle for review. Prior to convening the Board, those teams identified cystic endometrial hyperplasia, which is commonly referred to as uterine polyps, as the most common lesion. Cystic endometrial hyperplasia occurs in aging rats spontaneously and is most commonly associated with age-related endocrine disturbances. Uterine polyps are considered to be a localized form of endometrial hyperplasia and have no tendency to undergo malignant transformation and, therefore, are not considered precancerous in nature (Ref. 30).

The Searle study also supports a safety factor of about 1,000 with respect to the induction of uterine polyps. Thus, the agency concludes that the possibility that uterine polyps will occur as the result of aspartame ingestion is very remote (Ref. 29).

Because the polyps were not considered precarcinogenic, they were not an issue specifically addressed by the Board and the Commissioner. Nonetheless, Mr. Turner could have raised the issue at the hearing or before the Commissioner. He could have sought judicial review of the Commissioner's decision, but did not. He has had an adequate opportunity to be heard.

3. *Carcinogenic potential of formaldehyde.* The objections stated that there are no studies available for FDA to use in assessing the chronic toxicity and carcinogenic potential of methanol and formaldehyde formed from methanol metabolism in the body (Monte, p. 4; Turner, p. 12).

The agency does not agree with this assertion. In its original submission to FDA in support of the use of aspartame for dry uses, Searle included the results of chronic feeding studies of aspartame in the dog, the mouse, and the rat (Ref. 31). The results of another chronic study that corroborate the Searle study are available through the open literature (Ref. 28). One of the major objectives of this type of chronic study is a comprehensive histopathological examination of virtually all organ systems in order to assess both the chronic toxic and carcinogenic potential of the administered compounds.

Before approving the original petition for aspartame for dry uses, FDA analyzed the chronic feeding studies and concluded that aspartame was safe. Although these studies were designed to assess the toxicity and potential carcinogenicity of aspartame, they also tested the toxicity and potential carcinogenicity of aspartame's metabolites. The metabolic studies submitted by the petitioner demonstrate that all ingested aspartame is broken down in the gastrointestinal tract into its constituents, aspartic acid, phenylalanine, and methanol. Because the aspartame molecule is 10 percent methanol by weight and because the dosages used in the chronic studies were quite high (rat: 1 to 8 g/kg body weight, mouse: 1 to 4 g/kg body weight, and dog: 1 to 4 g/kg body weight), the exposure of these species to methanol in these four chronic studies was as high as 400 to 800 mg/kg body weight per day, a very significant dose. Based on an ADI for human exposure of 50 mg of aspartame per kg body weight per day (or 5 mg/kg body weight of methanol), these doses represent an 80- to 160-fold exaggeration of methanol exposure in the chronic animal studies when compared with the very high but

conceivable levels of human exposure to methanol through aspartame ingestion.

The Searle studies also ensured comparable dosages and durations of exposure to formaldehyde, because, as discussed above, methanol is metabolized to formaldehyde on a one-to-one molar basis. Thus, contrary to the objections, both methanol and formaldehyde were thoroughly tested, and FDA reviewed the results of those tests prior to approving aspartame for dry uses.

The hearing request cites a recent study indicating that formaldehyde, administered intranasally to rats, produced carcinomas at the site of application—the nasal turbinates (Ref. 32). The site of the carcinomas strongly indicates that the neoplastic process is a localized, not a systemic, reaction to the known irritating and cytotoxic properties of formaldehyde. No increase in tumor incidence was observed at sites remote to direct exposure (Ref. 32). The same study supports the further conclusion that direct exposure to relatively high concentrations of formaldehyde gas is necessary before the carcinogenic process occurs.

In addition, there is another series of chronic studies in the scientific literature, which FDA considered prior to the approval of aspartame for dry uses, in which hexamethylenetetramine was administered in the drinking water in doses of 0.5 to 5 percent to three strains of mice for 60 weeks and to Wistar rats in drinking water at 1 percent for 104 weeks (Ref. 33). Because hexamethylenetetramine is broken down in the acid medium (Ref. 34) of the stomach to formaldehyde, these studies directly tested whether orally administered formaldehyde is carcinogenic (Ref. 33). In the hexamethylenetetramine studies, no evidence of carcinogenic activity was found in any of the test groups.

The fact that aspartame when ingested in doses up to 8 gm/kg body weight (800 mg/kg formaldehyde) produced no carcinogenic effect is strong evidence that formaldehyde exposure from the oral route of administration is without carcinogenic risk. Any question regarding adequacy of dosing from these studies is resolved by the results from the studies with hexamethylenetetramine where doses of up to 1,500 mg/kg body weight formaldehyde were ingested by mice and rats without any carcinogenic effect. Thus, the inhalation study is not appropriate for use in determining whether formaldehyde is a systemic carcinogen and in evaluating the safety of aspartame. There is no issue of fact, because it has been demonstrated that formaldehyde is not a systemic carcinogen. No hearing is required, because the objection does not submit sufficient evidence to raise a serious question about aspartame's systemic carcinogenicity. Although the agency does not believe that a hearing is justified in view of the hexamethylenetetramine studies, the objectors may request reconsideration as provided in 21 CFR 10.33 and are free to submit comments on the hexamethylenetetramine studies, or on any other studies that are or may become available.

4. *Two human cancers in clinical studies.* One of the objections claims that the Commissioner failed to assign sufficient significance in his decision approving aspartame for dry uses to the finding of two human cancers at the eleventh week of a 13-week study on aspartame (Turner, p. 17). One insulin-dependent diabetic developed an adenocarcinoma of the breast and one non-insulin-dependent diabetic developed a reticulosarcoma of the stomach.

The agency as well as a reviewing pathologist concluded that these types of cancer are associated with a pathological process requiring many months to years for development into a malignant phase. Therefore, the cancers arising in these two patients receiving aspartame were considered to be coincidental and unrelated to aspartame intake.

As with so many of Mr. Turner's objections, that issue was before the Board and the Commissioner in the earlier proceeding. Mr. Turner could have appealed the Commissioner's decision. That he chose not to do so means that he may not raise the issue again at this time. He has had an adequate opportunity to be heard, and no new hearing is required.

F. Interpretation of Data From Clinical Studies

Mr. Turner's objection alleges that FDA failed to give adequate credence to the potential for adverse reactions related to the use of aspartame observed in the clinical studies (Ref. 35). The objection pointed out that there were five times as many complaints reported by aspartame users as by the control group in that study (Turner, p. 22).

FDA did evaluate these results. The clinical study referred to in the objection was only one of several clinical studies, which included normal adults and children, as well as obese and diabetic adults, conducted by the petitioner and submitted to the agency in support of its petition on dry uses of aspartame (Ref. 7). Based on an analysis of the results from all these studies, FDA concluded that there was no evidence of any consistent or obvious pattern of specific complaints from aspartame use.

All the data from these studies were available prior to the earlier hearings. Mr. Turner could have raised the issue at the hearing or before the Commissioner but did not do so. He has had an adequate opportunity to be heard, and no hearing is required on the issue. Moreover, in the absence of any additional data bearing on the clinical study, Mr. Turner's objection constitutes nothing more than an allegation, and raises no material issue of fact upon which a hearing could he held.

