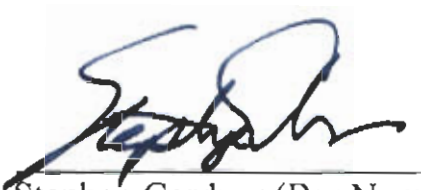
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

In re Center for Science in the Public Interest,	)	
	)	No. 05-
Petitioner.	)	

PETITION FOR A WRIT OF MANDAMUS

The Center for Science in the Public Interest ("CSPI") petitions the Court to issue a Writ of Mandamus pursuant to its authority under Federal Rule of Appellate Procedure 21, the All Writs Act, 28 U.S.C. § 1651(a), and the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355, compelling Respondent Food and Drug Administration ("FDA") to complete its review of the regulatory status of salt, and either affirm its current status or declare it a food additive. In support of this petition, CSPI submits the accompanying memorandum.

Dated: February 24, 2005



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UNITED STATES COURT OF APPEALS
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No. 05-

In re Center for Science in the Public Interest,
Petitioner.

On Petition for a Writ of Mandamus
Compelling Respondent Food and Drug Administration
to Take Agency Action Unreasonably Delayed

MEMORANDUM IN SUPPORT OF PETITION FOR A WRIT OF MANDAMUS

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INTRODUCTION

Petitioner Center for Science in the Public Interest ("CSPI") seeks a writ of mandamus compelling respondent Food and Drug Administration ("FDA") to take prompt action to protect the great majority of Americans who consume unhealthy amounts of salt.[1] Reducing salt intake is one of the single most important steps that a person can take to prevent cardiovascular disease. Reducing per capita salt consumption in the United States could save tens of thousands of lives each year.

In 1983, CSPI sued FDA seeking to force the agency to complete its safety review of sodium, to regulate the quantity of salt added to processed foods, and to require sodium content labeling on processed foods. CSPI lost that case because the court found that FDA was "continuing to work on this issue." *CSPI v. Novitch*, Food, Drug & Cosm. L. Rep. (CCH) ¶38,275 (D.D.C. June 11, 1984), Addendum at 5a ("*CSPI v. Novitch*"). Nonetheless, the court also stated that (1) "the FDA must make a decision on the [regulatory] status of salt after it has completed its review" and (2) FDA regulation "clearly indicates" that FDA was required to make a determination on salt's safety. *Id.* In the more than 20 years since then, however, FDA has taken no further action on the regulatory status of salt. *See* 56 Fed. Reg.

[1] Sodium is the deleterious component of salt. Sodium is 39% of salt by weight. 21 CFR § 101.74(a). This memorandum uses both "sodium" and "salt," depending on the context.

60825, 60826 (1991) (reviewing regulatory history of salt). During that same time period, the dangers of salt have become increasingly clear.

Accordingly, Petitioner seeks an order directing FDA to publish in the Federal Register a proposed rule either affirming or denying the "GRAS" ("generally recognized as safe") status of salt and providing an opportunity for comment on that proposal. Without the Court's intervention, FDA will almost certainly continue to delay. Because the millions of Americans at risk of hypertension and cardiovascular disease are paying for FDA's delay with their health, the Court should compel FDA to take prompt action.

CSPI also requests that the Court retain jurisdiction and order FDA to file monthly status reports to ensure compliance with the timetable imposed by the Court.

STATEMENT OF THE ISSUE

Whether FDA has unreasonably delayed reviewing the GRAS status of salt and either affirming the GRAS status or determining salt to be a food additive, where (a) FDA regulations in effect for more than 30 years require it to take such action, (b) more than 20 years ago, FDA represented in court that it would consider proposing a change in the GRAS status of salt if certain interim measures did not reduce salt consumption, and (c) evidence of the risks of excess salt consumption has continued to mount during the period of FDA's inaction.

STATUTES INVOLVED

The pertinent provisions of the Administrative Procedure Act ("APA"), the All Writs Act, and the Food, Drug, and Cosmetic Act ("FDCA") are set out in the addendum to this memorandum.

JURISDICTION

This Court has jurisdiction over this petition for mandamus under the All Writs Act, 28 U.S.C. § 1651(a); the APA, 5 U.S.C. §§ 555(b) & 706(1); and the judicial review provision of the FDCA, 21 U.S.C. § 348(g). *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70, 75, 79 (D.C. Cir. 1984) ("*TRAC*").[2]

PARTIES

Petitioner CSPI is a nationwide, non-profit organization headquartered in Washington, DC, with approximately 800,000 American members and subscribers. Since its formation in 1971, CSPI has been a strong advocate for nutrition and

[2] Section 348(g) provides that judicial review of an FDA order issued with respect to the regulatory status of a food additive, including the amendment or repeal of a regulation respecting a food additive, may be taken by the applicant by filing a written petition that the application be set aside in the United States Court of Appeals for the circuit wherein the applicant resides or has its principal place of business or in the United States District Court for the District of Columbia. Accordingly, because this petition "might affect the Circuit Court's future jurisdiction," it is "subject to the exclusive review of the Court of Appeals." *TRAC*, 750 F.2d at 78-79; *see American Foreign Serv. Ass'n v. Baker*, 895 F.2d 1460, 1461 (D.C. Cir. 1990) ("*TRAC* stands for the proposition that cases should be brought in the same judicial forum whether the complaint is about agency action or failure to act.").

health, food safety, alcohol policy, and sound science. Its award-winning newsletter, *Nutrition Action HealthLetter*, is the largest-circulation health newsletter in North America, providing reliable information on nutrition and health. CSPI's twin missions are to conduct innovative research and advocacy programs in health and nutrition, and to provide consumers with current, useful information about their health and well-being. FDA has awarded CSPI's executive director a Commissioner's Special Citation, the highest award that FDA gives to non-employees.

Respondent FDA is the agency responsible for implementing the Food, Drug, and Cosmetic Act, including regulation of food additives and food ingredients generally recognized as safe.

STATEMENT OF THE CASE

A. Health Effects of Excess Salt Consumption

Consumption of excessive sodium in the form of salt can cause hypertension (or high blood pressure), a condition that increases the risk of a heart attack or stroke for millions of Americans. The relationship between salt and hypertension is so well established that it is set forth in an FDA regulation adopted in 1993. 21 C.F.R. § 101.74(a)(2).

Hypertension is extraordinarily common and increasingly widespread. "Hypertension is the leading cause of strokes in the United States, and is a major contributor to heart attacks, heart failure, and kidney failure." 47 Fed. Reg. 26580

(1982) (FDA notice); *see also* 56 Fed. Reg. 60825 (FDA notice) ("Individuals with high blood pressure have an increased risk of developing stroke, heart disease, and several types of kidney disease."). In 1982, FDA said that "as many as 60 million individuals may have hypertension." 47 Fed. Reg. 26584. That number is now estimated to be 65 million. *Blood Pressure Rates On Rise Again in U.S.*, N.Y. Times, Aug. 24, 2004, at A7 (also noting that an additional 45 million people have pre-hypertension). And FDA's parent Department of Health and Human Services ("HHS") has warned that "[n]early all American adults will develop hypertension (high blood pressure) during their lifetime." HHS & USDA, *Dietary Guidelines Advisory Committee Report*, Part E at 14 (2005), *at* www.health.gov/dietaryguidelines/dga2005/report.

As early as 1904, scientists began to recognize the role of dietary sodium in the development of hypertension. 47 Fed. Reg. 26580. Although salt is not the only dietary source of sodium, it "is the single greatest contributor of sodium in the American food supply." *Id.*; *see also* 21 C.F.R. § 101.74 (salt is 39% sodium by weight). Accordingly, "a reduction in sodium intake almost always means reducing one's salt intake." 47 Fed. Reg. 26580.

FDA recommends that individuals consume no more than 2,400 mg of sodium per day (six grams of salt). 21 C.F.R. § 101.74(b)(4). Likewise, every edition of the Dietary Guidelines for Americans, which was first published in 1980 by

HHS and the Department of Agriculture ("USDA"), has advised Americans to reduce their intake of salt. *See* 47 Fed. Reg. 26581 (FDA reference to 1980 Guidelines). The maximum level is now 2,300 mg/day for healthy young adults but 1,500 mg/day for middle-aged and older adults, African Americans, and people with hypertension. Dietary Guidelines for Americans (2005) ("*2005 Dietary Guidelines*"), *at* www.healthierus.gov/dietaryguidelines. FDA has recognized that the average American adult consumes much more sodium than these recommended levels. Kurtzweil*, Scouting for Sodium*, FDA Consumer (Sept. 1994, Sept. 1995), *at* vm.cfsan.fda.gov/~dms/fdsodium.html; 56 Fed. Reg. 60828; 47 Fed. Reg. 26581.

FDA has also long recognized the link between salt intake and hypertension. In June, 1982, when FDA proposed a rule regarding sodium labeling on certain foods, FDA stated that "[h]ypertension is the leading cause of strokes in the United States, and is a major contributor to heart attacks, heart failure, and kidney failure." 47 Fed. Reg. 26580. A separate notice published concurrently with the proposed labeling rule reiterated the risks posed by high salt consumption. 47 Fed. Reg. 26590 (1982). Two years later, FDA commentary accompanying the final rule on sodium labeling for certain foods again affirmed the benefits of reducing dietary sodium. 49 Fed. Reg. 15510 (1984).

