

Originally Processed With FOIA(s):
2023-1278-S

FOIA Number:
2023-1267-S

CASE MARKER

**This is not a textual record. This is used as an
administrative marker by the George Bush Presidential
Library Staff.**

Record Group/Collection: George H.W. Bush Presidential Records
Collection/Office of Origin: Chief of Staff, White House Office of
Series: Zoellick, Robert B., Files
Subseries:

OA/ID Number: 45577
Folder ID Number: 45577-002

Folder Title:
Food Labeling RBZoellick [2]

Stack:

Row:

Section:

Shelf:

Position:

G

FOOD LABELING REGULATIONS

This presents for your decision three issues concerning food labeling regulations that must soon be issued by the Secretary of Health and Human Services and the Secretary of Agriculture. The Secretaries and interested agencies have striven over many months to reach agreement on the issues raised by these complex and important rules. All of these issues have now been resolved except for three: (1) the most appropriate definition of the term "light;" (2) the scope of regulation of restaurant foods; and (3) the format of the nutrition label for food products. The Secretaries have not been able to agree on these issues. The issues are therefore presented for your decision.

Background.

The Nutrition Labeling and Education Act (NLEA) requires the Secretary of Health and Human Services (HHS) to issue regulations governing labeling of food products. The NLEA provides that the regulations must require food products to carry a nutrition information panel on the label. The regulations are also required to define the types of comparative nutrition claims that can be made on the label (such as "light," "low" or "reduced").

The NLEA only applies to foods regulated by the Food and Drug Administration (FDA). Products containing more than a de minimis (two percent) meat content are regulated by the Department of Agriculture (USDA). Secretary Madigan has proposed a labeling regimen for meat food products that parallels the HHS proposal for other food products. (The food processing industry and consumer groups prefer a common rule for both types of products.)

The food labeling rules as a whole encompass 29 distinct HHS rules and one parallel USDA rule. The HHS rules alone will consume over 1,000 pages in the Federal Register. The regulations are expected to have a major impact on nutrition and health, as well as impose significant costs in the food production, food marketing and restaurant industries.

The NLEA contains a "hammer provision" that required the proposed rule (issued by HHS one year ago) to become the final rule automatically if the final regulations were not issued by November 8, 1992. The hammer fell when the final rule was not issued by that date. The proposed rule now given final effect by the hammer provision is not supported by either HHS or USDA

or any other agency. When the three issues presented here are resolved, the final regulations will be published and supersede the proposed rule. However, it will be necessary to have a short public comment period before the final regulations are published. Expedition is warranted since there is a strong public interest in issuing these important rules as soon as possible. (The regulations will have a delayed effective date to allow for planning and implementation.)

Issues For Decision

Issue One: Use of Term "Light"

The NLEA requires the issuance of rules that provide definitions for a variety of comparative claims such as "less," "low" and "light." The NLEA prohibits use of these terms unless the food product to which they refer meets the definitions. Both USDA and HHS agree that the definition of "light" should refer to a minimum reduction of two key elements: fat and/or calories. The following issues remain concerning the definition of "light".

Sodium. USDA proposes that the term "light" also may be used when the product contains 50 percent less sodium. HHS maintains that only reduced fat and calories, and not reduced sodium, should qualify a product as "light." HHS argues that the term "light" is such an important signal to consumers that it should apply to only the most important elements of a food. HHS believes that the value of the term "light" would be diluted by allowing it to refer to a reduction only in sodium, an element HHS believes is less important than fat or calories. HHS also points out that there are other terms available to describe lower salt products, such as "low sodium" or "lightly salted."

USDA argues that, in view of the importance of sodium consumption to many consumers, usage of the term "light" in connection with sodium should be permitted. USDA also urges that use of "less" and "lower" to describe salt content would not be as valuable as a descriptive term as the term "light." To meet HHS' concerns about retaining the value of the term "light," USDA proposes that when a product has only reduced sodium it must be identified as "light in sodium," although USDA also proposes that "light" may in such cases also be in the name, such as "light bologna." USDA also proposes that the words "in sodium" be of equal size, to avoid disproportionate emphasis on the term "light."

Decision:

_____ HHS position: "light" refers only to fat or calories.

_____ USDA position: "light" refers to fat or calories, or sodium if labeled "light in sodium."

_____ Other: _____

Fat and/or Calorie Reduction. USDA would define "light" as one-third less in calories or 50 percent less in fat. HHS would define "light" the same way, except that, for a food that has more than 50 percent of calories from fat, only a 50 percent reduction in fat (not one-third less calories) would qualify as "light." HHS argues that products should not be labeled "light," even if the calorie count has been reduced one-third, where fat content remains the dominant source for the remaining calories. HHS points out that descriptive terms are available in this situation other than "light," such as "reduced calories." USDA believes that consumers are provided useful information by use of the term "light" where calories have been reduced by one-third, even if fat remains the dominant source of calories (which will be the case for many meat and poultry products). USDA is concerned that the HHS definition will serve as a disincentive for producers to develop meat and poultry products that reduce calories by one-third even though the fat in those products cannot be reduced by 50 percent.

Decision:

_____ HHS position: one-third less calories or 50 percent less fat; 50 percent less fat required where more than 50 percent of calories are from fat.

_____ USDA position: one-third less calories or 50 percent less fat.

_____ Other: _____

Printing of Factual Information. HHS believes that the defined term "light" (as well as others such as "reduced" or "low") should be the only permitted statements about nutrients. HHS thus would not permit any factual nutrient statements, even if accurate, unless the product also met the requirements of

the terms defined by HHS or the label stated that the product did not meet the terms. For example, if a product did not meet the definition of "low calorie," the seller could not state the number of calories the product contains anywhere (other than on the nutrition panel) unless the product label also stated "not a low calorie product."