G. Quality of Data

One objection claims that the research submitted by G. D. Searle should not have been relied upon for evaluating the safety of aspartame because the research was conducted in a flawed and inaccurate manner (Turner, p. 23). This issue was presented to the Commissioner in the earlier proceeding on the dry uses of aspartame and although decided adversely to Mr. Turner, he failed to seek judicial or administrative review of the issue. Although Mr. Turner is estopped from relitigating this issue a second time, the agency has nevertheless considered it and concluded that the quality of the data is adequate.

The agency believes that there has been an adequate confirmation of the quality of the studies to provide reliable evidence for the safety assessment of aspartame. In fact, a comprehensive review of the authenticity of the aspartame research data was performed on the 15 pivotal studies submitted by G. D. Searle. Three of these studies were audited by FDA and 12 by UAREP. This was a massive undertaking and took over 2 years to complete. UAREP concluded that the studies were authentic and, on December 13, 1978, submitted to FDA its 1,062 page report. The agency agreed with UAREP that those 12 studies, as well as the 3 studies which it had reviewed, were indeed authentic. In addition to determining the authenticity of these studies, the report by UAREP also contained detailed observations of how these studies were conducted.

Although UAREP, like the agency, noted some procedures and irregularities that warranted improvement, none were of such a serious nature as to invalidate an entire study. In view of the fact that the objection has provided no new information on the quality or design of Searle's data, the agency believes that it

is adequately addressed in the Commissioner's final decision on aspartame (46 FR 38285 at 38301).

H. Labeling of Food Containing Aspartame

One objection contends that foods containing aspartame are not adequately labeled, but provides no information to support the position that current requirements are insufficient (Monte, p. 10). Current regulations require that the label of any food containing aspartame shall bear a prominent and conspicuous notice to phenylketonurics that the product contains phenylalanine.

No other susceptible consumer group has been identified by the objection, nor has it identified the "substantial dangers" (Monte, p. 10) posed by the regulated uses of aspartame. Accordingly, the agency concludes that the issue raised is one of policy, not fact, and is not resolvable by a hearing.

V. Summary and Conclusions

Under 21 CFR 170.3(i), the safety of a food additive means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. FDA's regulations reflect the Congressional judgment that the additive must be properly tested and the tests carefully evaluated, but the additive need not, indeed cannot, be shown to be safe to an absolute certainty. As the House of Representatives Report on the Food Additives Amendment stated:

Safety requires proof of a reasonable certainty that no harm will result from the proposed use of the additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

H.R. Report No. 2284, 85th Cong., 2d Sess., 1958.

Aspartame has been exhaustively tested for safety and the data have been reviewed by the agency over the course of 11 years. In addition, FDA referred portions of the safety on aspartame to outside groups of scientists for additional review, prior to approving aspartame for dry uses. The safety testing conducted for aspartame surpasses the testing requirements for direct food additives developed by the agency and set forth in its "REDBOOK" (Ref. 4). As discussed in Section I. above, the safety issues associated with the dry uses of aspartame were the subject of additional scrutiny at a hearing before the Public Board of Inquiry conducted by three scientists. Finally, the Commissioner reviewed the safety issues and the Board's conclusions on them so that he could reach a final decision on the safety of aspartame for dry uses.

After reviewing all the points raised in the objections, FDA concludes that the following issues were fully dealt with in the earlier proceeding leading to the approval of aspartame for dry uses: brain lesions and mental retardation, consumption levels, aspartame's potential for causing brain tumors, uterine polyps in rats, two human cancers and other alleged adverse reactions in clinical studies, and the quality of Searle's safety data submitted in support of the dry uses of aspartame. In the current proceeding, Mr. Turner submitted an objection covering each of these points even though, as had been pointed out before, he was a participant in the earlier proceeding. He had the opportunity to present evidence before the Board of Inquiry; he had the opportunity to question participants in that hearing; and he had the opportunity to and did file exceptions to the Board's findings. He also had the opportunity to appeal the Commissioner's decision on the dry use petition to the Court of Appeals as provided by section 409(g)(1) of the act (21 U.S.C. 348(g)(1)) or to petition for administrative reconsideration under 21 CFR 10.33. He has thus had a full and fair opportunity to present his case and have it considered in the proceeding on the dry uses of aspartame. No more is required.

The objections in the current proceeding have raised some points that present issues of law and policy, not issues of fact, specifically the allegations concerning safety testing requirements for decomposition products, consumption estimates, and labeling requirements. As explained in the specific sections discussing these points, FDA will not hold a hearing where the objection raises only issues of law or policy because these kinds of issues are not proper for resolution at a hearing.

One objection argued that because formaldehyde produced tumors at the site of administration (intranasally) in rats, FDA could not properly conclude that this metabolite of aspartame was not a systemic carcinogen. The objection offered no additional data, other than the reference to the intranasal study, that could be relied upon to solve the issue at a hearing. Considered in its factual setting, this study is inadequate to justify a conclusion that formaldehyde is a systemic carcinogen. FDA will not grant a hearing if the material submitted, even if accurate, is insufficient to justify the factual determinations urged.

Finally, the objections made a number of unsubstantiated allegations, specifically that aspartame might cause potential adverse behavioral effects, that various decomposition products of aspartame may be toxic, that the consumption estimates of aspartame are inaccurate, and that aspartame may cause cancer. In each of these cases, the objections have proferred no data on which a meaningful hearing might be based. Thus, no hearing is required on those issues.

For the reasons stated in this conclusion and in the discussion above, FDA is denying the objections and requests for a hearing.

Dated: February 17, 1984.

Mark Novitch,

Acting Commissioner of Food and Drugs.

Appendix—References

The following information has been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from R. J. Wurtman to Sanford A. Miller, July 21, 1983.

2. Wurtman, R. J. letter to the editor, *New England Journal of Medicine*, 309:429-430.

3. Letter from P. A. LaChance to Anthony Brunetti, December 2, 1982.

4. Food and Drug Administration, "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food," **Federal Register** of October 15, 1982 (47 FR 46141).

5. Kokoski, C. J., Transcript of Aspartame Public Board of Inquiry, Vol. 1, January 30, 1980, pp. 16-24.

6. Stegink, L. D., M. C. Brummel, K. McMartin, G. Martin-Amat, L. J. Filer, Jr., G. L. Baker, and R. R. Tephly, "Blood Methanol Concentrations in Normal Adult Subjects Administered Abuse Doses of Aspartame," *Journal of Toxicology and Environmental Health*, 7:281-290, 1981.

7. Food Additive Master File 134, Studies E-60, E-61, E-64, E-65, and E-67.

8. Food Additive Master File 134, Studies E-37, E-38, E-42, E-48, E-56, and E-57.

9. Food Additive Master File 134, Studies E-50, E-68, and E-71.

10. FAP 2A3661, Memoranda from Food Additives Evaluation Branch, January 18 and March 15, 1983.

11. Food Additive Master File 134, Study E-15.

12. Food Additive Master File 134, Study E-93.

13. Martin-Amat, G., K. E. McMartin, S. S. Hayreh, M. S. Hayreh, and T. R. Tephly, "Methanol Poisoning: Ocular Toxicity Produced by Formate," *Toxicology and Applied Pharmacology*, 45:201-208, 1978.

14. Martin-Amat, G., T. R. Tephly, K. E. McMartin, A. B. Makar, M. S. Hayreh, S. S. Hayreh, G. Baumbach, and P. Cancilla,

"Methyl Alcohol Poisoning. II. Development of a Model for Ocular Toxicity in Methyl Alcohol Poisoning Using the Rhesus Monkey," *Archives of Ophthalmology*, 95:1847–1850, 1977.