In 1994, FDA confirmed that "[s]odium has long been a major dietary factor in reducing the risk of, and controlling high blood pressure." *Scouting for Sodium, supra* p.6. Accordingly, FDA permits low-sodium foods to bear labels claiming that diets low in sodium may reduce the risk of hypertension. 21 C.F.R. § 101.74(c)(2).

The vast majority of sodium—77%—does not come from salt added at the dining table, but rather from processed foods. *2005 Dietary Guidelines*, at 42. FDA has authority to regulate the quantity of salt in processed foods, *see infra* at B, and thus can take a meaningful step toward reducing salt consumption. And doing so could save thousands of lives—by one expert estimate, as many as 150,000 per year. Havas, Roccella, Lenfant, *Reducing the Sodium Content of the American Diet*, 94 Am. J. Pub. Health 19-22 (2004) (estimate based on 50% less sodium in processed and restaurant foods); *see also* NIH, *Implementing Recommendations for Dietary Salt Reduction* 21 (1996), *at* www.nhlbi.nih.gov/health/prof /heart/hbp/hbp_salt.pdf ("It is critical that the food industry reduce . . . the content of sodium in generally available processed foods . . . .").

B. Statutory and Regulatory Framework

FDA has distinguished among four types of food ingredients: (1) GRAS ingredients, (2) prior sanctioned ingredients, (3) food additives, and (4) interim food additives.

1. GRAS. Ingredients "generally recognized as safe" by "experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food" may be used in foods without express FDA approval. 21 C.F.R § 170.30. The basis for the experts' views may be either scientific procedures or—in the case of substances used in food prior to January 1, 1958 (when the FDCA was amended to add the food additive section, 21 U.S.C. § 348)—through experience based on common use in food. *Id*.

2. Prior Sanctions. Food ingredients that FDA (or predecessor agencies) granted companies permission to use before 1958 have "prior sanction" status. *Id*. § 170.18; *see* 21 U.S.C. § 321(s)(4) ("food additive" does not include ingredients used in accordance with sanction or approval granted prior to enactment of food additives provisions of FDCA).

3. Food Additive. The FDCA prohibits the marketing of adulterated food. 21 U.S.C. § 331(a). A food that contains a food additive is deemed adulterated unless the additive has been approved through a regulation "prescribing the conditions under which such additive may be safely used." *Id*. § 348(a)(2). A "food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation promulgated under [21 U.S.C. § 348] before it may be directly or indirectly added to food." 21 C.F.R. § 170.30(g). A food additive regulation may be issued on FDA's initiative, 21 U.S.C. § 348(d), or in response to a petition request-

ing FDA to issue a regulation prescribing the conditions under which an additive may be safely used, such as the amounts that may be added to different foods, *id*. § 348(b)(1).

4. Interim Food Additive. An ingredient previously determined to be GRAS may later become subject to the requirement of a food additive regulation if new information requires reconsideration of the GRAS status. 21 C.F.R. § 170.30(l); *id*. § 180.1(a). In the event that "new information raises a substantial question about the safety" of an ingredient, FDA may adopt an "interim food additive regulation" to allow for the "continued use of the substance for a limited period of time while the question raised is being resolved by further study." *Id*. § 180.1(a). Interim use is only allowed if "there is a reasonable certainty that the substance is not harmful and that no harm to the public health will result." *Id*. FDA may reconsider the GRAS status of an ingredient either on its own initiative or in response to a citizen petition. *Id*. § 170.38(b).

From 1958 to 1962, to eliminate confusion regarding the status of many substances that were being used in food at the time the 1958 amendment was enacted, FDA established partial lists of substances that it considered to be either GRAS, 21 C.F.R. Part 182, or subject to prior sanction, *id*. Part 181. Decisions as to GRAS status were made without a detailed scientific review of the data and information available at that time. *Id*. § 170.30(e). Salt was one of the ingredients preliminarily

considered GRAS, based only on its common use in food and without a detailed scientific review by "experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food." *Id*. § 182.1(a).

In 1969, the President directed FDA to review the GRAS status of many substances. 38 Fed. Reg. 20054 (1973). In response to this directive, FDA established regulations and, in 1970, began its GRAS review of more than 400 substances—including salt. *See* 47 Fed. Reg. 26591; 21 C.F.R. § 170.30(e), (f); *id*. § 182.1(a).

FDA explained this process:

> FDA's decisions to place substances on the original GRAS lists were based on the data available at the time the lists were established and on the then current state of knowledge in the field of toxicology. Likewise, the pre-1958 approvals by FDA and USDA that qualified substances for prior-sanctioned status reflected the best safety judgments that could be made at the time based on existing knowledge. During the ensuing years, however, as more data became available on the properties of particular substances and as the science of toxicology developed, it became apparent that, in order to ensure the safety of the food supply, the agency's earlier safety determinations should be reviewed and modified where appropriate. Thus, FDA initiated the GRAS review program in 1970.

47 Fed. Reg. 26591.

To facilitate its GRAS review, FDA contracted with the Federation of American Societies for Experimental Biology ("FASEB") to evaluate available data and make recommendations to FDA. Thus, FDA effectively recognized

FASEB as "experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food." FDA gave FASEB a choice of five recommendations from which to choose as to each ingredient reviewed. The strongest recommendation FASEB could make was that "FDA should prohibit or limit the use of the substance in food because, when used at present levels, the material may have shown some adverse effect, and evidence is insufficient to determine whether the adverse effect occurring is deleterious to health."

FDA stated that, after evaluating the FASEB report for each ingredient reviewed, it "will publish in the Federal Register a proposal to (1) affirm GRAS status, (2) publish a prior sanction, (3) establish an interim food additive regulation, (4) establish a permanent food additive regulation, (5) eliminate use of the ingredient." 38 Fed. Reg. 20053.

C. Regulation of Salt and CSPI's 1983 Lawsuit

In 1979, FASEB completed the evaluation of salt commissioned by FDA as part of the GRAS review program. That evaluation noted that 10 to 30 percent of the population of the United States is genetically predisposed to hypertension and is exposed to a higher risk by ingestion of salt at current levels. 47 Fed. Reg. 26581. FASEB concluded that it could not give salt a clean bill of health—that the "evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to the health when it is used at levels that are now cur-

rent." 47 Fed. Reg 26592. FASEB recommended that FDA take steps to lower salt consumption because of the potential for adverse health effects. *Id*.

Three years later, in a 1982 Federal Register notice, FDA discussed the FASEB report:

> The agency considered five regulatory options in determining a rational response to the current concern about salt intake. These five options are: 1. To propose to revoke the GRAS status of salt, declare it to be a food additive, and propose a food additive regulation that prescribes the permitted uses and use levels of salt in manufactured food. 2. To propose to revoke the GRAS status of salt, declare it to be a food additive, and propose an interim food additive regulation that prescribes the permitted uses and use levels of salt in manufactured foods to current uses and use levels pending the completion of additional safety studies. 3. To defer action on the GRAS status of salt, but to propose a regulation requiring the labels of all manufactured foods containing added salt to declare quantitatively the total sodium content of the food. 4. To propose to affirm salt as GRAS with specific limitations, and to define those limitations as informative labeling that would adequately alert the public to the health risks associated with a high level of sodium intake. 5. To defer any action on the current GRAS status of salt until the agency can assess the impact of the sodium labeling regulations proposed elsewhere in this issue of the Federal Register and the efforts by manufacturers to reduce voluntarily the salt and sodium content of their products.

47 Fed. Reg. 26592. FDA chose option 5, which was inconsistent with what it said it would do in response to the FASEB recommendation. *See* 38 Fed. Reg. 20053.

The same day that FDA published its discussion of the FASEB report, FDA proposed a regulation to require manufacturers to state the sodium content on processed foods, but only when nutrition labeling was otherwise required or pro-

vided voluntarily. 47 Fed. Reg. 26587. FDA did not propose any regulation to require processed food manufacturers to reduce the salt content of their products.

Instead of regulation, FDA said that it would leave reduction up to the food companies, because it "believe[d] that a voluntary program will produce the desired results with less regulatory burden. Moreover, the food industry is in the best position to reduce sodium levels in processed food and to provide more information to consumers. The Commissioner believes that the industry should be given a chance to do so." 47 Fed. Reg. 26594.

Thus, FDA announced that it would "defer any action on the current GRAS status of salt until the agency can assess the impact of [proposed] regulations . . . and the efforts by manufacturers to reduce voluntarily the salt and sodium content of their products." *Id*. at 26592. FDA further stated that "if no significant progress occurs toward these goals [reducing sodium in processed foods and informing consumers] in a reasonable time the agency will consider additional regulatory actions . . . ." *Id*. at 26593.

Meanwhile, in 1978, CSPI had submitted two petitions to FDA relating to salt. The petitions asked FDA to set tolerances for sodium in processed foods, to reclassify salt from GRAS to food additive status, and to require sodium labeling of processed foods. By letter dated August 18, 1982, FDA denied both petitions. Referring to its proposed sodium labeling rule, FDA "tentatively rejected revision"

of and "deferred action" on salt's GRAS status until it could assess the effect of labeling and other voluntary actions, and "tentatively reject[ed]" CSPI's request that salt be regulated as a food additive with limits on its use in processed food. *Cf. CSPI v. Novitch*, Addendum at 5a.

CSPI then sued FDA, seeking, among other things, (1) a declaration that FDA's decision to defer indefinitely a regulatory decision on the safety of current levels of salt consumption violated the FDCA, 21 U.S.C. §§ 342, 348, & 371, and agency regulations, and constituted unreasonable delay under the APA, 5 U.S.C. § 706(1); and (2) an order compelling FDA to complete its review of salt within a reasonable time, to be set by the court. *CSPI v. Novitch*, at 6a.