HHS contends that allowing use of such information, although factually accurate, would lead to confusion and proliferation of accurate but misleading claims. Others maintain, however, that allowing factually accurate statements will, on balance, benefit consumers. Restricting simple, accurate statements in the market place denies the consumer quick access to truthful information with which to make informed choices on his own. The restriction on accurate statements may also reduce the incentive to make improvements that are not as great as the thresholds set by the terms defined by the regulation. For example, a producer may be less likely to reduce fat in a product by 20 percent if, as HHS proposes, the reduced fat content could not be shown on the product label.

Decision:

_____ HHS position: allow factually accurate nutrient claims, only if (a) the product meets the terms defined by HHS; such as "reduced" or "light," or (b) the label states that the product does not meet the terms.

_____ Alternative position: allow factual nutrient statements without HHS provisos.

_____ Other: _____

Issue Two: NLEA Application in Restaurants.

The NLEA specifically exempts restaurants from its requirement that all food products carry a nutrition information label. However, the Department of Justice has advised, and USDA and HHS agree, that nutrient claims by restaurants are subject to the NLEA. There is no question, therefore, that some regulation of nutrient claims by restaurants is required as a matter of law.

USDA and HHS disagree about whether claims on menus should be covered under the NLEA.

HHS proposes that all nutrient claims by restaurants be regulated, including claims on menus. USDA proposes that claims on menus be exempted. USDA believes that there would be a chilling effect on provision of information by restaurants, perhaps leading restaurants to provide no health information or to be required to retain lawyers to review their menus. The Department of Justice advises that the NLEA does not require that menus be treated as labeling, so an exemption for menus is permitted. HHS expresses concern, however, about whether exempting menus would be sustained by the courts as reasonable, since menus do contain descriptions of items served by the restaurant. Indeed, menus are the primary and often the only information provided by a restaurant about the food it serves. Moreover, HHS strongly asserts that not covering menus as labeling could undermine its enforcement of all food and drug laws, since it has covered as "labeling" items similar to menus such as pamphlets, signs and placards.

Decision:

_____	USDA: exempt restaurant menus
_____	HHS: regulate restaurant menus

Issue Three: Nutrition Label Format

Under the NLEA, every food product (except food served in restaurants) must carry a nutrition information panel. The NLEA also specifies the nutrient items that must appear on the panel, e.g., total fat, carbohydrate, cholesterol, etc. The statute requires that the label must be designed so that (a) the public can readily observe and comprehend the information on the label, and (b) the relative significance of the nutrients can be understood in the context of a total daily diet. USDA and HHS agree that the panel should state the amount of each of the listed nutrients that is found in the food, e.g., 13 grams of total fat. There remain two fundamental differences between the agencies, however.

HHS proposes that, in addition to listing nutrients and amounts, the panel should state the total daily amount a person should have of each nutrient (called the "daily value") and the percentage of that daily total found in the food. (The HHS proposed format is shown at attachment 1.) USDA contends that the total daily amount and the percentage for each nutrient should not be listed on the panel; instead, only general dietary guidelines would be stated in a footnote. (The USDA proposed format is shown at attachment 2.)

The two differences between HHS and USDA are thus whether a daily reference value should be shown, and, if so, whether the percentage of the value should also be shown. HHS argues that showing a total daily amount and a percentage that the food supplies of the total daily amount enables consumers to understand the relative value of a serving of the product to their total diet. Without this relative value information, HHS maintains, the consumer would not know the significance of a particular amount of a nutrient.

Moreover, according to HHS, public health research demonstrates that percentages have a utility to the consumer. Use of a percentage, HHS believes, allows consumers to take advantage of the information provided in a practical way, permitting them to make their own choices quickly and effectively.

USDA believes, however, that the HHS approach excessively regulates or prescribes the diet, and that the USDA proposed label is less confusing and more informative. USDA argues particularly that by requiring that a single percentage of daily value be shown for a nutrient, HHS must base the daily value on a single average diet (set by HHS at 2,000 calories per day). USDA asserts that any one daily value level is incorrect for most of the population, as shown by the fact that only 25 percent of the population has a dietary need at or below the 2,000 calorie level.

HHS replies that the 2,000 calorie level is justified because it errs on the side of a lower, rather than a higher intake of fat. HHS also asserts that it would be inappropriate to use a range of calorie intake levels, rather than a single level (such as 2,000 calories). While use of a range would take account of the range of dietary needs in the population, HHS believes that consumers would, unjustifiably, tend to place themselves in a higher part of the range, and thus to consume higher amounts of fat and calories.

During discussions on this issue, a third compromise option was developed. It is shown at attachment 3. Under the compromise option, daily values are indicated, as HHS seeks. However, instead of a single value (as proposed by HHS), a range of daily values is shown. A percentage of daily value is not shown, so all information is in the same unit, making it easier to follow. (The format also uses the HHS footnote that explains daily value and the USDA format information showing equations of grams of a nutrient and calories.) This proposal combines the USDA proposal to eliminate the percentage and the HHS proposal to include daily values, and resolves the one-size-fits-all, single daily value problem by showing a range of

values. Inclusion of daily values would permit consumers to evaluate the food product in terms of their total daily intake of food. Elimination of the percentage enables a range of daily values to be displayed, allowing consumers to more adequately relate the information to their own situations.

Decision:

- _____ USDA format: content disclosure alone
(with dietary guidelines).
- _____ HHS format: content disclosure, single
daily value and percentage of daily value.
- _____ Compromise format: content disclosure,
range of daily values, all in the same unit
(but with no percentage).