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Part VII

Department of Energy

Office of Secretary
Economic Regulatory Administration

Natural Gas Imports; Policy Guidelines and Delegation Orders; Procedural Orders

DEPARTMENT OF ENERGY

Office of the Secretary

New Policy Guidelines and Delegation Orders From Secretary of Energy to Economic Regulatory Administration and Federal Energy Regulatory Commission Relating to the Regulation of Imported Natural Gas

AGENCY: Department of Energy.

ACTION: Issuance by the Secretary of Energy of new policy guidelines and delegation orders, superseding current delegation orders, to the Administrator of the Economic Regulatory Administration and to the Federal Energy Regulatory Commission relating to importation of natural gas.

SUMMARY: These new delegation orders and policy guidelines are the result of a review of the federal government's policies and procedures for regulating the importation of natural gas into the United States. The guidelines set forth a new policy direction for gas import arrangements and provide the basis for authorizing import arrangements through revised regulatory procedures. The policy emphasis is on import agreements structured to supply natural gas to American consumers at competitive prices and responsive to changes in the markets served. The revised regulatory procedures are designed to implement the policy guidelines.

Modifications are made to the regulatory responsibilities for gas imports shared by the Economic Regulatory Administration and the Federal Energy Regulatory Commission. These are set forth in new delegation orders from the Secretary of Energy to the ERA Administrator and the Commission.

Introduction

The United States presently imports approximately 5 percent of its natural gas. Although this percentage is small on a national basis, certain regions of the country are dependent on imported gas for over 50 percent of their needs. While the quantity of gas imported into the U.S. has dropped significantly during the recent period of surplus domestic gas deliverability, imported gas will likely be increasingly required over the longer term to supplement domestic gas production. Most industry projections suggest a growing demand for imported gas later in this decade.

Natural gas is currently imported from Canada, Mexico, and Algeria. In 1983, 78 percent of imported gas came from Canada, 14 percent from Algeria, and 8 percent from Mexico. Most import contracts are relatively long-term, with some involving significant capital investment for transportation systems and related facilities. These costs, along with higher prices charged by gas exporters, have generally resulted in imported gas being more expensive than domestic natural gas.

Pipelines were willing to pay the higher cost of imported gas, until recently, because the higher cost imports were combined with substantial volumes of less expensive, price-controlled domestic gas in pipeline systems. In fact, many long-term import contracts were negotiated by U.S. pipelines on the assumption that lower priced domestic gas would continue to be available to offset higher cost imports and that competing oil prices would continue to rise. The Natural Gas Policy Act of 1978, which established a new system of price controls on domestic gas, reinforced the economic rationale of long-term import arrangements for high-priced gas. These economic factors, along with the determination of U.S. pipeline companies to protect against recurrence of the gas shortages experienced in the 1970's, were the major impetus behind many import arrangements in effect today.

Few foresaw five years ago the gas deliverability surplus that exists in the United States today. The effects of the economic recession, falling world oil prices, conservation efforts, and the increasing ability of industry to switch between oil and gas have lowered the demand for natural gas. This decreased demand—combined with long-term contracts containing high take-or-pay requirements for expensive domestic and imported gas, and the pricing regulations of the NGPA—has had severe economic consequences for the American gas consumer.

The cause of the situation can be traced to government regulation. In particular, wellhead price controls imposed by the NGPA, with 28 categories of gas at different prices, have thwarted the effects of supply and demand that otherwise would force competitive pricing and supply arrangements. Legislative proposals to reform the NGPA are currently before the Congress, and the Administration has proposed—and supports—legislation that removes price controls on gas and allows market forces to operate.

In its efforts to deregulate natural gas, the Administration has considered the question of legislative or administrative action affecting imported gas and has held the position that U.S. governmental action requiring changes to existing gas import contracts is inappropriate. While it is recognized that many import arrangements are similar to domestic supply contracts, with inflexible take-or-pay and pricing terms, important distinctions exist between international and domestic contracts that require a different approach to the problems associated with gas imports.

The foremost distinction is the matter of jurisdiction. Gas import arrangements are international commercial agreements, subject to the policies and laws of both the buyer's and the seller's governments. United States trade policy strongly supports contract sanctity as an important factor in international commercial transactions. Unilateral legislative or administrative action by the government to change agreements undermines this policy and the long-standing principles generally adhered to by this country in conducting trade.

Another distinction is the long-term need for, and reliance on, imported gas the the United States. While the U.S. is now experiencing a domestic gas deliverability surplus, the situation will likely change in the future. Governmental action that, in effect, unilaterally renegotiates gas import contracts to the short-term advantage of the U.S. could jeopardize gas import supplies when the demand for imported gas increases in the future.

The inappropriateness of unilateral governmental action to modify existing import arrangements does not argue against the need for changes. There is ample evidence that most imported gas is not competitive in the markets served, placing a heavy financial burden on U.S. gas consumers. Present import arrangements have all been subject to U.S. government regulatory review and authorization pursuant to provisions of the Natural Gas Act under policies of the former Federal Power Commission and, since 1977, the Department of Energy. The decisions on import applications issued by the FPC and the Administrator of the Economic Regulatory Administration (under authority delegated by the Secretary of Energy) have constituted governmental policy on natural gas imports.

In view of today's changed circumstances and the need to establish natural gas trade on a market-competitive basis, it is appropriate that the previous policies be assessed and policy changes be made, as needed. The policy guidelines set forth here are designed to establish natural gas trade on a market-competitive basis and to provide immediate as well as long-term benefits to the American economy from this trade.

The application of the policy to gas import regulatory proceedings is also set forth, as are changes in the regulatory responsibilities for imported gas shared by the Economic Regulatory Administration and Federal Energy Regulatory Commission. The Department of State, with its primary responsibility for foreign policy, will continue to be consulted on the foreign policy aspects of gas import regulatory decisions.

Gas Imports Policy Goal

The goal of these policy guidelines conforms with the goal of the President's 1983 National Energy Policy Plan " * * * to foster an adequate supply of energy at reasonable costs." The U.S. government has adopted two strategies to achieve this goal:

- To minimize federal control and involvement in energy markets, and
- To promote a balanced and mixed energy resource system.

The government's objective in the area of natural gas imports is that a supply of gas supplemental to domestic production be available to the American consumer at competitive prices, while avoiding undue dependence on unreliable sources of supply.

The market, not government, should determine the price and other contract terms of imported gas. U.S. buyers should have full freedom—along with the responsibility—for negotiating the terms of trade arrangements with foreign sellers. The federal government's primary responsibility in authorizing imports should be to evaluate the need for the gas and whether the import arrangement will provide the gas on a competitively prices basis for the duration of the contract while miminizing regulatory impediments to a freely operating market. In addition, the government must determine that the U.S. does not become unduly dependent on unreliable supplies.

The policy and regulatory guidelines herein will accomplish several important objective. First, they outline the basis upon which the federal government, to the extent that it regulates natural gas trade, concludes that future gas trade should be conducted. Suppliers of imported gas, and governmental authorities regulating the export of this gas, will have the benefit of knowing the policy and regulatory considerations that will be applied by this government in authorizing gas imports.