Before the litigation was decided, FDA finalized its proposed sodium labeling rule. 49 Fed. Reg. 15510 (1984). Soon thereafter, the district court dismissed CSPI's suit. In rejecting CSPI's claim that FDA's failure to issue a final decision on the GRAS status of salt violated 21 C.F.R. § 170.30(f), the court relied on the fact that "the regulations do not specify a time frame in which the agency must take action on the GRAS status of salt" and on FDA's representation that "it will consider proposing a change in the GRAS status of salt if there is no substantial reduction in the sodium content of processed foods and if information[al] sodium labeling is not adopted after a reasonable period of time." *CSPI v. Novitch*, Addendum at 12a.

The court also noted that "the agency's final rule on voluntary sodium content labeling was promulgated in April 1984, thus indicating that the agency is continuing to work on this issue." For these reasons, the court held that, as of June 1984, the "decision to defer revision in the GRAS status of salt is rational and does not violate 21 C.F.R. § 170.30(f.)." *Id*.

For similar reasons, the district court rejected CSPI's unreasonable delay claim. *Id*. at 13a. The court noted that FDA had received FASEB's salt report in 1979, issued a proposed rule in 1982, and finalized that rule in 1984. Because "[t]he effectiveness of the new rule [would] have a part in determining what action the agency [would] take with regard to the GRAS status of salt," and because FDA was "moving forward with its voluntary programs" and "examining additional scientific and medical data on the effects of sodium consumption," the court held that the delay was not unreasonable at that time. *Id*.

Although the court dismissed the case, it also stated that:

> *FDA must make a decision on the GRAS status of salt after it has completed its review*; i.e., after the voluntary programs have been in effect for a reasonable period of time and FDA has had an opportunity to assess their impact and to review new scientific studies on sodium chloride consumption. Title 21, Code of Federal Regulations, section 170.30(f) clearly indicates that FDA must review those food additives classified as GRAS, including salt, *and* either affirm and GRAS or determine them to be a food additive or subject to a prior sanction.

Id. at 12a (initial emphasis added, later emphasis in original).

In 1987, FDA compared the sodium content of packaged foods sold in 1981—before FDA asked manufacturers voluntarily to reduce the sodium content of processed foods—with the content of the same foods sold in 1986—after FDA sought voluntary action. FDA found that, on the whole, the industry had "not reduced the sodium content of established product lines." FDA, *Sodium Content of the Retail Food Supply: 1986*, Food and Label Package Survey—FLAPS (July 1987). More specifically, "the pre 1981 average was 500 mg [of sodium]/100 g [of product] and the post 1981 average was 499 mg/100 g." *Id*.

In light of the inadequacy of FDA's voluntary nutrition labeling programs for various substances, including sodium, Congress passed the Nutrition Labeling and Education Act ("NLEA") in 1990. The NLEA, passed as an amendment to the FDCA, mandates nutrition labeling on processed foods, for fat, sodium, cholesterol, and other nutrients. 21 U.S.C. § 343(q)(1)(D). FDA's regulations implementing the nutrition labeling requirements of the NLEA became effective in 1994. *See* 21 C.F.R. § 101.9(c)(4). The NLEA does not, however, address the GRAS status of salt. That issue remains before FDA.

More than 17 years after FDA's own survey showed the failure of the voluntary program to reduce the salt content of processed foods, and more than 14 years after Congress required mandatory sodium labeling for almost all FDA-regulated packaged foods, FDA still has not made a decision on the GRAS status of salt. In

the meantime, millions of Americans have died of heart attacks and strokes associated with hypertension, due in part to the high salt content of packaged foods.

REASONS THE WRIT SHOULD ISSUE

The Court should issue a writ of mandamus to stop FDA's unreasonable delay in completing its regulatory review of the GRAS status of salt. In statements dating back at least as far as 1982, FDA has acknowledged the dangers of excess salt consumption. Moreover, through 21 C.F.R. § 170.30(e), FDA has "affirmatively committed itself" to action. *See Cutler v. Hayes*, 818 F.2d 879, 895 & n.138 (D.C. Cir. 1987). Yet since announcing in 1984 its intent to await the outcome of voluntary efforts by manufacturers, FDA has taken no action at all.

Where unreasonable delays in agency action adversely affect the interests served by government regulation, the Court will compel the agency to act. *See In re American Rivers & Idaho Rivers United*, 372 F.3d 413, 420 (D.C. Cir. 2004); *Cutler v. Hayes*, 818 F.2d at 894-99; *TRAC*, 750 F.2d 70, 76-77, 79 (D.C. Cir. 1984); *Public Citizen Health Research Group v. FDA*, 740 F.2d 21, 32, 33 (D.C. Cir. 1984) ("*PCHRG v. FDA*"); *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1153-54 (D.C. Cir. 1983) ("*PCHRG v. Auchter*"); *see also Public Citizen Health Research Group v. Chao*, 314 F.3d 143 (3d Cir. 2002).

These cases are based on the unambiguous language of the Administrative Procedure Act, 5 U.S.C. §§ 555(b) & 706(1). As this Court has stated, an unjusti-

fied agency delay is "an outright violation of 5 U.S.C. § 555(b)'s mandate that agencies decide matters in a reasonable time . . . ." *TRAC*, 750 F.2d at 79. Moreover, Congress, in 5 U.S.C. § 706(1), has specifically "instructed statutory review courts to compel agency action that has been unreasonably delayed." *Id*.; *see generally Sierra Club v. Thomas*, 828 F.2d 783, 792-96 (D.C. Cir. 1987).

This Court has identified three guidelines to determine whether an agency has engaged in unreasonable delay.[3] First, a court should "ascertain the length of the time that has elapsed since the agency came under a duty to act and should evaluate any prospect of an early completion." *Cutler v. Hayes*, 818 F.2d at 897; *see also PCHRG v. FDA*, 740 F.2d at 32 ("There must be a 'rule of reason' to govern the time limit to administrative proceedings.") (citation omitted). Although "[t]here is 'no *per se* rule as to how long is too long' to wait for agency action, . . .

[3] These guidelines reflect the considerations stated in *TRAC*:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'" *In re Am. Rivers & Idaho Rivers United*, 372 F.3d at 418 (quoting *TRAC,* 750 F.2d at 80).

a reasonable time for agency action is typically counted in weeks or months, not years." *In re Am. Rivers & Idaho Rivers United*, 372 F.3d at 419 (citation omitted).

Second, "[t]he reasonableness of the delay must be judged 'in the context of the statute' which authorizes the agency's action." *Cutler v. Hayes*, 818 F.2d at 897 (quoting *PCHRG v. Auchter*, 702 F.2d at 1158 n.30; *National Congress of Hispanic American Citizens v. Marshall*, 626 F.2d 882, 888 (D.C. Cir. 1979)). As part of this inquiry, a court "must also examine the extent to which the delay may be undermining the statutory scheme . . . by frustrating the statutory goal . . . ." *Id*. at 897-98. Here, where the "agency is charged with the administration of a statutory scheme whose paramount concern is protection of the public health, the pace of agency decisionmaking must account for this statutory concern." *PCHRG v. FDA*, 740 F.2d at 34.

Third, "and perhaps most critically, the court must examine the consequences of the agency's delay." *Cutler v. Hayes*, 818 F.2d at 898. "The deference traditionally accorded an agency to develop its own schedule is sharply reduced when injury likely will result from avoidable delay." *Id*. Accordingly, "[d]elays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake." *Id*. (quoting *PCHRG v. Auchter*, 702 F.2d at 1157).

Here, application of these guidelines demonstrates that FDA's failure to proceed with GRAS consideration constitutes unreasonable agency delay.

1. Length of the delay. In the 1970s, FDA began its GRAS review of salt by commissioning an evaluation of its safety. That evaluation was completed in 1979. In 1982, FDA issued two Federal Register notices discussing the dangers of excess salt consumption. In 1984, FDA issued a final rule announcing sodium labeling of some salt-containing foods and a voluntary program for manufacturers to reduce salt in their products. At that time, FDA stated that it would review the effect of the labeling and voluntary program before completing its review of the GRAS status of salt. Through the 1990s, FDA reiterated its concern about the connection between salt and hypertension, and in 1993, FDA formalized its knowledge in a regulation that expressly links salt consumption with hypertension. 21 C.F.R. § 101.74(a)(2). Yet FDA has taken no action to finalize its review of salt's GRAS status.

Measuring FDA's response from 1984, when FDA announced the voluntary program for manufacturers to reduce salt content in food and stated its intent to study the outcome of the program, FDA's delay exceeds 20 years—a whole generation. Even starting the clock in 1994, when sodium labeling became mandatory for all processed foods, the delay exceeds 10 years. Accordingly, the "prospect of an early completion" is nonexistent. Far too many years have passed without ac-

tion. *See PCHRG v. Brock*, 823 F.2d 626, 628 (D.C. Cir. 1987) ("With lives hanging in the balance, six years is a very long time."); *see also Midwest Gas Users Ass'n v. FCC*, 833 F.2d 341 (D.C. Cir. 1987) (citing *MCI Telecomms. Corp. v. FCC*, 627 F.2d 322, 340 (D.C. Cir. 1980) ("Although the issue of whether delay is unreasonable necessarily turns on the facts of each particular case, the Court has stated generally that a reasonable time for an agency decision should encompass 'months, occasionally a year or two, but not several years or a decade.'").