HHS PROPOSAL

Nutrition Facts

Serving Size 1/2 cup (114g)

Servings Per Container 4

Amount Per Serving**Calories 260** **Calories from Fat 120**

	% Daily Value	Daily Value* for 2,000 calorie diet
Total Fat 13g	20%	Less than 65g
Saturated Fat 5g	25%	Less than 20g
Cholesterol 30mg	10%	Less than 300mg
Sodium 660mg	28%	Less than 2,400mg
Total Carbohydrate 31g	11%	300g
Dietary Fiber 0g	0%	25g
Sugars 5g		
Protein 5g		
Vitamin A 4% • Vitamin C 2% • Calcium 15% • Iron 4%		

*This Daily Value is a reference only. Your Daily Value may vary depending on your calorie needs. Typical intakes for women are 1600-2200 calories, for men 2000-3000 calories and for children (ages 4-14) 1800-2500 calories. More information can be obtained from, Dietary Guidelines, Consumer Information Center, Pueblo, CO 81002.

USDA PROPOSAL

Nutrition Facts

Serving Size 1 cup (253 g)
 Servings Per Container 1

Amount Per Serving

Calories 260 Calories from Fat 75

Total Fat
 (1g=9 calories) 8.5g

Saturated Fat 3.5g

Cholesterol 35mg

Sodium 1010mg

Total Carbohydrate
 (1g=4 calories) 22g

Complex Carbohydrate 18g

Sugars 4g

Dietary Fiber 9g

Protein
 (1g=4 calories) 25g

Vitamin A 20% • Vitamin C 2% • Calcium 8% • Iron 45%

*Use this nutrition information to help you plan your total daily diet. The Dietary Guidelines recommend that Americans: Eat a wide range of foods. Choose a diet with plenty of vegetables, fruits, and grain products. Choose a diet low in fat (30% of calories or less), saturated fat (less than 10% of calories), and cholesterol. Use sugar, salt and sodium only in moderation.

COMPROMISE PROPOSAL

Nutrition Facts

Serving Size 1 cup (253 g)
 Servings Per Container 1

Amount Per Serving

Calories 260

Calories from Fat 75

Daily Value*

Total Fat (1g=9 calories)	8.5g	53-93g
Saturated Fat	3.5g	18-31g
Cholesterol	35mg	300mg
Sodium	1010mg	2400mg
Total Carbohydrate (1g=4 calories)	22g	240-420g
Complex Carbohydrate	8g	
Sugars	4g	
Dietary Fiber	9g	18-32g
Protein (1g=4 calories)	25g	40-70g

Vitamin A 20% • Vitamin C 2% • Calcium 8% • Iron 45%

*This Daily Value is a reference only. Your Daily Value may vary depending on your calorie needs. Typical intakes for women are 1,600-2,200 calories, for men 2,000-3,000 calories and for children (ages 4-14) 1,800-2,500 calories. More information can be obtained from, Dietary Guidelines, Consumer Information Center, Pueblo CO 81002

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

November 16, 1992

Memorandum for Robert B. Zoellick

Re: Food Labeling Regulations

Pursuant to your memorandum of November 13th, nothing in my memorandum of the same date should be interpreted as prejudging our ability to carry out the directives arrived at as a result of our further discussions.

I look forward to our meeting, as soon as possible. Thank you.

A handwritten signature in cursive script that reads "Louis W. Sullivan".
Louis W. Sullivan, M.D.

RBZ

FYI - 9

THE PRESIDENT

November 17, 1992

Ok, JAB III:

I have read the food labelling paper.

My inclination is across the board to opt for less rather than more. We've gone regulation crazy; but on to the next step suggested in the attached.

Let's you, Bob Z and I visit on this.

9



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

November 13, 1992

MEMORANDUM FOR ROBERT B. ZOELLICK

Re: Food Labeling Regulations

My staff has reported to me on the meeting held Thursday to discuss the draft options memorandum for the President. By extracting issues from the broad legal, factual and public health policy context in which I am obligated to consider them, the memo provides an inadequate basis for decisionmaking. Thus, if these issues are presented to the President, a meeting will be necessary.

My principal concern, however, is that the memorandum fails to include what I regard to be the practical options for resolving this matter. I would like to make a few points that you should consider as you move this matter forward and then address these options.

On the format issue, I made a decision based on my statutory mandate, extensive research, and a large administrative record. Neither of the alternative formats presented in the options memo adequately achieves the statutory and public health goals for which I am responsible. I would be unable to adopt either of them.

On restaurants, I have adopted the most flexible approach possible to ease compliance by restaurants with the requirements of NLEA. Under no circumstance can I say that menus are not labeling. It is imperative for the welfare of consumers and the restaurant industry that I adopt the "reasonable basis" compliance standard, which we developed in response to public comments and input from the restaurant industry. The compliance guidelines suggested by USDA have no statutory basis and would effectively legalize even glaring violations of law.

I have carefully considered USDA's definition of "light in sodium." With respect to the products FDA regulates, the "light in sodium" descriptor is appropriate only for products that are low in fat and calories. USDA should be free to define the term as Secretary Madigan see fit for USDA-regulated products. For reasons we have discussed, I also am not prepared to adopt any definition for "light" for high fat foods that are not reduced 50% in fat.

The Deputy Chief of Staff - Page 2

I am surprised to learn that the draft options memo includes for presentation to the President two issues on which HHS and USDA do not disagree. On absolute amount declarations, there are specific statutory constraints, and we are being as flexible as the law allows. The 25 percent threshold for comparative claims assures nutritionally significant (and readily achievable) differences in products claimed to be "less" and "reduced" and is generally supported by industry. I feel these issues should not be raised in this memo.

Finally, we must not lose sight of the fact that we are at the end of a rulemaking process in which my decisions have been guided by a detailed statute and an elaborate rulemaking record. In my judgment, it is unwise -- and unfair to the President -- to ask him to resolve specific issues at this stage of the proceeding. This risks, among other things, having the President select options that are not legally defensible on the basis of the available record.