Second, the guidelines establish a regulatory framework for buyers and sellers to negotiate contracts based on traditional competitive and market considerations, with minimal regulatory constraints and conditions. The government, while ensuring that the public interest is adequately protected, should not interfere with buyers' and sellers' negotiation of the commercial aspects of import arrangements. The thrust of this policy is to allow the commercial parties to structure more freely their trade arrangements, tailoring them to the markets served. Thus, with the presumption that commercial parties will develop competitive arrangements, parties opposing an import will bear the burden of demonstrating that the import arrangement is not consistent with the public interest.

Third, the regulatory procedures and process are being simplified and rendered more expeditious, permitting prompter government review of proposed import arrangements.

Background on U.S. Gas Imports

In 1938 the Congress passed the Natural Gas Act, which assigned the Federal Power Commission responsibility, under section 3, for authorizing imports and exports of natural gas. The FPC was required to grant import and export authorizations unless it determined that they would "not be consistent with the public interest." Prior to the 1950's, imports of gas were negligible, with section 3 proceedings primarily involving gas exports.

In the early 1950's, the FPC started to authorize gas imports from Canada and Mexico. Imports from Mexico began in 1952, reaching about 50 Bcf annually in the mid-sixties, and by 1982, nearly 100 Bcf annually. Imports from Canada in the early 1950's were small, amounting to approximately 3 Bcf per year. The demand for Canadian gas increased, however, with annual imports in the 1970's averaging approximately 900 Bcf. Canadian gas exports in 1983 amounted to 713 Bcf, representing 78 percent of all U.S. natural gas imports.

Until the mid-1970's, the price for Canadian gas was negotiated by U.S. buyers and Canadian sellers on a cost-of-service basis.(*1*) The prices negotiated differed depending on the point of importation and market factors. The Canadian government, however, maintained the requirement of government approval of gas export prices.

As the volume of gas exports increased in the mid-1970's, the Canadian government took a more active pricing role, with the National Energy Board requiring exported gas to be priced "in relation to energy alternatives in the United States." (*2*) In 1973, after finding that gas exports were under-priced in relation to alternative fuels in the U.S., the NEB pursuaded exporters to increase prices, and in 1975, directed price escalations that increased the average border price from $1.00 to $1.60 (Cdn) per MMBtu. This development essentially ended the pricing of Canadian gas through buyer-seller negotiations.

In 1976, the NEB proposed a further increase in the average border price together with differentiated border prices set by the Canadian government that significantly raised the costs to U.S. customers. With the government of Canada now acting as a single seller of Canadian pipeline gas to the United States and about to unilaterally impose a system of differential border prices, the U.S. government objected. In a series of government-to-government consultations, the United States strongly opposed the price increases and the manner in which they were being determined without reliance upon buyer-seller negotiations. Rather than accept differential prices determined by the Canadian government, the U.S. proposed the concept of a uniform border price, which the Canadian government adopted in June 1976.

By April 1977, Canada had become a substantial net importer of crude oil, and the NEB determined that exported gas would be priced on the basis of the cost of displacing imported crude oil in Eastern Canada with Canadian gas. This concept—called "substitution value"—became the main criterion for the Canadian government's determination of the export price of gas. Because of the rapid escalation of the price of imported oil in the late 1970's, the NEB, using the substitution value concept, raised the border price six times between 1977 and 1981—from $1.94 (Cdn) to $4.94 (U.S.) per MMBtu.(*3*) These increases were approved by U.S. regulatory agencies because of rising prices of alternate fuels in the U.S.

Also in 1977, the Department of Energy Organization Act was passed by Congress. This Act abolished the Federal Power Commission and transferred authority over gas imports to the Secretary of Energy. The Secretary delegated primary responsibility for authorizing imports to the Administrator of the Economic Regulatory Administration. In reviewing gas import applications under section 3 of the Natural Gas Act, the ERA Administrator followed the guidelines set forth by the Secretary that required consideration of "the price proposed to be charged at the point of importation." (*4*) To this end, the Administrator assessed the reasonableness of the unit cost of an import on a case-by-case basis, using

the price of alternate fuels in the relevant geographic region as a basis for comparision.

When, in January 1980, the NEB announced an increase in the export price from $3.45 to $4.47 per MMTu, questions were raised by U.S. energy officials as to whether the Canadian substitution value approach resulted in reasonble prices to U.S. gas consumers. Discussions on this issue were held with Canadian energy officials in February 1980. On March 25, 1980, Canadian Energy Minister Lalonde proposed in a letter to U.S. Secretary of Energy Duncan a "Statement of Principles on Canadian Gas Export Pricing." This proposal suggested that Canadian gas exports be based on the average cost of crude oil imported into Eastern Canada, with certain transportation adjustments.

Secretary Duncan responded on March 26, 1980, that "To the extent the pricing mechanism * * * meets our regulatory requirements * * * [he] would support this mechanism for the pricing of Canadian natural gas." This exchange of letters constitutes what is now sometimes called the "Duncan-Lalonde agreement."

U.S. energy officials belived this understanding would result in greater price predictability and market stability. The Economic Regulatory Administration began using a national comparison test instead of comparing the import price with alternate fuels prices in a particular geographic region. The agency developed a composite alternate fuel oil price based on prices in major U.S. markets.(5) This method of measuring alternate fuels prices was considered appropriate when assessing a uniform border price for Canadian gas. It also provided gas importers guidance for use in negotiations with Canadian suppliers.

Near the time of the Duncan-Lalonde letters, new volumes of Mexican gas began to be imported. Uniformity in border prices for Canadian and Mexican gas was viewed by the U.S. as a desirable policy objective, and the ERA thus established a maximum authorized border price for Mexican gas equal to the Canadian border price.(6)

During the late 1960's and early 1970's, several American firms introduced plans to import liquefied natural gas from Algeria and Indonesia in the face of projected declines in U.S. gas supplies. Although Boston Gas Company occasionally imported Algerian LNG during the late 1960's, the Distrigas Corporation of Boston became the first regular LNG importer in 1971, with an authorization to import annually 15.4 million MMBtu from Algeria, primarily for winter peaking purposes in New England, New York, and New Jersey.

In early 1978 Columbia LNG Corporation, Consolidated System LNG Company and Southern Energy Company began to import approximately one Bcf per day of Algerian LNG for use in the mid-Atlantic and southeastern states. However, this project was suspended and effectively terminated in April 1980 when the parties failed to agree on price changes proposed by Sonatrach, the Algerian exporter. Several other proposed LNG import projects also were terminated, either after the ERA found that the pricing methods did not contain adequate consumer safeguards or because the projects encountered environmental opposition. On the other hand, the FPC authorized in 1977 an LNG import by the Trunkline LNG Company, which began in 1982 to import approximately 450,000 Mcf per day of Algerian LNG for base load use in the Midwest.

By the fall 1982, Canadian gas imports were entering U.S. pipelines in volumes and at a price that began to be uncompetitive in most U.S. markets. Consumers served by Canadian gas, as well as high-cost domestic gas and Algerian LNG, experienced large increases in the price of delivered gas. These circumstances were especially acute in the north central and western coastal states.

Late in 1982, informal discussions between the U.S. and Canadian governments began on problems relating to gas trade. These were followed by reactivation of the U.S.-Canadian Energy Consultative Mechanism (ECM), a forum established in 1979 by the governments for periodic exchanges on bilateral energy issues. A meeting of the ECM was held in February 1983, at which natural gas trade was a key agenda item; and following working group meetings and informal diplomatic discussions, a second ECM session was held in late September. At this second meeting, the U.S. proposed discontinuance of the uniform border price and the establishment of a new trade framework designed to put gas trade on a market-sensitive basis.