2. Statutory Context. Assessing the reasonableness of the delay in the context of the statute, FDA again falls short. Although neither the FDCA nor 21 C.F.R. § 170.30 sets forth a time period within which FDA must act, FDA has expressly recognized its duty. 21 C.F.R. § 170.30(f). And as the district court held more than 20 years ago, the "FDA must review those food ingredients classified as GRAS, including salt, *and* either affirm . . . GRAS or determine them to be a food additive or subject to a prior sanction." *CSPI v. Novitch*, Addendum at 10a (emphasis in original); *see also* 47 Fed. Reg. 26591.

Thus, the Court need not determine for itself whether FDA should review and make a determination about the GRAS status of salt. *See Cutler v. Hayes*, 818 F.2d at 895 & n.138; *cf. PCHRG v. FDA*, 740 F.2d at 33 (declining to evaluate scientific evidence before agency to determine whether evidence mandated finding that aspirin products are misbranded). FDA has already made that decision. And

pursuant to this regulatory mandate, FDA began its salt review more than a quarter of a century ago.

In the intervening time, FDA's parent HHS has confirmed the dangers of excess salt consumption in increasingly strong language, as reflected in the various editions of the Dietary Guidelines for Americans:

- **1980**: "The major hazard of excessive sodium is for persons who have high blood pressure. . . . Since most Americans eat more sodium than is need, consider reducing your sodium intake." www.health.gov/dietary guidelines/1980thin.pdf.

- **1985**: "A major hazard of excessive sodium is for persons who have high blood pressure." www.health.gov/dietaryguidelines/1985thin.pdf.

- **1990**: "In the United States, about one in three adults has high blood pressure. If these people restrict their salt and sodium, usually their blood pressure will fall. Some people who do not have high blood pressure may reduce their risk of getting it by eating a diet with less salt and other sources of sodium. At present there is no way to predict who might develop high blood pressure and who will benefit from reducing dietary salt and sodium. However, it is wise for most people to eat less salt and sodium because they need much less than they eat and reduction will benefit those people whose blood pressure rises with salt intake." www.health.gov/dietaryguidelines /1990thin.pdf.

- **1995**: "Many studies in diverse populations have shown that a high sodium intake is associated with higher blood pressure. Most evidence suggests that many people at risk for high blood pressure reduce their chances of developing this condition by consuming less salt or sodium." www. health.gov/dietaryguidelines/dga95/sodium.htm.

- **2000**: "Many people can reduce their chances of developing high blood pressure by consuming less salt." www.health.gov/dietaryguidelines/ dga2000/document/choose.htm#salt.

- **2005**: "Nearly all Americans consume substantially more salt than they need. Decreasing salt intake is advisable to reduce the risk of elevated blood pressure." *2005 Dietary Guidelines* at 39.

- **2005**: "Therefore, any program for reducing the salt consumption of a population should concentrate primarily on reducing the salt used during food processing and on changes in food selection (*e.g.*, more fresh, less-processed items, less sodium-dense foods) and preparation." *Id*.

Yet FDA has neither revised the regulatory status of salt nor affirmed it as GRAS. "When the public health may be at stake, the agency must move expeditiously to consider and resolve the issue before it." *PCHRG v. FDA*, 740 F.2d at 34. *Accord PCHRG v. Brock*, 823 F.2d at 629 ("When lives are at stake, as they assuredly are here, OSHA must press forward with energy and perseverance . . .."). In this instance, FDA has not moved expeditiously. In fact, it is not moving at all.

3. Consequences. The consequences of FDA's delay are clear. Americans' salt consumption remains excessive; the number of Americans with hypertension is astoundingly high; and heart attacks and strokes associated with hypertension continue to mount.

Although CSPI does not suggest that revoking the GRAS status of salt and regulating the salt content of processed foods would lower the blood pressure of every American, health experts agree that reducing salt consumption is one of the most important steps that can be taken to prevent hypertension. *See supra* pp. 4-7. FDA's delay thus translates into tens of thousands of preventable heart attacks and strokes *for each year of delay*.

Thus, FDA's inaction fails all three of this Court's guidelines for assessing unreasonable delay. Now, the Court need only let FDA know that "enough is enough." *PCHRG v. Brock*, 823 F.2d at 627 ("[W]e have seen it happen time and time again, that agency action Congress has ordered for the protection of the public health all too easily becomes hostage to bureaucratic recalcitrance, factional in-fighting, and special interest politics. At some point, we must lean forward from the bench to let an agency know, in no uncertain terms, that enough is enough.")

CSPI therefore asks the Court to declare that FDA has unreasonably delayed completing its GRAS review of salt and to order FDA to complete that review within 180 days. CSPI further requests that the Court require FDA to submit status reports monthly until the completion of its review.

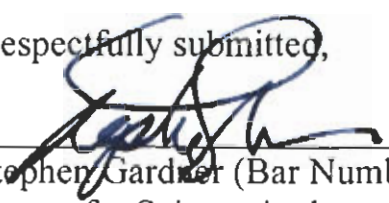
Ample precedent gives the Court the authority to grant the relief requested. *See*, *e.g.*, *In re American Rivers & Idaho Rivers United*, 372 F.3d at 420 (ordering FERC to respond to petition within 45 days); *Environmental Defense Fund v. EPA*, 852 F.2d 1316 (D.C. Cir. 1988) (ordering EPA to issue proposed rules within 33 days and final rule three months later); *Public Citizen v. Heckler*, 602 F. Supp. 611, 614 (D.D.C. 1985) (directing agency to publish a proposed rule reflecting its decision on petition concerning pasteurization of raw milk within 60 days); *see also TRAC*, 750 F.2d at 81 (retaining jurisdiction, ordering agency to inform court of its timetable within 30 days, and requiring progress reports every 60 days thereafter).

RELIEF SOUGHT

Petitioner asks the Court to declare that FDA has unreasonably delayed completing its review of and making a decision about the GRAS status of salt. Petitioner asks that the Court issue a writ of mandamus directing FDA to publish, within 180 days of the Court's order, a notice (1) stating its decision either to affirm or revoke the GRAS status of salt, and (2) if FDA revokes salt's GRAS status, proposing guidelines for adding salt to processed foods, such as limits on amounts per serving and special labeling, and providing an opportunity for the public to comment on the proposal. The Court should also retain jurisdiction to monitor FDA's compliance with the Court's order and should require FDA to file monthly reports with the Court to ensure that FDA abides by the timetable imposed by the Court.

Dated: February 24, 2005

Respectfully submitted,



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Counsel for Petitioner CSPI

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

In re Center for Science in the Public Interest,	)	
	)	No. 05-
Petitioner.	)	

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici. Petitioner is Center for Science in the Public Interest ("CSPI"). CSPI is a nationwide, non-profit organization headquartered in Washington, DC, with approximately 800,000 American members and subscribers. Since its formation in 1971, CSPI has been a strong advocate for nutrition and health, food safety, alcohol policy, and sound science. Its award-winning newsletter, Nutrition Action HealthLetter, is the largest-circulation health newsletter in North America, providing reliable information on nutrition and health. CSPI's twin missions are to conduct innovative research and advocacy programs in health and nutrition, and to provide consumers with current, useful information about their health and well being. Respondent is the Food and Drug Administration. At present, there are no amici or intervenors.

B. Rulings Under Review. Because the instant petition contends that agency action has been unreasonably delayed, no rulings or orders are presented for review.

C. Related Cases. There are no related cases. A similar case was before the district court in 1983-1984, *CSPI v. Novitch*, D.D.C. No. 83-0801 (see Addendum at 5a).

Dated: February 24, 2005

Stephen Gardner
Counsel for Petitioner

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

In re Center for Science in the Public Interest,	)	
	)	No. 05-
Petitioner.	)	

DISCLOSURE STATEMENT

Pursuant to FRAP 26.1, and CR 26.1, petitioner Center for Science in the Public Interest ("CSPI") states that it is a non-profit corporation, it has no parent corporation, and no publicly held corporation has any ownership interest in it. CSPI has approximately 800,000 American members and subscribers. CSPI is a strong advocate for nutrition and health, food safety, alcohol policy, and sound science.

Dated: February 24, 2005

Stephen Gardner
Counsel for Petitioner

CERTIFICATE OF SERVICE

I certify that, on February 24, 2005, I caused a true and correct copy of the foregoing Petition and Memorandum, together with the attached Addendum, to be served on the following by United States Mail:

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Alberto Gonzales
Attorney General
Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Stephen Gardner

UNITED STATES COURT OF APPEALS
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In re Center for Science in the Public Interest,	)	
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Petitioner.	)	

ADDENDUM

Page

Administrative Procedure Act

5 U.S.C. § 555(b)

A person compelled to appear in person before an agency or representative thereof is entitled to be accompanied, represented, and advised by counsel or, if permitted by the agency, by other qualified representative. A party is entitled to appear in person or by or with counsel or other duly qualified representative in an agency proceeding. So far as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function. With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it. This subsection does not grant or deny a person who is not a lawyer the right to appear for or represent others before an agency or in an agency proceeding.

5 U.S.C. § 706(1)

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--(1) compel agency action unlawfully withheld or unreasonably delayed . . ..

All Writs Act

28 U.S.C. § 1651(a)

The Supreme Court and all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law.