We thus are left with two basic options, neither of which was included in the draft options memorandum:

- Option One: Instruct me not to issue my final rules. In this case, the rules I proposed last year and that became final this week by operation of the statute will remain in place with respect to FDA-regulated products. Necessary improvements would have to be made by the next Administration, with the food industry remaining in a state of enormous uncertainty until then, and the Administration vulnerable to legal challenge for "unreasonable delay" of these statutorily mandated and now overdue regulations.
- Option Two: Clear my final rules and authorize Secretary Madigan to proceed as he sees fit. This would mean a substantial achievement for the Bush Administration and consumers, even if USDA does not issue final rules or the HHS and USDA rules are not identical.

The Deputy Chief of Staff - Page 3

In light of my statutory responsibility and deadline, and the importance of food labeling reform to our Healthy People 2000 initiative, I feel strongly about the need to move forward with my regulations. If cleared to do so, I would proceed as expeditiously as possible, consistent with protecting the procedural integrity of the rulemaking. If some other course is contemplated, I must take the matter up personally with the President.

I appreciate your cooperation in working toward a prompt resolution of this matter.


Louis W. Sullivan, M.D.

③ Make the 'lite' choice on food labels

Two years ago, Congress gave regulators what appeared to be a simple mandate: End the confusing clutter of information in supermarkets and devise a meaningful, uniform label for foods.

Now a messy fight within the Bush administration threatens to set back this needed reform. The White House should intervene quickly to settle the dispute and issue rules so shoppers can have easily understood labels within a year or two.

After a year of negotiations, nearly 4,000 pages of regulations were supposed to be finalized Monday. But Agriculture Secretary Edward Madigan and Dr. David Kessler, commissioner of the Food and Drug Administration, couldn't agree on a few things.

The spat isn't some inconsequential, bureaucratic food fight over turf; it's a fundamental difference over policy and the purposes of the 1990 Nutrition Labeling and Education Act. And, while the lesson may be that there's no perfect food label, Madigan seems closer to the mark than Kessler.

The chief argument centers on the format of the label—specifically, how it should disclose the fat content of foods. The two also disagree on how restaurants should be included under the labeling law.

Kessler wants to list the amounts of fat, sodium, cholesterol and calories per serving and compare these to the government's recommended maximum in a daily diet of 2,000 calories. The numbers would be expressed as a "Daily Value" or "DV"—a percentage of the recommended amount.

Madigan, who as an Illinois congressman helped write the law, argues convincingly that FDA's formula is "too complex and fails to meet the statutory provisions that requires the label be easily understood."

There's also a risk that people would use the FDA's label to select foods even if they eat less or more than 2,000 calories a day. Individual calorie needs vary depending on factors such as age, gender and activity.

Madigan prefers a simple label that would list the amounts of nutrients in a food and carry warnings about sodium, sugar and such, but not assign daily values. If there must be daily values, he argues, they should be based on a range of calorie intakes, although this, too, seems unnecessarily complicated.

As to restaurants, the FDA proposes limiting the use of terms such as "low-fat" and "fresh" on menus unless there's some basis for the claim. Smaller eateries fear they may be required to produce recipes or conduct costly laboratory analyses to support menu descriptions. Madigan wisely favors voluntary guidelines.

Critics say Madigan is fighting the FDA label because it would steer people away from high-fat foods like meat. He denies it, and it really doesn't matter, because he's playing a useful role.

Americans don't want menu police or prescriptions from Washington on what is politically correct to eat. They want detailed, uniform, straightforward information about their food so they can make sound, healthy dietary decisions. Madigan has set the table for the White House to provide this.

Chi Trib-Editorial 11/13 #18



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

November 16, 1992

Memorandum for Robert B. Zoellick

Re: Food Labeling Regulations

Pursuant to your memorandum of November 13th, nothing in my memorandum of the same date should be interpreted as prejudging our ability to carry out the directives arrived at as a result of our further discussions.

I look forward to our meeting, as soon as possible. Thank you.

Louis W. Sullivan
Louis W. Sullivan, M.D.

FOOD LABELING REGULATIONS

This presents for your decision three issues concerning food labeling regulations that must soon be issued by the Secretary of Health and Human Services and the Secretary of Agriculture. The Secretaries and interested agencies have striven over many months to reach agreement on the issues raised by these complex and important rules. All of these issues have now been resolved except for three: (1) the most appropriate definition of the term "light;" (2) the scope of regulation of restaurant foods; and (3) the format of the nutrition label for food products. The Secretaries have not been able to agree on these issues. The issues are therefore presented for your decision.

Background.

The Nutrition Labeling and Education Act (NLEA) requires the Secretary of Health and Human Services (HHS) to issue regulations governing labeling of food products. The NLEA provides that the regulations must require food products to carry a nutrition information panel on the label. The regulations are also required to define the types of comparative nutrition claims that can be made on the label (such as "light," "low" or "reduced").

The NLEA only applies to foods regulated by the Food and Drug Administration (FDA). Products containing more than a de minimis (two percent) meat content are regulated by the Department of Agriculture (USDA). Secretary Madigan has proposed a labeling regimen for meat food products that parallels the HHS proposal for other food products. (The food processing industry and consumer groups prefer a common rule for both types of products.)

The food labeling rules as a whole encompass 29 distinct HHS rules and one parallel USDA rule. The HHS rules alone will consume over 1,000 pages in the Federal Register. The regulations are expected to have a major impact on nutrition and health, as well as impose significant costs in the food production, food marketing and restaurant industries.