During 1983, the Canadian government announced three actions that affected the pricing of gas exports. In April it announced a reduction in the uniform border price from $4.94 to $4.40 per MMBtu and, in July, a price-discount arrangement, termed the Volume Related Incentive Pricing (VRIP) program, whereby gas purchased above certain base volumes is discounted to $3.40 per MMBtu.

A third action was taken on November 1, which involved changes to the VRIP program giving U.S. importers more flexibility in purchasing discounted gas.

Diplomatic efforts relating to imported gas from Algeria and Mexico were also undertaken in 1983. Officials from the departments of State and Energy held discussions with energy officials of the Algerian government, and although no governmental agreements or understandings encompass U.S.-Algerian gas trade, these discussions enabled both governments to review fully the current conditions and problems relating to their gas trade. Algerian officials received briefings on the U.S. gas market, the competitive position of Algerian gas, and U.S. policy direction with respect to domestic and imported gas. Similarly, U.S. energy officials met with Mexican officials in Mexico City in March 1983 to discuss U.S. gas market conditions. Mexico matched Canada's reduction of the border price from $4.94 to $4.40 per MMBtu on May 1, 1983.

During this period when the U.S. demand for imported gas dropped significantly, U.S. importers began efforts to renegotiate their contracts with foreign suppliers. These efforts resulted primarily in volume relief, providing substantial savings to U.S. gas consumers. Most recently, the importer of the largest volume of Algerian gas announced that effective December 12, 1983, it was suspending LNG purchases for an indefinite period. At this time, contract renegotiation activity between U.S. importers and foreign sellers continues, with some renegotiated contracts now before regulatory agencies for approval.

The Review of Gas Import Policy

During the past year an interagency review of U.S. gas import policy and regulations was undertaken involving the Department of Energy, Federal Energy Regulatory Commission, and Department of State, along with consultations with members of Congress and congressional staff. Public participation came primarily through two public conferences on imported gas sponsored by the Department of Energy.(7)

The first conference, held January 18, 1983, addressed problems of existing gas import arrangements. The majority of the conference participants—which included pipeline companies, distribution companies, end-users, state agencies, and consumer interests—asserted that a more flexible approach to pricing was needed, that prices

should be set by direct buyer-seller negotiations, and that governments should establish a simplified regulatory review process. Many indicated that load loss was a result of NGPA-allowed price rises, provisions of current contracts with high take-or-pay clauses and conservation effects from high gas costs—which could be reduced or reversed if buyers could negotiate more competitive prices and more reasonable take-or-pay provisions.

The second conference, held September 7–9, 1983, addressed specific issues relating to the implementation of policy changes recommended at the first conference. The majority of the nearly 90 presentations stated that the U.S. and Canadian governments should eliminate the uniform border price and develop a regulatory system that would allow for direct buyer-seller negotiations. General guidelines were favored over strict regulatory standards or criteria, with preference that the government maintain an oversight role to ensure that the interests of importers and their customers are protected.

The conclusions reached from the policy review process appear to be shared broadly by all interested parties to the gas trade issue. There is a common view that imported gas is generally not competitive in today's U.S. markets and that changes are required in governmental policy and regulations to bring about competitive gas trade. Buyers and sellers believe that government regulation prevents freely negotiated import arrangements and market-responsive adjustments to these arrangements. Virtually all parties believe that the governments, in regulating the terms and conditions of gas import trade, have previously sanctioned arrangements that are now uncompetitive in the marketplace.

Policy Guidelines

The U.S. policy goal for gas imports, as earlier stated, is to have a supply of natural gas supplemental to domestic production available on a competitive, market-responsive basis, while avoiding undue dependence on unreliable sources of supply. Government regulation of imports should facilitate trade arrangements consistent with this policy goal.

Section 3 of the Natural Gas Act requires the government to authorize an import of natural gas unless "the proposed importation will not be consistent with the public interest" (emphasis added).

Congress did not define "public interest," thus giving broad discretion to the government in establishing criteria that an importer must fail to meet for the government to deny an authorization to import. The policy guidelines herein are intended to provide a clear definition of public interest.

The policy cornerstone of the public interest standard is competition. Competitive import arrangements are an essential element of the public interest, and natural gas imported under agreements that provide for the sale of gas in volumes and at prices responsive to market demands largely meets the public interest test. On the other hand, import arrangements with contract terms and conditions that restrict the competitiveness of the gas over time should be considered, presumptively, not in the public interest.

This policy approach presumes that buyers and sellers, if allowed to negoitate free of constraining governmental limits, will construct competitive import agreements that will be responsive to market forces over time. The specific commerical terms and conditions of a particular arrangement should be negotiated by the parties pursuant to the discrete requirements of the buyer's market and not directed by government regulators. The government's role in authorizing such agreements should be to evaluate whether the arrangement assures the competitiveness of the import throughout the contract period and to provide a review process whereby affected parties have sufficient opportunity to demonstrate that the import is not consistent with the public interest. Those market participants who stand to benefit or suffer as a result of the importation have the best available knowledge of their market and should provide the information upon which the competitiveness of the arrangment can be judged.

The price paid for imported gas by U.S. importers has often been considered the key test of an import's competitiveness. The price of gas, however, is only one factor in determining the market competitiveness of the import. Pricing considerations, standing alone, will not longer be the base for authorizing or denying an import application, or for modifying or revoking an authorization. The emphasis will be on the provisions of the import agreement that establish the basis price and that allow price adjustments during the life of the agreement.

While the competitiveness of an import arrangement is now the primary consideration for authorization, other considerations will continue to be relevant. The security of the foreign supply, in particular, remains a regulatory consideration in meeting the objective of avoiding undue dependence on unreliable sources of supply. Need will continue as a consideration; however, it is recognized to be a function of competitiveness. Under competitive gas import trade arrangements, buyers will be presumed to have markets for gas actually purchased, unless otherwise demonstrated by participants in the regulatory process.

Thus, proposed import arrangements that are found competitive are presumed to have demonstrated the need for the import. National energy requirements will remain a factor in assessing long-term import arrangments, as the nation's energy security is a continuing policy consideration.

Finally, it is recognized that uniform regulatory strictures do not facilitate the establishment of competitive, market-responsive import arrangements and will not be applied. The terms and conditions of an arrangement that is competitive for one market may not be competitive in another. Thus, new import arrangements dependent on substantial capital financing that will provide new supplies to regions needing additional gas may require contract provisions, such as minimum volumes and prices, that may not be competitive in other regions. There also may be unique situations involving extensions or modifications of existing gas import arrangements, such as the prebuild portions of the Alaska Natural Gas Transportation System, that merit special consideration.

Regulatory Guidelines

Pursuant to section 3 of the Natural Gas Act and the Delegation Order from the Secretary of Energy to the ERA Administrator, an application to import gas must be approved unless it is determined that the import is not consistent with the public interest. This determination is based on a number of "considerations" addressed in an import authorization proceedding and stated in the Delegation Order. These considerations provide, in effect, the test that a proposed import arrangement must fail for an authorization to be denied. These policy guidelines provide notice of the manner in which the Administrator will exercise authority under section 3 of the Natural Gas Act to review natural gas import applications. The guidelines do not establish binding and inflexible rules; rather they set forth certain rebuttable presumptions and contemplate flexible application of the considertions outlined below to the facts of individual cases.