Food, Drug, and Cosmetic Act

21 U.S.C. § 321(s)

The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include-- (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or (2) a pesticide chemical; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C.A. § 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C.A. § 601 et seq.]; (5) a new animal drug; or (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

21 U.S.C. § 331(a)

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

21 U.S.C. § 348(a)

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342(a) of this title, unless--

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (j) of this section;

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or
(3) in the case of a food additive as defined in this chapter that is a food contact substance, there is--
(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or
(B) a notification submitted under subsection (h) of this section that is effective.
While such a regulation relating to a food additive, or such a notification under subsection (h)(1) of this section relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i) of this section, a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 342(a)(1) of this title.

21 U.S.C. § 348(d)

The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

21 U.S.C. § 348(g)(1)

In a case of actual controversy as to the validity of any order issued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

Code of Federal Regulations

21 CFR § 170.30(e)

Food ingredients were listed as GRAS in Part 182 of this chapter during 1958-1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to a prior sanction. All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§ 170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in Part 184 or § 186.1 of this chapter.

21 CFR § 170.30(f)

The status of the following food ingredients will be reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction pursuant to § 170.35, § 170.38, or § 180.1 of this chapter . . ..

21 CFR § 170.30(g)

A food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation promulgated under section 409 of the act before it may be directly or indirectly added to food.

US-DIST-CT, FD&C-RPTR ¶38,275 (June 11, 1984)

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, ET AL. v. DR. MARK NOVITCH, ET AL.,

In the United States District Court for the District of Columbia
No. 83-801
Memorandum Opinion filed June 11, 1984.

MEMORANDUM OPINION

GREEN, J.L., District Judge: Plaintiffs, Center for Science in the Public Interest ("CSPI") and its executive director, Michael F. Jacobson, brought this action against the Commissioner of the Food and Drug Administration ("FDA") and the Secretary of the Department of Health and Human Services, challenging FDA's decision not to take particular regulatory and enforcement actions concerning the sodium content and labeling of processed foods, as well as FDA's failure to fulfill its statutory duties relating to the regulation of sodium chloride (salt).

This matter is presently before the Court on defendants' motion to dismiss or for summary judgment, plaintiffs' opposition thereto, plaintiffs' motion for summary judgment, defendants' opposition thereto, the *amicus curiae* memorandum submitted by the American Public Health Association, and the entire record herein. After hearing oral argument on the motions and for the reasons stated below, the Court grants defendants' motion for summary judgment and denies plaintiffs' motion for summary judgment.

FACTUAL BACKGROUND

Sodium Content Labeling

On July 10, 1978, plaintiffs CSPI, a tax-exempt, nonprofit consumer and advocacy organization with an interest in improving national health policies, and its executive director, Michael F. Jacobson, submitted two citizen petitions to the FDA, seeking the issuance of a regulation requiring, in part, the mandatory disclosure of sodium content on the label of processed foods. Exhibits I and II attached to Defendants' Motion to Dismiss or for Summary Judgment ("Defendants' Motion").

By letter dated August 18, 1982, FDA formally notified plaintiffs that their two petitions had been denied. Exhibit V attached to Defendants' Motion. With regard to the petition seeking mandatory sodium content labeling on processed foods, the FDA indicated that "[i]t agrees that consumers would benefit from improved information on food labels regarding sodium content. For a number of reasons, however, the agency does not agree that sodium labeling should be mandatory for all food products." *Id.* at 2. The agency indicated, *inter alia,* that it did not believe that the regulatory burden that would be created by mandatory sodium labeling was justified, thus, was proposing a voluntary approach. *Id.* at 3.

On June 18, 1982, FDA published in the *Federal Register* a proposed rule that would require manufacturers to declare the sodium content on processed foods only when nutrition labeling is required or provided voluntarily. 47 Fed. Reg. 26,580, 26,587 (1982). On November 15, 1982, plaintiffs submitted comments to the FDA concerning the June 18, 1982 notices in the *Federal Register.* Exhibit VI attached to Defendants' Motion.

On April 18, 1984, FDA published the final rule pertaining to food labeling and the declaration of sodium content of foods on food labels. 49 Fed. Reg. 15,510 *et seq.* (1984). This final rule amends the food labeling regulations to specify, *inter alia,* that sodium content of foods must be included in nutrition labeling information whenever nutrition labeling appears on food labels. *Id.* at 15,510.

Safety Review of Sodium Chloride

The Food Additives Amendment of 1958, section 409 of the Federal Food, Drug and Cosmetic Act ("FDC Act" or "Act"), 21 U.S.C. §348, requires all new ingredients used after 1958 to be classified as either "food additives" or "generally recognized as safe" ("GRAS"). 21 U.S.C. §§321(s), 348. Ingredients classified as GRAS are exempt from pre-market clearance procedures. Food ingredients in use prior to 1958, including salt, were deemed "prior sanctioned" for many uses and also exempt from pre-market clearance procedures. *See* 47 Fed. Reg. 26,590, 26,593 (1982).

In 1969, the FDA began a systematic review of all ingredients used in food that were listed in

GRAS, including salt, to determine whether they should be affirmed as GRAS or determined to be a food additive or subject to a prior sanction. *See* 21 C.F.R. §§170.30(e)-(f). The regulations pertaining to the GRAS review program indicate that:

> (e) Food ingredients were listed as GRAS in Part 182 of this chapter during 1958-1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to prior sanction. All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in Part 184 or §186.1 of this chapter.
>
> (f) The status of the following food ingredients [including salt] will be reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction pursuant to §170.35, §170.38, or §180.1 of this chapter[.]

21 C.F.R. §§170.30(e)-(f), 182.1(a) (1983).

To facilitate the GRAS review program, the FDA entered into a contract with the Federation of American Societies of Experimental Biology ("FASEB"). Through its Select Committee on GRAS Substances ("Select Committee"), FASEB evaluates the data relating to the properties of each food ingredient, initially categorized as GRAS, and makes recommendations to the FDA concerning appropriate action to take with respect to each substance under review. 47 Fed. Reg. 26,590, 26,591 (1982).

The FDA then reviews FASEB's evaluation, considers any additional information not available to FASEB, and makes its own determination with regard to the GRAS status of the substance. *Id.*

In July 1979, FASEB submitted to the FDA its final report on salt, entitled "Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients." FASEB stated in pertinent part:

> It is the prevalent judgment of the scientific community that the consumption of sodium chloride in the aggregate should be lowered in the United States. The Select Committee agrees and favors development of guidelines for restricting the amount of salt in processed foods, a major contributor of dietary sodium. Adequate labeling of the sodium content of foods would help meet these objectives.
>
> The evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to the health of a significant proportion of the public when it is used at levels that are now current and in the manner now practiced.

47 Fed. Reg. 26,590, 26,592 (1982).

On June 18, 1982, the FDA published a policy notice in the *Federal Register* announcing its decision "[t]o defer any action on the current GRAS status of salt until the agency can assess the impact of the [proposed] sodium labeling regulations. [1] ... and the efforts by manufacturers to reduce voluntarily the salt and sodium content of their products." *Id.* at 26,592.

On May 2, 1983, [2] plaintiffs filed an amended complaint for declaratory and injunctive relief, seeking an order: (1) declaring that the FDA's denial of a rulemaking petition requesting sodium content labeling for processed food is unlawful because (a) it allows the introduction of misbranded foods into interstate commerce, in violation of the FDC Act, 21 U.S.C. §301 *et seq.* and (b) it is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. §706(2)(A); (2) enjoining the FDA from failing to enforce section 403 of the FDC Act which prevents the introduction of misbranded foods into interstate commerce, 21 U.S.C. §331(a); (3) declaring that the FDA's decision to indefinitely defer any regulatory decision on the safety of current levels of salt consumption violates sections 402, 409, and 701 of the FDC Act, 21 U.S.C. §§342, 348, 371, as well as the agency's own regulations and procedures, and the APA, 5 U.S.C. §706(2)(A), and constitutes an unreasonable delay under the APA, 5 U.S.C. §706(1); and (4) compelling the FDA to follow its procedures by completing its safety review of current levels of salt consumption within a reasonable time set by the Court.

CONCLUSIONS OF LAW

Defendants move to dismiss this action pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim on which relief can be granted. In the alternative, defendants move for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure because defendants contend that there is no genuine issue as to any material fact and they are entitled to judgment as a matter of law.

Plaintiffs also have moved for summary judgment. They contend that (1) defendants have violated the APA and the FDC Act by denying the petition for rulemaking filed by plaintiffs in 1978 seeking mandatory sodium content labeling and (2) defendants have violated the APA and the FDC Act by issuing a final policy notice which postpones indefinitely regulatory action on the safety of current levels of sodium chloride consumption.

A. *Sodium Content Labeling*

1. *Defendants' Motion to Dismiss Count I*

In Count I of the amended complaint, plaintiffs allege that FDA's denial of their rulemaking petition was unlawful because, by refusing to require sodium content labeling on all processed foods, the FDA has allowed the introduction of misbranded foods into interstate commerce, in violation of the FDC Act. *See* 21 U.S.C. §343. Defendants moved to dismiss Count I on the grounds of ripeness because a final rule had not yet been promulgated concerning sodium content labeling. As discussed *supra* p. 3, the FDA published its final rule on this issue on April 18, 1984. Therefore, even assuming *arguendo* that this argument had merit, it is no longer valid. [3]

Defendants also argue that, regardless of the ripeness argument, Count I of the amended complaint must be dismissed under the APA, 5 U.S.C. §701(a)(2). Section 701(a)(2) provides that judicial review of agency action is not permitted if that "agency action is committed to agency discretion by law." *See also* discussion *infra* pp. 10-11. Defendants argue that FDA's decision to refrain from instituting enforcement actions involving the misbranding provisions of the FDC Act is committed to the FDA's discretion and therefore, is not reviewable by the Court.