The NLEA contains a "hammer provision" that required the proposed rule (issued by HHS one year ago) to become the final rule automatically if the final regulations were not issued by November 8, 1992. The hammer fell when the final rule was not issued by that date. The proposed rule now given final effect by the hammer provision is not supported by either HHS or USDA or any other agency. When the three issues presented here are resolved, the final regulations will be published and supersede

the proposed rule. However, it may be necessary to have a short public comment period before the final regulations are published. Whether or not a comment period is provided, expedition is warranted since there is a strong public interest in issuing these important rules as soon as possible. (The regulations will have a delayed effective date to allow for planning and implementation.)

Issues For Decision

Issue One: Use of Term "Light"

The NLEA requires the issuance of rules that provide definitions for a variety of comparative claims such as "less," "low" and "light." The NLEA prohibits use of these terms unless the food product to which they refer meets the definitions. Both USDA and HHS agree that the definition of "light" should refer to a minimum reduction of two key elements: fat and/or calories. The following issues remain concerning the definition of "light".

Sodium. USDA proposes that the term "light" also may be used when the product contains 50 percent less sodium. HHS maintains that only reduced fat and calories, and not reduced sodium, should qualify a product as "light." HHS argues that the term "light" is such an important signal to consumers that it should apply to only the most important elements of a food. HHS believes that the value of the term "light" would be diluted by allowing it to refer to a reduction only in sodium, an element HHS believes is less important than fat or calories. HHS also points out that there are other terms available to describe lower salt products, such as "low sodium" or "lightly salted."

USDA argues that, in view of the importance of sodium consumption to many consumers, usage of the term "light" in connection with sodium should be permitted. USDA also urges that use of "less" and "lower" to describe salt content would not be as valuable as a descriptive term as the term "light." To meet HHS' concerns about retaining the value of the term "light," USDA proposes that when a product has only reduced sodium it must be identified as "light in sodium," although USDA also proposes that "light" may in such cases also be in the name, such as "light bologna." USDA also proposes that the words "in sodium" be of equal size, to avoid disproportionate emphasis on the term "light."

Decision:

- _____ HHS position: "light" refers only to fat or calories.
- _____ USDA position: "light" refers to fat or calories, or sodium if labeled "light in sodium."
- _____ Other: _____

Fat and/or Calorie Reduction. USDA would define "light" as one-third less in calories or 50 percent less in fat. HHS would define "light" the same way, except that, for a food that has more than 50 percent of calories from fat, only a 50 percent reduction in fat (not one-third less calories) would qualify as "light." HHS argues that products should not be labeled "light," even if the calorie count has been reduced one-third, where fat content remains the dominant source for the remaining calories. HHS points out that descriptive terms are available in this situation other than "light," such as "reduced calories." USDA believes that consumers are provided useful information by use of the term "light" where calories have been reduced by one-third, even if fat remains the dominant source of calories (which will be the case for many meat and poultry products). USDA is concerned that the HHS definition will serve as a disincentive for producers to develop meat and poultry products that reduce calories by one-third even though the fat in those products cannot be reduced by 50 percent.

Decision:

- _____ HHS position: one-third less calories or 50 percent less fat; 50 percent less fat required where more than 50 percent of calories are from fat.
- _____ USDA position: one-third less calories or 50 percent less fat.
- _____ Other: _____

Printing of Factual Information. HHS believes that the defined term "light" (as well as others such as "reduced" or "low") should be the only permitted statements about nutrients. HHS thus would not permit any factual nutrient statements, even if accurate, unless the product also met the requirements of

the terms defined by HHS or the label stated that the product did not meet the terms. For example, if a product did not meet the definition of "low calorie," the seller could not state the number of calories the product contains anywhere (other than on the nutrition panel) unless the product label also stated "not a low calorie product."

HHS contends that allowing use of such information, although factually accurate, would lead to confusion and proliferation of accurate but misleading claims. Others maintain, however, that allowing factually accurate statements will, on balance, benefit consumers. Restricting simple, accurate statements in the market place denies the consumer quick access to truthful information with which to make informed choices on his own. The restriction on accurate statements may also reduce the incentive to make improvements that are not as great as the thresholds set by the terms defined by the regulation. For example, a producer may be less likely to reduce fat in a product by 20 percent if, as HHS proposes, the reduced fat content could not be shown on the product label.

Decision:

- _____ HHS position: allow factually accurate nutrient claims, only if (a) the product meets the terms defined by HHS, such as "reduced" or "light," or (b) the label states that the product does not meet the terms.
- _____ Alternative position: allow factual nutrient statements without HHS provisos.
- _____ Other: _____

Issue Two: NLEA Application in Restaurants.

The NLEA specifically exempts restaurants from its requirement that all food products carry a nutrition information label. However, the Department of Justice has advised, and USDA and HHS agree, that nutrient claims by restaurants are subject to the NLEA. There is no question, therefore, that some regulation of nutrient claims by restaurants is required as a matter of law.

USDA and HHS disagree about the extent to which nutrient claims by restaurants should be regulated. Specifically, the

agencies disagree on (1) whether menus should be covered; and (2) about the scope of regulation of restaurants.

Menus. HHS proposes that all nutrient claims by restaurants be regulated, including claims on menus. USDA proposes that claims on menus be exempted. USDA believes that there would be a chilling effect on provision of information by restaurants, perhaps leading restaurants to provide no health information or to be required to retain lawyers to review their menus. The Department of Justice advises that the NLEA does not unambiguously require that menus be treated as labeling, so some form of exemption for menus may be permitted but that this is not yet resolved. HHS expresses concern, however, about whether exempting menus would be sustained by the courts as reasonable, since menus do contain descriptions of items served by the restaurant. Indeed, menus are the primary and often the only information provided by a restaurant about the food it serves. Moreover, HHS strongly asserts that not covering menus as labeling could undermine its enforcement of all food and drug laws, since it has covered as "labeling" items similar to menus such as pamphlets, signs and placards.