The following are the considerations now applicable to import arrangements

which, as of this date, have not received Section 3 approval by the Economic Regulatory Administration or the Federal Energy Regulatory Commission. They shall apply to applications currently pending that seek approval of amendments or extensions to existing import arrangements, as well as applications involving new imports. The application of these guidelines to authorizations previously granted with no pending application for amendment or extension is addressed in the discussion below on implementation. These considerations are contained in Delegation Order No. 0204–111 signed by the Secretary of Energy on February 15, 1984.

The competitiveness of the import

The terms and conditions of the gas purchase contract, taken together, must provide a supply of gas that the importer can market competitively over the term of the contract. The contract arrangement must be sufficiently flexible to permit pricing and volume adjustments, as required by market conditions and available competing fuels, including domestic natural gas. Contract flexibility is a function of certain provisions which may include, but are not limited to: the volume of gas under contract, base price, price review or adjustment mechanisms, take-or-pay obligations, make-up provisions, length of the contract, and other terms which may affect marketability of the gas. No prescribed set of provisions are being dictated as determinative of contract flexibility, allowing the importer to negotiate the import arrangement it considers necessary for the gas to remain marketable over the life of the contract. The importer will be required to demonstrate that the provisions in the proposed import arrangement, collectively, ensure that the gas will be competitive.

Contracts should also contain provisions to protect the parties in the event of changes in the circumstances in which the contract is expected to operate, and to permit contractual adjustments in such circumstances. Examples of such provisions include renegotiation clauses, arbitration clauses, "market-out" clauses, and similar arrangements. Again, no specific or predetermined provision to permit contract adjustments is favored, allowing the contracting parties discretion to determine the approach most suitable to their import arrangement.

Import agreements that are negotiated between buyer and seller should result in contracts that provide a competitive energy source for the duration of the import. The competitiveness of an import arrangement will not be assessed by a narrow inquiry into individual contract terms but rather a consideration of the whole fabric of the arrangement. Those opposing an import have to show that the arrangement, as a whole, is not competitive or sufficiently flexible to respond to changing market conditions.

Need for the natural gas

The need for the imported gas will be addressed in terms of the marketability of the proposed import. Need for a gas supply is intrinsically related to its anticipated marketability. Thus, if the imported gas is competitive in the proposed market area and, through its contract terms, will remain competitive throughout the contract period, then the rebuttable presumption exists that the gas is needed in that market. To the extent that there is a specific objection on the grounds of need for the import, the focus should be on the overall energy requirements in the market that can be competitively met by domestic natural gas and other fuels.

National energy requirements will also be a factor, particularly in assessing long-term import arrangements, as the energy security of the nation remains a policy consideration.

Security of supply

The security of gas supply and its transportation to the U.S. border remain important components of the public interest, especially those under long-term arrangements. An import will be considered secure if it does not lead to undue dependence on unreliable sources of supply. Thus, imports involving relatively larger volumes and longer time periods must demonstrate relatively greater reliability of supply than smaller scale imports for a shorter time period in the application for authorization.

Security of a proposed import supply can be demonstrated by reference to the historical reliability of the supplier to provide a dependable source of gas to the United States and other countries. Reference can be made to any gas reserves committed to the import arrangement for the term of the contract.

Attention will be given to the advantage provided to the nation by a reliable supply of imported natural gas, which adds to the diversity of energy sources and provides an added measure of energy security during any period of energy shortage or emergency.

In additon to the above considerations, the Administrator will consider international trade policy, foreign policy, and national security interests that may bear on an import authorization. In so considering these and other factors as may be appropriate, the Department of State will be consulted in accordance with section 102(10) of the DOE Organization Act.

Regulation of Gas Imports by ERA and FERC

Under the Department of Energy Organization Act, the Secretary of Energy was given responsibility for implementing the provisions of the Natural Gas Act relating to natural gas imports and exports. This authority, formerly vested in the Federal Power Commission, was given to the Secretary in recognition that a policy official accountable to the President should have jurisdiction over the regulation of gas imports to the extent that the regulatory decisions affect national and international energy policy, foreign policy, and national security interests.

The Department of Energy legislation also established the Federal Energy Regulatory Commission, in which was vested the authority to regulate certain aspects of domestic natural gas within the United States. This authority, exercised *inter alia* under the Natural Gas Act and Natural Gas Policy Act, includes the regulation of wellhead prices and transportation rates for gas produced in the United States and gas transported in interstate commerce to the American consumer. In view of the fact that imported gas reaches the consumer through the same transportation systems that deliver domestically produced gas, the Secretary delegated to the FERC certain regulatory responsibilities for imports that it exercises over domestic gas, including siting, construction of facilities, and ratemaking. This authority was delegated to the FERC with the recognition that the Secretary maintained the policy responsibilities for gas imports, and that the FERC should exercise its authority in a manner consistent with the gas import policy determinations established by the Secretary.

In delegating his responsibility to authorize imports to the Administrator of the Economic Regulatory Administration, the Secretary made an exception for imported gas transported through the Alaska Natural Gas Transportation System (ANGTS). Authority was delegated to the FERC to authorize the importation of Canadian gas using the "prebuild" portions of the system while these portions were being financed, constructed, and placed in

initial operation, along with the financing of the overall ANGTS project.

The division of regulatory responsibilities for imported natural gas brought about by the Department of Energy Organization Act, and the assignment of these responsibilities to the ERA Administrator and the FERC, presented inherent problems of coordination and regulatory consistency that did not exist when this responsibility was all exercised by the FPC. While the ERA and the FERC have carried out their respective responsibilities in an effective and conscientious manner, the lines of jurisdiction and authority between the two agencies have not been entirely clear. This lack of clarity is a concern that was expressed by a number of gas importers during the policy review process, with the observation that the ERA and the FERC sometimes both review the same issues.

While a two-part regulatory process is unavoidable under the enabling legislation, some efficiencies can be achieved through clarification of the ERA and FERC gas import responsibilities and through streamlining some aspects of the process. This is the objective in the issuance of new delegation orders to the ERA Administrator and the Commission. These revised orders seek to make a clearer distinction between the responsibility of the Administrator in exercising the Secretary's authority to approve natural gas imports and the FERC's responsibility to regulate the imported gas within the domestic natural gas system. These orders are also issued with the goal of achieving uniform application of these policy guidelines to all natural gas imports.

Under the new delegation orders, all gas imports—including gas transported through the ANGTS prebuild—will be authorized by the ERA Administrator. Delegation Order No. 0204–8, which gave this authority for ANGTS to the FERC, is being rescinded. The Administrator will exercise this authority consistent with the policy guidelines set forth in this notice and contained in new Delegation Order No. 0204–111.

The FERC, under the revised delegation orders, maintains its responsibilities for exercising sections 4, 5, and 7 authority under the Natural Gas Act over gas authorized for import by the Administrator. Gas authorized for importation is subject to the FERC's review of issues pertaining to siting, construction, and operation of pipeline facilities, and to the rates proposed to be charged for the interstate transportation and sale of the gas. The FERC review, in effect, will address the regulatory matters relevant to the imported gas upon its entry into the United States and as it flows through domestic gas transportation systems. In its regulatory decisions on a gas supply authorized for importation, the Commission will adopt the terms and conditions attached by the ERA Administrator to the import authorization, thus acting consistently with the determinations made by the Administrator and the policy considerations reflected in the authorization.