The agency decision at issue in this case, however, is a denial of a rulemaking petition, rather than a decision to refrain from instituting enforcement actions. Plaintiffs are asking the Court to require the FDA to promulgate a mandatory sodium content labeling rule deeming foods without sodium content information to be misbranded. *See* Plaintiffs' Memorandum of Points and Authorities in Opposition to Defendants' Motion to Dismiss at 8-9. Therefore, defendants' arguments with regard to enforcement actions are inapposite to the instant case and the Court must deny defendants' motion to dismiss Count I.

2. *Scope of Judicial Review*

The threshold issue before the Court is whether it has the authority to review FDA's denial of plaintiffs' rulemaking petition seeking mandatory sodium content labeling. At the outset, the Court notes that FDA's denial of plaintiffs' petitions constitutes final agency action. FDA made it clear in its letter denying plaintiffs' petition that "the agency does not agree that sodium labeling should be mandatory for all food products." Exhibit V attached to Defendants' Motion. Moreover, in the FDA's policy notice concerning deferral of the determination of salt's GRAS status, the FDA stated that it had "considered and *rejected* mandatory sodium content labeling." 47 Fed. Reg. 26,594 (1982) (emphasis added).

Section 10 of the APA provides that all final agency action is subject to judicial review unless precluded by statute or committed to agency discretion by law. 5 U.S.C. §701(a)(1) & (2). "This section establishes a 'strong presumption' of reviewability, and the exceptions of 5 U.S.C. §701(a)(1) & (2) should therefore, be construed narrowly." *Chaney. v. Heckler,* 718 F.2d 1174, 1183 (D.C. Cir. 1983) (case citations omitted). `[A]gency action' includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or *denial thereof,* or failure to act[.]" 5 U.S.C. §551(13) (emphasis added). The APA gives courts the power to "compel agency action unlawfully withheld or unreasonably delayed[,]" *id.* at §706(1), as well as the power to "hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law...." *Id.* at §706(2)(A).

In *WWHT, Inc. v. FCC,* 656 F.2d 807 (D.C. Cir. 1981), the United States Court of Appeals for the District of Columbia Circuit addressed the is-

sue of whether and under what circumstances a reviewing court may require an agency to institute rulemaking proceedings after the agency has denied a petition for rulemaking. *Id.* at 809. The court held that:

> [E]xcept where there is evidence of a "clear and convincing legislative intent to negate review," *Natural Resources Defense Council v. S.E.C.,* 606 F.2d 1031, 1043 (D.C. Cir. 1979), an agency's denial of a rulemaking petition is subject to judicial review. However, we believe that the decision to institute rulemaking is one that is largely committed to the discretion of the agency, and that the scope of review of such a determination must, of necessity, be very narrow.

Id. Therefore, the Court must first determine if a "clear showing" has been made "that judicial review would be inappropriate." *Natural Resources Defense Council v. SEC,* 606 F.2d at 1043.

Defendants argue that the denial of plaintiffs' petition is not reviewable pursuant to the second exception enunciated in section 10, *i.e.,* that this action is committed to agency discretion by law. In *WWHT, Inc. v. FCC,* however, the court indicated that:

> [W]here the proposed rule pertains to a matter of policy within the agency's expertise and discretion, the scope of review should "perforce be a narrow one, limited to ensuring that the [agency] has adequately explained the facts and policy concerns it relied on and to satisfy ourselves that those facts have some basis in the record." [*Natural Resources Defense Council v. SEC,*] 606 F.2d at 1053.

WWHT, Inc. v. FCC, 656 F.2d at 817. Therefore, the Court finds that defendants' denial of plaintiffs' petition is reviewable, although the scope of that review must be narrow.

With regard to the "record" on review, *see id.* at 817-18, the Court notes that it is faced with a somewhat unique situation in the instant case. Although the FDA informed plaintiffs that their petition seeking mandatory sodium content labeling on processed foods was denied, the agency has promulgated a final rule amending the food labeling regulations to:

> (1) Establish definitions for the terms "sodium free," "very low sodium," "low sodium," and "reduced sodium," (2) provide for the proper use of these terms in the labeling of foods, (3) provide for the inclusion of potassium content information in the nutrition labeling format on a voluntary basis, (4) provide for the appropriate use of such terms as "without added salt," "unsalted," and "no salt added," and (5) *specify that sodium content of foods be included in nutrition labeling information whenever nutrition labeling appears on food labels.*

49 Fed. Reg. 15,510 (1984) (emphasis added). This final rule provides for voluntary sodium labeling rather than mandatory labeling, as sought by plaintiffs. Not only has FDA promulgated a food labeling rule, but it also has provided its rationale for promulgating a voluntary rather than mandatory rule. As a result, the record in this case is more extensive than in a case where the agency simply denied the rulemaking petition and never promulgated any related rules.

To determine whether FDA's discretionary decision not to promulgate the rule sought by plaintiffs was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[,]" 5 U.S.C. §706(2)(A), the Court must conduct:

> a review that is `searching and careful,'" *Citizens to Preserve Overton Park [v. Volpe,* 401 U.S. 402, 416 (1971)], yet in the last analysis, diffident and differential." *NRDC,* 606 F.2d at 1049 (footnote omitted). The agency's decision that the public interest does not require the promulgation of specific rules for the time being must be sustained "if it violates no law, is blessed with an articulated justification that makes a 'rational connection between the facts found and the choice made,' and follows upon a 'hard look' by the agency at the relevant issues." *Action for Children's Television v. FCC,* 564 F.2d 458, 479 (D.C. Cir. 1977) (footnote omitted). The agency's determination is essentially a legislative one, and the reviewing court should do no more than assure itself that the agency acted "in a manner calculated to negate the dangers of arbitrariness and irrationality...." *Id.* at 472, n. 24.

WWHT, Inc. v. FCC, 656 F.2d at 817.

"The [C]ourt is not empowered to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park v Volpe,* 401 U.S. 402, 416 (1971). "The 'arbitrary and capricious' standard requires that agency action be affirmed if a ra-

tional basis exists therefor; it is not for [the Court] to inquire into whether the decision is wise as a matter of policy, for that is left to the discretion and developed expertise of the agency." *Sierra Club v. EPA,* 540 F.2d 1114, 1123 (D.C. Cir 1976), *cert. denied,* 430 U.S. 959 (1977) (footnotes omitted). An agency has presented "a rational basis for its decision ... if it 'demonstrably has given reasoned consideration to the issues, and has reached a result which rationally flows from its conclusions.'" *Id.* at 1124 (footnotes omitted) (citing *National Association of Food Chains, Inc. v. Interstate Commerce Commission,* 535 F.2d 1308, 1314 (D.C. Cir. 1976)). "If the reasoning behind the agency's action is logical ... that action must be allowed to stand." *Federal Property Management Corp. v. Harris,* 603 F.2d 1226, 1231 (6th Cir. 1979).

Finally, the court notes that because the agency action in this case involves sodium chloride, an ingredient that has been linked to hypertension and other health problems, *see* 47 Fed. Reg. 26,580, 26,581 (1982), the Court must "ensure that the [agency] has made a reasoned decision, which conforms to the legislative language and purpose." *Wellford v. Ruckelshaus,* 439 F.2d 598, 601 (D.C. Cir. 1971) (footnote omitted). "[C]lose scrutiny of administrative action is particularly appropriate when the interests at stake are not merely economic interests in a license or a rate structure, but personal interests in life and health." *Id.* (footnote omitted).

3. *Was FDA's Decision Rational?*

In the instant case, the FDA decided that *mandatory* labeling was not required at the present time. Rather, the agency decided to initiate a voluntary labeling program and promulgated rules to that effect. The Court must determine whether the FDA has provided a rational basis for its decision to deny plaintiffs' citizen petition and whether it has given reasoned consideration to all of the issues.

In promulgating the final rule on voluntary sodium content labeling, the FDA indicated that:

> [It] is confident that food manufacturers will continue and expand efforts voluntarily to increase sodium content labeling. Comments on the proposal have included additional commitments from food manufacturers to provide sodium labeling information. In addition, FDA data show that the number of food commodities bearing sodium content information is increasing and this increase is not just from foods that are low or very low in sodium content.... FDA believes that a reduction in the sodium content of the overall food supply will be much more likely in an atmosphere that encourages the food industry to market a greater variety of foods that are lower in sodium.

Id. (citation omitted). Moreover, the FDA has established a "comprehensive monitoring program" to measure the progress being made in supplying consumers with sodium content information on food labels. FDA also indicated that "[i]n the event that the agency's current program does not achieve the desired effects, additional measures will be considered." *Id.*

This final rule comports with FDA's rationale in denying plaintiffs' citizen petition. The agency denied the petition because it believed that the regulatory burden created by mandatory sodium content labeling was not justified. Exhibit V at 3 attached to Defendants' Motion. In its denial letter, the FDA stated that it believed that the food "industry should have the opportunity to provide additional sodium labeling voluntarily before [3the agency] consider[s] any further labeling requirements." *Id.*

Plaintiffs contend, however, that the FDA has a specific obligation to require quantitative sodium labeling on all processed foods and cite the provisions of the FDC Act prohibiting the misbranding of food products, 21 U.S.C. §343. The FDC Act describes misbranded articles as follows:

> If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

21 U.S.C. §321(n). According to plaintiffs, food labels lacking sodium content information are misbranded because they fail to reveal material

consequences which may result from the customary and usual use of the product.