Scope of regulation. To the extent that menus are covered, HHS proposes that a restaurant need only be able to show some "reasonable basis" for the restaurant's nutrient claim on a menu (such as a claim that an item is "low calorie"). HHS also proposes that certain claims on a menu be exempt, such as "light fare" as a description of a category of menu items.

USDA proposes that mitigating measures be added to the HHS proposal. USDA urges adoption of a small business exemption for menus, so that the rules would not apply to the menus of single-location restaurants or chains of ten or fewer restaurants. While the NLEA provides a small business exemption for the requirement to place a nutrition label on all food products, it contains no such exemption for the nutrient claims provisions at issue here. This suggests that no such exemption was intended for nutrient claims, although it should not preclude granting a limited, de minimis exemption, such as an exemption for menus of small restaurants.

As an alternative to a small business exemption, USDA proposes that the "reasonable basis" test of HHS should be only a general guideline, not the sole means of avoiding a violation for small businesses. To the extent of its enforcement discretion, FDA would take action only if the menu is materially misleading and the restaurant personnel preparing the menus knew that the descriptions were materially inconsistent with the guidelines, or knew the actual

composition of the food items described in the nutrient claim was materially different from the item's description. This enforcement guideline would provide some mitigation for small business; however, FDA laws are primarily enforced by state and local governments that would retain discretion to enforce the law in a manner that could weaken the mitigating effect of the standard. HHS opposes a small business exemption and mitigating enforcement measures, even for chains of ten or fewer restaurants. HHS maintains that even such small chains or single location restaurants should be required to demonstrate a reasonable basis for nutrient claims on a menu.

Decision:

_____ USDA: exempt restaurant menus (to the extent permitted by law)

_____ HHS: regulate restaurant menus

To the extent menus are covered:

_____ USDA: (a) include small restaurant exemption for menus, or

_____ (b) include mitigating enforcement provisions as described above.

_____ HHS: do not include small restaurant exemption or mitigating enforcement provisions.

Issue Three: Nutrition Label Format

Under the NLEA, every food product (except food served in restaurants) must carry a nutrition information panel. The NLEA also specifies the nutrient items that must appear on the panel, e.g., total fat, carbohydrate, cholesterol, etc. The statute requires that the label must be designed so that (a) the public can readily observe and comprehend the information on the label, and (b) the relative significance of the nutrients can be understood in the context of a total daily diet. USDA and HHS agree that the panel should state the amount of each of the listed nutrients that is found in the food, e.g., 13 grams of total fat. There remain two fundamental differences between the agencies, however.

HHS proposes that, in addition to listing nutrients and amounts, the panel should state the total daily amount a person should have of each nutrient (called the "daily value") and the

percentage of that daily total found in the food. (The HHS proposed format is shown at attachment 1.) USDA contends that the total daily amount and the percentage for each nutrient should not be listed on the panel; instead, only general dietary guidelines would be stated in a footnote. (The USDA proposed format is shown at attachment 2.)

The two differences between HHS and USDA are thus whether a daily reference value should be shown, and, if so, whether the percentage of the value should also be shown. HHS argues that showing a total daily amount and a percentage that the food supplies of the total daily amount enables consumers to understand the relative value of a serving of the product to their total diet. Without this relative value information, HHS maintains, the consumer would not know the significance of a particular amount of a nutrient.

Moreover, according to HHS, public health research demonstrates that percentages have a utility to the consumer. Use of a percentage, HHS believes, allows consumers to take advantage of the information provided in a practical way, permitting them to make their own choices quickly and effectively.

USDA believes, however, that the HHS approach excessively regulates or prescribes the diet, and that the USDA proposed label is less confusing and more informative. USDA argues particularly that by requiring that a single percentage of daily value be shown for a nutrient, HHS must base the daily value on a single average diet (set by HHS at 2,000 calories per day). USDA asserts that any one daily value level is incorrect for most of the population, as shown by the fact that only 25 percent of the population has a dietary need at or below the 2,000 calorie level.

HHS replies that the 2,000 calorie level is justified because it errs on the side of a lower, rather than a higher intake of fat. HHS also asserts that it would be inappropriate to use a range of calorie intake levels, rather than a single level (such as 2,000 calories). While use of a range would take account of the range of dietary needs in the population, HHS believes that consumers would, unjustifiably, tend to place themselves in a higher part of the range, and thus to consume higher amounts of fat and calories.

During discussions on this issue, a third, compromise option was developed. It is shown at attachment 3. Under the compromise option, daily values are indicated, as HHS seeks. However, instead of a single value (as proposed by HHS), a range of daily values is shown. A percentage of daily value is

not shown, so all information is in the same unit, making it easier to follow. (The format also uses the HHS footnote that explains daily value and the USDA format information showing equations of grams of a nutrient and calories.) This proposal combines the USDA proposal to eliminate the percentage and the HHS proposal to include daily values, and resolves the one-size-fits-all, single daily value problem by showing a range of values. Inclusion of daily values would permit consumers to evaluate the food product in terms of their total daily intake of food. Elimination of the percentage enables a range of daily values to be displayed, allowing consumers to more adequately relate the information to their own situations.

Decision:

- _____ USDA format: content disclosure alone
(with dietary guidelines).
- _____ HHS format: content disclosure, single
daily value and percentage of daily value.
- _____ Compromise format: content disclosure,
range of daily values, all in the same unit
(but with no percentage).