The goal of this Administration is to have a deregulated natural gas market, whereby buyers and sellers operating entirely under market forces can provide gas to consumers at prices competitive with alternative fuels. Until this goal is fully reached, natural gas transported and sold within the United States will remain subject to certain regulatory considerations. Gas delivered to U.S. markets from foreign sources is subject to these considerations. Under these policy guidelines and delegated authorities, the ERA Administrator and the FERC can fulfill their respective regulatory responsibilities in a manner that improves the regulatory process while establishing competitive natural gas trade.

Implementation

The policy guidelines herein set forth are now effective, and the regulatory considerations presented above and contained in the new delegation orders will be applied to all gas import arrangements that have not received section 3 authorization by either the Economic Regulatory Administration or Federal Energy Regulatory Commission. Import applications, including requests for modification of existing authorizations and authorizations of new contracts currently pending before either agency, will be reviewed within this new policy and regulatory framework by the Economic Regulatory Administration. Pending applications that require expeditious approval and that do not fully comport with these guidelines may be granted conditional authorizations.

Pursuant to Section (j) of Delegation Order No. 0204–111, imports previously authorized by the ERA and FERC shall remain in full force and effect unless or until they are rescinded, amended or superseded through appropriate regulatory proceedings. The ERA will not on its own motion initiate such proceedings unless an agreement between the United States and the government of a gas exporting country so requires. The guidelines will apply to pending cases including requests to modify existing authorizations. The ERA Administrator will issue a procedural order that specifies the dockets that are directly and immediately affected by these new guidelines.

U.S. companies that import natural gas under arrangements that are not fully consistent with these policies and the provisions of Delegation Order No. 0204–111 are encouraged to negotiate changes to such arrangements to bring them into conformity with these policies and provisions. The ERA will give prompt attention to import authorization amendments submitted by importers as a result of these negotiation efforts. To the extent that such amendments bring an import arrangement more into conformity with these guidelines, they will benefit from the presumption that they are in the public interest, and opposing parties will bear the burden to rebut the presumption.

These policy guidelines and regulatory changes are designed to avoid instability or uncertainty in existing natural gas trade and establish a smooth transition to competitive trade arrangements, with minimal regulatory requirements and governmental involvement. The policy guidelines should permit parties engaged in gas trade to craft arrangements competitive for the markets served. The import authorization process is designed to fulfill the governments's statutory responsibilities without regulating the specific terms and conditions of individual trade arrangements.

The delegation orders are effective February 22, 1984, the date of publication in the **Federal Register.**

Issued in Washington, D.C. on February 15, 1984.

Donald Paul Hodel,

Secretary of Energy.

Notes

1. Cost of service is defined as the sum total of proper operating and depreciation expenses, taxes, and a reasonable return on the net valuation of the property devoted to providing natural gas service. A two-part demand-commodity rate, with periodic price adjustments, is then designed to produce revenues equivalent to the cost of service.

2. National Energy Board Act.

3. On January 3, 1977, $1.94 (Cdn) was equal to $193 (U.S.).

4. DOE Delegation Order No. 0204–54 to the Economic Regulatory Administration (44 FR 56735, October 2, 1979). In recognition of the expertise of the Federal Energy Regulatory Commission in the areas of interstate transportation and resale of natural gas and construction and operation of facilities, the Secretary delegated to FERC authority over certain activities related to gas imports. (DOE Delegation Order No. 0204–55 to the Federal

Energy Regulatory Commission [44 FR 56735, October 2, 1979]).

5. DOE/ERA Opinion No. 14B, *Inter-City Minnesota Pipelines Ltd. Inc., et al.*, 1 ERA para 70508 (*Federal Energy Guidelines*, May 15, 1980).

6. DOE/ERA Opinion No. 16A, *Border Gas, Inc.*, 1 ERA para 70511 (*Federal Energy Guidelines*, May 15, 1980).

7. 47 FR 57756, December 28, 1982; 48 FR 34501, July 29, 1983.

[Delegation Order No. 0204-110]

Rescission of Delegation to the Federal Energy Regulatory Commission

Pursuant to the authority vested in me as Secretary of Energy, Department of Energy Delegation Order Nos. 0204–8 and 0204–14 are hereby rescinded.

All actions pursuant to Delegation Order Nos. 0204–8 and 0204–14 taken prior to and in effect on the date of this Order shall remain in full force and effect unless or until rescinded, amended or superseded.

This Order is effective February 22, 1984, the date of publication in the **Federal Register.**

Donald Paul Hodel,

Secretary of Energy.

[Delegation Order No. 0204-111]

To the Administrator of the Economic Regulatory Administration

Pursuant to the authority vested in me as the Secretary of Energy ("Secretary") by the Natural Gas Act (Act of June 21, 1938, ch. 556, 52 Stat. 821 (15 U.S.C. § 717)) ("NGA") and Sections 301(b), 402(f), and 642 of the Department of Energy Organization Act (Pub. L. No. 95–91, 91 Stat. 565 (42 U.S.C. § 7101 *et seq.*)), there is hereby delegated to the Administrator of the Economic Regulatory Administration ("Administrator") the authority under section 3 of the NGA to regulate the imports and exports of natural gas.

(a) The Administrator shall regulate imports (including place of entry) based on a consideration of such matters as the Administrator finds in the circumstances of a particular case to be appropriate, which may include, but are not limited to, the following matters:

1. Competitiveness of the import;
2. Need for the natural gas;
3. Security of supply.

(b) The Administrator shall regulate exports (including place of exit) based on a consideration of the domestic need for the gas to be exported and such other matters as the Administrator finds in the circumstances of a particular case to be appropriate.

(c) In exercising the authority delegated by this Order, the Administrator may attach such terms and conditions as the Administrator shall determine to be appropriate.

(d) The authority delegated by this Order does not include the authority to approve the construction and operation of particular facilities, the site at which such facilities shall be located, and, with respect to natural gas that involves the construction of new domestic facilities, the place of entry for imports or exit for exports, except the Administrator is authorized to disapprove the construction and operation of particular facilities, the site at which such facilities shall be located, and, with respect to natural gas that involves the construction of new domestic facilities, the place of entry for imports or exit for exports, on the basis of matters considered pursuant to paragraphs (a) and (b) of this Order.

(e)(1) With respect to ERA Docket No. 77–001–LNG, in addition to the functions enumerated in paragraphs (a), (b) and (c) above (and notwithstanding paragraph (d) above), the Administrator is authorized to perform all functions related to the regulation of the importation and distribution of natural gas through, and construction and operation of, facilities at Oxnard, California.

(2) This delegation does not amend or supersede 10 CFR § 1000.1(d) (42 FR 55534, October 17, 1977) or DOE Delegation Order No. 0204–1.

(f) The authority delegated to the Administrator may be further delegated (except to the Federal Energy Regulatory Commission) in whole or in part, as may be appropriate.

(g) Paragraph 6 of Delegation Order No. 0204–4, is amended to read as follows:

"6. The functions delegated to the Administrator of ERA by Delegation Order No. 0204–111."

(h) This Order supersedes Delegation Order No. 0204–54.

(i) In exercising the authority delegated by this Order, or redelegated pursuant thereto, the delegates shall be governed by the rules, regulations and procedures of the Department of Energy and the policies prescribed by the Secretary or the Secretary's delegate.

(j) All actions pursuant to any authority delegated prior to this Order, or pursuant to any authority delegated by this Order taken prior to and in effect on the date of this Order, are hereby confirmed and ratified, and shall remain in full force and effect as if taken under this Order, unless or until rescinded, amended, or superseded.