FDA argues, however, that:

> The decision as to what labeling information is necessary to avoid a food's being deemed misbranded turns both on the scientific data demonstrating the gravity of the public health issue, and the Commissioner's policy judgment about what approach will advance the agency's goals and effect the efficient enforcement of the act.

49 Fed. Reg. 15,510, 15,511 (1984). Although the FDA reiterates that excess sodium consumption aggravates hypertension in susceptible individuals, it "continues to believe that the agency should focus its regulatory efforts on providing information to consumers so that they can structure their diets to meet individual health needs, and on working with manufacturers to reduce the amount of sodium in processed foods." *Id.*

The FDA had to consider not only those individuals susceptible to hypertension, but also "the traditional role of salt in our food supply, and the practical problems of attempting to limit the amount of sodium that would be permitted to be used in food." *Id.* As a result of these policy considerations, FDA determined that a voluntary labeling program was the best alternative at the present time. The agency also indicated, however, that additional measures would be considered if its current program were not successful. *Id.* at 15,510.

Although plaintiffs argue that defendants should be compelled to institute rulemaking proceedings leading to the promulgation of rules requiring mandatory labeling, the Court notes that "[a]dministrative rule making does not ordinarily comprehend any rights in private parties to compel an agency to institute [rulemaking] proceedings or to promulgate rules." *Rhode Island Television Corp. v. FCC,* 320 F.2d 762, 766 (D.C. Cir. 1963). Moreover, "[i]t is only in the rarest and most compelling of circumstances that [the United State Court of Appeals for the District of Columbia Circuit] has acted to overturn an agency judgment not to institute rulemaking." *WWHT, Inc. v. FCC,* 656 F.2d at 818.

Under the circumstances of the instant case, the Court declines to overturn FDA's decision not to institute rulemaking with respect to mandatory labeling or to find that food labels lacking sodium content information are misbranded. The record indicates that the agency carefully considered plaintiffs' petition and made a rational decision that a voluntary labeling program was the most appropriate course of action at the present time. The FDA not only provided justifications for its decision not to promulgate a mandatory sodium content labeling program but also indicated that it would take stronger action if the voluntary approach did not achieve its purpose. The FDA should be given the opportunity to test these methods to determine if food manufacturers will provide sodium content labeling and lower the amount of sodium in processed foods voluntarily. *Cf. Action for Children's Television v. FCC,* 564 F.2d 458, 480 (D.C. Cir. 1977) (court found "no compelling reason why the [FCC] should not be allowed to give the [television] industry's self-regulatory efforts a reasonable period of time to demonstrate that they will be successful in rectifying the inadequacies of children's television"). Therefore, the Court finds that FDA's decision to deny plaintiffs' citizens petition and not to institute rulemaking with respect to mandatory sodium content labeling was not arbitrary, capricious, or an abuse of agency discretion under the APA, 5 U.S.C. §706(2)(A).

B. *Safety Review of Sodium Chloride*

Plaintiffs also contend that defendants have violated the APA and the FDC Act by issuing a final policy notice relating to the GRAS review of sodium chloride which postpones indefinitely regulatory action on the safety of current levels of sodium chloride consumption. According to plaintiffs, FDA's decision to defer any action on the current GRAS status of salt violates (1) the agency's own procedures set forth at 21 C.F.R. §170.30(f); (2) section 409 of the FDC Act, 21 U.S.C. §348; and (3) section 402 of the FDC Act, 21 U.S.C. §342. As a result, plaintiffs contend that this decision is arbitrary and capricious under the APA, 5 U.S.C. §706(2)(A). Plaintiffs also contend that FDA's deferral of action on the GRAS status of salt constitutes unreasonable delay, and thereby violates section 706(1) of the APA, 5 U.S.C. §706(1).

In opposition, defendants assert that FDA's decision to defer revision of the regulatory status of sodium chloride is consistent with the agency's regulations and with the requirements of the APA. The FDA contends that the decision not to change the regulatory status of salt was within its discretion and adequately explained in the *Federal Register* notice.

1. *Scope of Judicial Review*

At the outset, the Court must determine the proper scope of its review of FDA's Notice on the GRAS Safety Review of Sodium Chloride wherein FDA announced its decision to defer any revision in the regulatory status of salt. 47 Fed. Reg. 26,590 (1982). In this notice, FDA indicated that it was "not *now* proposing any change in the regulatory status of salt...." *Id.* (emphasis added). According to defendants, the scope of review must be narrow because "the agency has announced a regulatory decision but has deferred final decision until it has evaluated the results of its overall regulatory program." Defendants' Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment and in Support of Their Motion for Summary Judgment at 22.

The Court agrees that the scope of review must be narrow. Although FDA's decision is not final agency action, the deferral of this decision is in effect a denial of final agency action. *See* 5 U.S.C. §551(13); 21 C.F.R. §170.30(f). The Court must determine not only whether the deferral of a final decision on the GRAS status of salt has been "unreasonably delayed," 5 U.S.C. §706(1), but also whether the deferral was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. §706(2)(A). *See* discussion *supra* pp. 13-15.

2. *Does FDA's Decision Violate 21 C.F.R. §170.30(f) and 5 U.S.C. §706(1)?*

Plaintiffs argue that the FDA has violated GRAS review procedures by failing either to affirm salt as GRAS or to determine it to be a food additive or to find that it is subject to a prior sanction. *See* 21 C.F.R. §170.30(f) (1983). Rather than to take one of these three positions, the FDA decided "to defer any revision in the regulatory status of salt." 47 Fed. Reg. 26,590 (1982). The agency indicated that "[it] is not now proposing any change in the regulatory status of salt ... because the agency believes that the proposed sodium labeling regulations ... will respond to those concerns." *Id.*

After it received FASEB's recommendations pertaining to sodium chloride, the FDA considered the following five regulatory options "in determining a rational response to the current concern about salt intake[:]"

> 1. To propose to revoke the GRAS status of salt, declare it to be a food additive, and propose a food additive regulation that prescribes the permitted uses and use levels of salt in manufactured food.
>
> 2. To propose to revoke the GRAS status of salt, declare it to be a food additive, and propose an interim food additive regulation that prescribes the permitted uses and use levels of salt in manufactured foods to current uses and levels pending the completion of additional safety studies.
>
> 3. To defer action on the GRAS status of salt, but to propose a regulation requiring the labels of all manufactured food containing added salt to declare quantitatively the total sodium content of the food.
>
> 4. To propose to affirm salt as GRAS with specific limitations, and to define those limitations as informative labeling that would adequately alert the public to the health risks associated with a high level of sodium intake.
>
> 5. To defer any action on the current GRAS status of salt until the agency can assess the impact of the sodium labeling regulations proposed elsewhere in this issue of the *Federal Register* and the efforts by manufacturers to reduce voluntarily the salt and sodium content of their products.

Id. at 26,592.

FDA tentatively selected option five. After examining the scientific data and recognizing, *inter alia,* that salt "is used directly by consumers as well as added by food processors[,]" the FDA decided to see a reduction of salt through voluntary means, including sodium content labeling. *Id.* at 26,592-93. FDA indicated its agreement with FASEB that "a reduction of sodium chloride consumption by the population will reduce the frequency of hypertension" in susceptible individuals and decided that the best way to address the concerns about sodium consumption and hypertension would be to provide the public with information on the sodium content of foods. *Id.* at 26,593. Accordingly, FDA promulgated a final rule providing for voluntary sodium content labeling. FDA believed that providing information on the sodium content of foods rather than restricting sodium usage was the appropriate approach. Thus, the FDA deferred

deferred action on the GRAS status of sodium chloride. The agency emphasized, however, that "if there is no substantial reduction in the sodium content of processed foods and if information sodium labeling is not adopted after a reasonable time period, FDA will consider additional regulatory actions, including proposing a change in salt's GRAS status. *Id.*

Plaintiffs contend that this decision to defer an agency decision on the regulatory status of salt not only does not comport with FDA's own regulations which, according to plaintiff's, require that determinations of GRAS status be made as soon as the FASEB report is received and reviewed by FDA, but also constitutes unreasonable delay under 5 U.S.C. §706(1). In suport of these contentions, plaintiffs cite an FDA "Notice of Opportunity to Present Data Information and Views" which describes the GRAS review program and states in pertinent part:

> After evaluating this [FASEB] report, the Commissioner will publish in the *Federal Register,* an appropriate proposal to (1) affirm GRAS status, (2) publish a prior sanction, (3) establish an interim food additive regulation, (4) establish a permanent food additive regulation, or (5) eliminate food use of the ingredient.

38 Fed. Reg. 20,053 (1973).

The Court notes, however, that the preamble does not indicate a specific time frame in which the commissioner must act. It merely states that the commissioner "will publish" an appropriate proposal in the *Federal Register* after evaluating the FASEB report. Title 21, Code of Federal Regulations, section 170.30(f) also states only that "[t]he status of... food ingredients will be reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction...." 21 C.F.R. §170.30(f).

In the instant case, the FDA has decided to defer any revision in the regulatory status of salt "because the agency believes that the proposed sodium labeling regulations [which are now final] ... will respond to [the considerable health] concerns [about the use of salt in the food supply]. FDA is also announcing its policy of encouraging food manufacturers to reduce voluntarily the amount of added salt and other sodium-containing substances in processed foods." 47 Fed. Reg. 26,590 (1982).