HHS PROPOSAL

Nutrition Facts

Serving Size 1/2 cup (114g)

Servings Per Container 4

Amount Per Serving**Calories 260** Calories from Fat 120

	% Daily Value	Daily Value* for 2,000 calorie diet
Total Fat 13g	20%	Less than 65g
Saturated Fat 5g	25%	Less than 20g
Cholesterol 30mg	10%	Less than 300mg
Sodium 660mg	28%	Less than 2,400mg
Total Carbohydrate 31g	11%	300g
Dietary Fiber 0g	0%	25g
Sugars 5g		
Protein 5g		
Vitamin A 4% • Vitamin C 2% • Calcium 15% • Iron 4%		

*This Daily Value is a reference only. Your Daily Value may vary depending on your calorie needs. Typical intakes for women are 1600-2200 calories, for men 2000-3000 calories and for children (ages 4-14) 1800-2500 calories. More information can be obtained from, Dietary Guidelines, Consumer Information Center, Pueblo, CO 81002.

USDA PROPOSAL

Nutrition Facts

Serving Size 1 cup (253 g)
 Servings Per Container 1

Amount Per Serving

Calories 260 Calories from Fat 75

Total Fat

(1g=9 calories)

8.5g

Saturated Fat

3.5g

Cholesterol

35mg

Sodium

1010mg

Total

Carbohydrate

(1g=4 calories)

22g

Complex
Carbohydrate

18g

Sugars

4g

Dietary Fiber

9g

Protein

(1g=4 calories)

25g

Vitamin A 20% • Vitamin C 2% • Calcium 8% • Iron 45%

*Use this nutrition information to help you plan your total daily diet. The Dietary Guidelines recommend that Americans: Eat a wide range of foods. Choose a diet with plenty of vegetables, fruits, and grain products. Choose a diet low in fat (30% of calories or less), saturated fat (less than 10% of calories), and cholesterol. Use sugar, salt and sodium only in moderation.

COMPROMISE PROPOSAL

Nutrition Facts

Serving Size 1 cup (253 g)
 Servings Per Container 1

Amount Per Serving

Calories 260 Calories from Fat 75

Daily Value*

Total Fat (1g=9 calories)	8.5g	53-93g
Saturated Fat	3.5g	18-31g
Cholesterol	35mg	300mg
Sodium	1010mg	2400mg
Total Carbohydrate (1g=4 calories)	22g	240-420g
Complex Carbohydrate	8g	
Sugars	4g	
Dietary Fiber	9g	18-32g
Protein (1g=4 calories)	25g	40-70g

Vitamin A 20% • Vitamin C 2% • Calcium 8% • Iron 45%

*This Daily Value is a reference only. Your Daily Value may vary depending on your calorie needs. Typical intakes for women are 1,600-2,200 calories, for men 2,000-3,000 calories and for children (ages 4-14) 1,800-2,500 calories. More information can be obtained from, Dietary Guidelines, Consumer Information Center, Pueblo CO 81002

THE WHITE HOUSE
WASHINGTON

November 13, 1992

Memorandum for Secretary Sullivan

Re: Food Labeling Regulations

I shared your November 13 memo with Secretary Baker. We were not clear about the meaning of the following sentence in your discussion of the format alternatives (p. 1, para. 3): "I would be unable to adopt either of them."

We are also unclear about the meaning of the phrase (p. 1, para. 5), "I also am not prepared to adopt any definition for 'light' for high fat foods that are not reduced 50% in fat."

Secretary Baker asked me to ascertain whether these statements are your way of saying that you would refuse to implement the President's decisions in the event they are different from your recommendations and, if not, would you care to rephrase them. He would like to know your answer before we proceed with the paper and the meeting you requested.

I also note that your memo refers to various questions of legal interpretation. As your staff knows from the various interagency meetings, we have relied on the Justice Department to resolve differences of legal interpretation.

I would appreciate it if you could let me know promptly your answer to Secretary Baker's question. Thank you.



Robert B. Zoellick



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

November 13, 1992

MEMORANDUM FOR ROBERT ZOELICK

FROM: Bob Damus *RD*

SUBJECT: Food Labeling

Attached is the revised document.

This revision reflects some of the suggestions of HHS and USDA.

As you can see, in the menu area, the discussion and choices reflect the fact that Justice has not yet finally resolved certain matters.

FOOD LABELING REGULATIONS

This presents for your decision three issues concerning food labeling regulations that must soon be issued by the Secretary of Health and Human Services and the Secretary of Agriculture. The Secretaries and interested agencies have striven over many months to reach agreement on the issues raised by these complex and important rules. All of these issues have now been resolved except for three: (1) the most appropriate definition of the term "light;" (2) the scope of regulation of restaurant foods; and (3) the format of the nutrition label for food products. The Secretaries have not been able to agree on these issues. The issues are therefore presented for your decision.

Background.

The Nutrition Labeling and Education Act (NLEA) requires the Secretary of Health and Human Services (HHS) to issue regulations governing labeling of food products. The NLEA provides that the regulations must require food products to carry a nutrition information panel on the label. The regulations are also required to define the types of comparative nutrition claims that can be made on the label (such as "light," "low" or "reduced").

The NLEA only applies to foods regulated by the Food and Drug Administration (FDA). Products containing more than a de minimis (two percent) meat content are regulated by the Department of Agriculture (USDA). Secretary Madigan has proposed a labeling regimen for meat food products that parallels the HHS proposal for other food products. (The food processing industry and consumer groups prefer a common rule for both types of products.)

The food labeling rules as a whole encompass 29 distinct HHS rules and one parallel USDA rule. The HHS rules alone will consume over 1,000 pages in the Federal Register. The regulations are expected to have a major impact on nutrition and health, as well as impose significant costs in the food production, food marketing and restaurant industries.

The NLEA contains a "hammer provision" that required the proposed rule (issued by HHS one year ago) to become the final rule automatically if the final regulations were not issued by November 8, 1992. The hammer fell when the final rule was not issued by that date. The proposed rule now given final effect by the hammer provision is not supported by either HHS or USDA

or any other agency. When the three issues presented here are resolved, the final regulations will be published and supersede the proposed rule. However, it may be necessary to have a short public comment period before the final regulations are published. Whether or not a comment period is provided, expedition is warranted since there is a strong public interest in issuing these important rules as soon as possible. (The regulations will have a delayed effective date to allow for planning and implementation.)