(k) Nothing in this delegation shall preclude the Secretary from exercising any of the authority so delegated whenever in the Secretary's judgment the exercise of such authority is necessary or appropriate to adminsiter the functions vested in the Secretary.

This Order is effective February 22, 1984, the date of publication in the **Federal Register.**

Donald Paul Hodel,

Secretary of Energy.

[Delegation Order No. 0204-112]

Federal Energy Regulatory Commission

Pursuant to the authority vested in me as the Secretary of Energy ("Secretary") by sections 301(b), 402 (e) and (f), and 642 of the Department of Energy Organization Act (Pub. L. No. 95–91, 91 Stat. 565 [42 U.S.C. § 7101 *et seq.*]) the Natural Gas Act (Act of June 21, 1938, ch. 556, 52 Stat. 821 [15 U.S.C. § 717]) ("NGA"), and Executive Order No. 10485, as amended by Executive Order No. 12038, there is hereby delegated to the Federal Energy Regulatory Commission ("FERC") the authority to perform the following functions with respect to the regulation of imports and exports of natural gas:

(a) Approval or disapproval of the construction and operation of particular facilities, the site at which such facilities shall be located, and, with respect to natural gas that involves the construction of new domestic facilities, the place of entry for imports or exit for exports, except when the Administrator of the Economic Regulatory Administration ("Administrator") exercises the disapproval authority delegated pursuant to paragraph (d) of Delegation Order No. 0204–111.

(b) All functions under sections 4, 5, and 7 of the NGA.

(c) Issue orders, authorizations, and certificates which the FERC determines to be necessary or appropriate to implement the determinations made by the Administrator under Delegation Order No. 0204–111 and by the FERC under this Order. The FERC shall not issue any order, authorization, or certificate unless such order, authorization, or certificate adopts such terms and conditions as are attached by the Administrator pursuant to the authority delegated to the Administrator by Delegation Order No. 0204–111.

The delegate(s) may take such action as may be necessary and appropriate to carry out the functions delegated by this Order.

This Order supersedes Delegation Order No. 0204–55.

The authority delegated to the FERC may be further delegated within the FERC, in whole or in part, as may be appropriate.

In exercising the authority delegated by this Order, or redelegated pursuant thereto, the delegates shall be governed by the rules, regulations, and procedures of the FERC and shall be guided by the policies prescribed by the Secretary or the Secretary's delegate.

All actions pursuant to any authority delegated prior to this Order, or pursuant to any authority delegated by this Order taken prior to and in effect on the date of this Order, are hereby confirmed and ratified, and shall remain in full force and effect as if taken under this Order, unless or until rescinded, amended, or superseded.

Nothing in this Order shall preclude the Secretary from exercising any of his authority so delegated whenever in the Secretary's judgment the exercise of such authority is necessary or appropriate to administer the functions vested in the Secretary.

This Order is effective February 22, 1984, the date of publication in the **Federal Register.**

Donald Paul Hodel,

Secretary of Energy.

[FR Doc. 84-4748 Filed 2-22-84; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

Natural Gas Imports; Procedural Order Applying New DOE Policy Guidelines Relating to Importation of Natural Gas

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of issuance of a procedural order.

SUMMARY: The Secretary of Energy has issued new policy guidelines and delegation orders to the Administrator of the Economic Regulatory Administration and to the Federal Energy Regulatory Commission relating to the importation of natural gas. The Administrator has issued a procedural order initiating action to begin implementation of those new guidelines. The procedural order is attached as an appendix to this notice and is being published concurrently with the policy guidelines and delegation orders.

FOR FURTHER INFORMATION CONTACT:

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Michael T. Skinker (Office of General Counsel, Natural Gas and Mineral Leasing), U.S. Department of Energy, Forrestal Building, Room 6E-042, 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 252-6667

Issued in Washington, D.C., February 16, 1984.

Rayburn Hanzlik,

Administrator, Economic Regulatory Administration.

United States of America Department of Energy—Economic Regulatory Administration

Company name	*ERA Docket Nos.*
Borders Gas, Inc	79-31-NG.
Boundary Gas, Inc	81-04-NG.
Distrigas Corporation	77-011-LNG, 82-13-LNG.
Gas Service, Inc.; Manchester Gas Company.	81-22-LNG.
Great Lakes Gas Transmission Company.	80-02-NG, 81-01-NG, 83-07-NG.
Inter-City Minnesota Pipelines, Ltd.	80-01-NG, 82-15-NG.
Michigan Wisconsin Pipe Line Company.	80-04-NG, 81-18-NG, 81-34-NG.
Midwestern Gas Transmission Company.	80-06-NG, 81-16-NG, 81-32-NG.
Midwestern Gas Transmission Company; Great Lakes Gas Transmission Company.	83-08-NG.
Montana Power Company.	80-03-NG, 81-21-NG.
Natural Gas Pipeline Company of America.	82-01-NG.
Natural Gas Pipeline Company of America; Michigan Wisconsin Pipe Line Company; Tennessee Gas Pipeline Company; Texas Eastern Gas Pipeline Company.	79-15-NG.
Northern Natural Gas Company.	79-24-NG, 82-09-NG, 82-11-NG.
Northwest Pipeline Corporation.	80-05-NG, 81-31-NG, 83-06-NG.
Pacific Gas Transmission Company.	80-07-NG, 81-09-NG, 82-16-NG.
St. Lawrence Gas Company, Inc.	80-09-NG, 81-13-NG.
Tennessee Gas Pipeline Company.	81-24-NG, 82-10-NG, 82-13-NG.
Texas Eastern Gas Pipeline Company.	82-05-NG, 82-07-NG.
Texas Gas Transmission Corporation.	82-08-NG.
Transcontinental Gas Pipe Line Corp.	80-14-NG, 81-29-NG, 81-30-NG.
Transcontinental Gas Pipe Line Corp.; Tennessee Gas Pipeline Company.	79-08-NG.
Transcontinental Gas Pipe Line Corp.; Algonquin Gas Transmission Company; Texas Eastern Gas Pipeline Company.	81-02-NG.
Vermont Gas Systems, Inc.	80-10-NG, 83-09-NG.

Order Directing Applicants With Pending Gas Import Applications To Supplement Those Applications, Directing Importers With Existing Authorizations, To Report on Conformance of Arrangements With Guidelines, Providing Guidance on Alaska Natural Gas Transportation System Filings, and Terminating Suspended Proceedings

February 16, 1984.

I. Introduction

On February 15, 1984, the Secretary of Energy issued new policy guidelines and delegation orders to the Administrator of the Economic Regulatory Administration (ERA) and to the Federal Energy Regulatory Commission (FERC) relating to the authorization of imports of natural gas into the United States. The guidelines set forth a new policy designed to encourage greater participation of buyers and sellers of imported natural gas in establishing price and contract terms, and to ensure that import arrangements result in gas being imported on a competitive and market-responsive basis.

This order initiates action to implement the new policy guidelines. It requires applicant that have pending import applications and authorization amendments before the ERA to supplement their applications. The order also requests all importers with existing authorizations to assess their current import arrangements from the standpoint of conformity with the new policy and regulatory considerations, and to report to the ERA the results of this assessment. This report should include information on modifications the importer believes would be required for the arrangement to comply fully with the policy guidelines. The order further terminates earlier proceedings involving flowing gas imports from Canada that were suspended on December 16, 1980.