Because the regulations do not specify a time frame in which the agency must take action on the GRAS status of salt; the agency has indicated that it will consider proposing a change in the GRAS status of salt if there is no substantial reduction in the sodium content of processed foods and if information sodium labeling is not adopted after a reasonable period of time; and the agency's final rule on voluntary sodium content labeling was promulgated in April 1984, thus indicating that the agency is continuing to work on this issue, the Court finds that the agency's decision to defer revision in the GRAS status of salt is rational and does not violate 21 C.F.R. §170.30(f.).

The Court notes, however, that FDA must make a decision on the GRAS status of salt after it has completed its review, *i.e.,* after the voluntary programs have been in effect for a reasonable period of time and FDA has had an opportunity to assess their impact and to review new scientific studies on sodium chloride consumption. Title 21, Code of Federal Regulations, section 170.30(f) clearly indicates that FDA must review those food ingredients classified as GRAS, including salt, *and* either affirm and GRAS or determine them to be a food additive or subject to a prior sanction. 21 C.F.R. §170.30(f) (1983). *See also* 47 Fed. Reg. 26,590, 26,591 (1982).

Plaintiffs also contend that FDA's decision to defer making any revision in the regulatory classification of salt constitutes unreasonable delay under 5 U.S.C. §706(1). Claims of unreasonable delay under section 706(1) of the APA are sustainable only in extreme circumstances. *See, e.g., Public Citizen Health Research Group v. Auchter,* 702 F.2d 1150, 1157 (D.C. Cir. 1983) ("significant risk of grave danger" to workers and their offspring posed by ethylene oxide ("EtO"), a chemical found to be mutagenic and carcinogenic in humans, necessitates expedited rulemaking; Assistant Secretary's refusal to assign any priority status to EtO rulemaking constitutes unreasonable delay); *Nader v. FCC,* 520 F.2d 182, 206 (D.C. Cir. 1975) ("Although the issues are complicated, we can find no justification for a delay of ten years."); *Chromcraft Corp. v. EEOC,* 465 F.2d 745, 748 (5th Cir. 1972) (absent any suggestion that delay in investigating charges of discrimination has resulted from "slothfulness, lethargy, inertia or caprice" or from "a dilatory attitude," delay is not unreasonable); *Public Citizen v. Goyan,* 496 F.Supp. 364, 365 (D.D.C. 1980) (no showing of "intentional or otherwise unreasonable delay that in rare circumstances would cause a court to inter-

fere during ongoing administrative proceedings." (footnote and case citations omitted)); *Las Vegas Hawaiian Development Co. v. SEC,* 466 F.Supp. 928, 933 (D. Hawaii 1979) (mere fact of delay not sufficient; unreasonable delay must be shown).

In the instant case, the delay has been reasonable and has not resulted from FDA's inertia or dilatory attitude. FASEB issued its final report to the FDA on sodium chloride in July 1979. On June 18, 1982, the FDA published not only its notice to defer revision in the GRAS status of salt but also a proposed rule pertaining to voluntary food labeling. 47 Fed. Reg. 26,590 (1982); 47 Fed. Reg. 26,580 (1982). A final rule was promulgated on April 18, 1984. 49 Fed. Reg. 15,510 (1984). Although FDA has decided to defer any action on the GRAS status of salt, it has promulgated a final rule on voluntary sodium content labeling. The effectiveness of this rule will have a part in determining what action the agency will take with regard to the GRAS status of salt. Because the agency is moving forward with its voluntary programs on sodium content labeling and reducing sodium in processed foods, and is examining additional scientific and medical data on the effects of sodium consumption, the Court cannot find that the decision on the GRAS status of salt has been "unreasonably delayed," pursuant to 5 U.S.C. §706(1). The Court also does not believe that it would be appropriate or feasible to impose a specific timetable for further action in this case at the present time. *See McIlwain v. Hayes,* 690 F.2d 1041, 1049-50 (D.C. Cir. 1982).

3. *Does FDA's Decision Violate 21 U.S.C. §348?*

Plaintiffs also argue that the decision to defer action on the GRAS status of salt violates section 409 of the FDC Act, 21 U.S.C. §348, which pertains to the regulation of food additives. The term "food additive" does not include "any substance used in accordance with a sanction or approval granted prior to September 6, 1958...." 21 U.S.C. §321(s)(4). Salt is included in this group of substances that was determined to be GRAS prior to 1958. Not only is salt still considered GRAS but it also is subject to prior sanctions for many uses. *See* discussion *supra* p. 4; 21 C.F.R. §182.1. As a result, salt cannot be considered a food additive. According to plaintiffs, however, "[i]n its policy notice deferring its safety review, FDA has in effect conceded that current levels of consumption [of sodium] as commonly used in processed foods are no longer generally recognized as safe." Plaintiffs' Memorandum in Support of their Motion for Summary Judgment and in Opposition to Defendants' Motion for Summary Judgment at 42 (footnote omitted)("Plaintiffs' Memorandum"). Plaintiffs' argument is without merit. The FDA has deferred any revision of the GRAS status of salt; it has not changed that status. Therefore, the Court cannot find that FDA's decision to defer the GRAS review of salt violates section 409 of the FDC Act, 21 U.S.C. §348.

4. *Does FDA's Decision Violate 21 U.S.C. §342?*

Finally, plaintiffs argue that the decision to defer action on the GRAS status of salt violates section 402 of the FDC Act, 21 U.S.C. §342. Section 342 states in pertinent part:

> A food shall be deemed to be adulterated --
>
> (a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health....

21 U.S.C. §342.

The FASEB panel found that there was insufficient evidence to determine that the current levels of sodium chloride consumption were not deleterious. 47 Fed. Reg. 26,590, 26,592 (1982). As the FDA indicated in its GRAS Policy Notice:

> To establish that the use of salt renders a manufactured food adulterated, FDA would have the burden of showing that salt in food is a "poisonous or deleterious substance." The current uncertainty about the precise role of salt as a basic causative factor in essential hypertension, however, leaves unclear whether the use of salt in a particular food would render that food uniformly injurious to health.

Id. at 26,594.

Plaintiffs argue that FDA should declare adulterated only certain processed foods that contain deleterious amounts of sodium chloride. Plaintiff's Memorandum at 46 n. 32. Any decision on whether specific processed foods contain deleterious amounts of sodium chloride cannot be made, however, until the agency completes its review of the GRAS status of salt. The Court also notes that the cases cited by plaintiffs in support of their argument involve inapposite factual situations. In *United States v. Anderson Seafoods, Inc.,* 622 F.2d 157 (5th Cir. 1980), the court was faced with the problem of mercury, a known toxin, in swordfish.

The court found that all of the mercury could be treated as an "added substance" and regulated under section 342(a)(1) of the FDC Act, 21 U.S.C. §342(a)(1). Similarly, in *Continental Seafoods, Inc. v. Schweiker,* 674 F.2d 38, 39-41 (D.C. Cir. 1982), the court upheld FDA's decision to ban from import Indian shrimp that appeared to be adulterated. Tests conducted on a portion of the shrimp indicated that it was contaminated with poisonous salmonella bacteria.

In the instant case, however, FDA is not faced with a known toxin or poisonous substance. Although FDA recognizes that many individuals must limit their intake of salt, sodium chloride is an essential constituent of the body and is present naturally in many foods. 47 Fed. Reg. 26,580, 26,581 (1982). Moreover, FDA is responding to the problem of excess salt in processed foods by promulgating a voluntary sodium content labeling rule and by urging manufacturers to reduce the sodium content in processed foods. Given the current GRAS status of salt, the continuing efforts of FDA to lower the sodium content in processed foods, as well as the promulgation of the voluntary sodium content labeling rule, the Court cannot find that FDA's decision to defer revision of the GRAS status of salt violates section 402 of the FDC Act, 21 U.S.C. §342.

CONCLUSION

In accordance with the above, the Court finds that neither FDA's denial of plaintiffs' citizen petition seeking mandatory sodium content labeling on processed foods nor FDA's deferral of any action on the current GRAS status of salt was arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. Moreover, the Court finds that FDA's deferral of any action on the current GRAS status of salt does not constitute agency action that has been unreasonably delayed. Therefore, the Court grants defendants' motion for summary judgment and denies plaintiffs' motion for summary judgment. An appropriate order is attached.

ORDER

Upon consideration of defendants' motion to dismiss or for summary judgment, plaintiffs' opposition thereto, plaintiffs' motion for summary judgment, defendant's opposition thereto, the *amicus curiae* memorandum submitted by the American Public Health Association, the oral argument of the parties, and the entire record herein, and for the reasons stated in the accompanying memorandum opinion, it is by the Court this 11th day of June,

Ordered that defendants' motion for summary judgment be and hereby is granted; it is further

Ordered that plaintiffs' motion for summary judgment be and hereby is denied; and it is further

Ordered that this action be and hereby is dismissed. [1] [2] [3]

[1] As discussed *supra* p. 3, final sodium labeling regulations were published in the *Federal Register* on April 18, 1984. *See* 49 Fed. Reg. 15,510 *et seq.* (1984).

[2] Plaintiffs' original complaint was filed on March 22, 1983.

[3] The Court also rejects defendants' argument that "[e]ven if FDA issues a final rule during the pendency of this action, it would be unsuitable for this court to review the reasonableness of the rulemaking proceeding because the complete administrative record is not properly before this court." Defendants' Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment and in Support of their Motion for Summary Judgment at 4 n. 3. In this instance, the Court is reviewing the specific denial of plaintiffs' rulemaking petition seeking mandatory sodium content labeling.