Issues For Decision

Issue One: Use of Term "Light"

The NLEA requires the issuance of rules that provide definitions for a variety of comparative claims such as "less," "low" and "light." The NLEA prohibits use of these terms unless the food product to which they refer meets the definitions. Both USDA and HHS agree that the definition of "light" should refer to a minimum reduction of two key elements: fat and/or calories. The following issues remain concerning the definition of "light".

Sodium. USDA proposes that the term "light" also may be used when the product contains 50 percent less sodium. HHS maintains that only reduced fat and calories, and not reduced sodium, should qualify a product as "light." HHS argues that the term "light" is such an important signal to consumers that it should apply to only the most important elements of a food. HHS believes that the value of the term "light" would be diluted by allowing it to refer to a reduction only in sodium, an element HHS believes is less important than fat or calories. HHS also points out that there are other terms available to describe lower salt products, such as "low sodium" or "lightly salted."

USDA argues that, in view of the importance of sodium consumption to many consumers, usage of the term "light" in connection with sodium should be permitted. USDA also urges that use of "less" and "lower" to describe salt content would not be as valuable as a descriptive term as the term "light." To meet HHS' concerns about retaining the value of the term "light," USDA proposes that when a product has only reduced sodium it must be identified as "light in sodium," although USDA also proposes that "light" may in such cases also be in the name, such as "light bologna." USDA also proposes that the words "in sodium" be of equal size, to avoid disproportionate emphasis on the term "light."

Decision:

- _____ HHS position: "light" refers only to fat or calories.
- _____ USDA position: "light" refers to fat or calories, or sodium if labeled "light in sodium."
- _____ Other: _____

Fat and/or Calorie Reduction. USDA would define "light" as one-third less in calories or 50 percent less in fat. HHS would define "light" the same way, except that, for a food that has more than 50 percent of calories from fat, only a 50 percent reduction in fat (not one-third less calories) would qualify as "light." HHS argues that products should not be labeled "light," even if the calorie count has been reduced one-third, where fat content remains the dominant source for the remaining calories. HHS points out that descriptive terms are available in this situation other than "light," such as "reduced calories." USDA believes that consumers are provided useful information by use of the term "light" where calories have been reduced by one-third, even if fat remains the dominant source of calories (which will be the case for many meat and poultry products). USDA is concerned that the HHS definition will serve as a disincentive for producers to develop meat and poultry products that reduce calories by one-third even though the fat in those products cannot be reduced by 50 percent.

Decision:

- _____ HHS position: one-third less calories or 50 percent less fat; 50 percent less fat required where more than 50 percent of calories are from fat.
- _____ USDA position: one-third less calories or 50 percent less fat.
- _____ Other: _____

Printing of Factual Information. HHS believes that the defined term "light" (as well as others such as "reduced" or "low") should be the only permitted statements about nutrients.

HHS thus would not permit any factual nutrient statements, even if accurate, unless the product also met the requirements of the terms defined by HHS or the label stated that the product did not meet the terms. For example, if a product did not meet the definition of "low calorie," the seller could not state the number of calories the product contains anywhere (other than on the nutrition panel) unless the product label also stated "not a low calorie product."

HHS contends that allowing use of such information, although factually accurate, would lead to confusion and proliferation of accurate but misleading claims. Others maintain, however, that allowing factually accurate statements will, on balance, benefit consumers. Restricting simple, accurate statements in the market place denies the consumer quick access to truthful information with which to make informed choices on his own. The restriction on accurate statements may also reduce the incentive to make improvements that are not as great as the thresholds set by the terms defined by the regulation. For example, a producer may be less likely to reduce fat in a product by 20 percent if, as HHS proposes, the reduced fat content could not be shown on the product label.

Decision:

- _____ HHS position: allow factually accurate nutrient claims, only if (a) the product meets the terms defined by HHS, such as "reduced" or "light," or (b) the label states that the product does not meet the terms.
- _____ Alternative position: allow factual nutrient statements without HHS provisos.
- _____ Other: _____

Issue Two: NLEA Application in Restaurants.

The NLEA specifically exempts restaurants from its requirement that all food products carry a nutrition information label. However, the Department of Justice has advised, and USDA and HHS agree, that nutrient claims by restaurants are subject to the NLEA. There is no question, therefore, that some regulation of nutrient claims by restaurants is required as a matter of law.

USDA and HHS disagree about the extent to which nutrient claims by restaurants should be regulated. Specifically, the agencies disagree on (1) whether menus should be covered; and (2) about the scope of regulation of restaurants.

Menus. HHS proposes that all nutrient claims by restaurants be regulated, including claims on menus. USDA proposes that claims on menus be exempted. USDA believes that there would be a chilling effect on provision of information by restaurants, perhaps leading restaurants to provide no health information or to be required to retain lawyers to review their menus. The Department of Justice advises that the NLEA does not unambiguously require that menus be treated as labeling, so some form of exemption for menus may be permitted but that this is not yet resolved. HHS expresses concern, however, about whether exempting menus would be sustained by the courts as reasonable, since menus do contain descriptions of items served by the restaurant. Indeed, menus are the primary and often the only information provided by a restaurant about the food it serves. Moreover, HHS strongly asserts that not covering menus as labeling could undermine its enforcement of all food and drug laws, since it has covered as "labeling" items similar to menus such as pamphlets, signs and placards.

Scope of regulation. To the extent that menus are covered, HHS proposes that a restaurant need only be able to show some "reasonable basis" for the restaurant's nutrient claim on a menu (such as a claim that an item is "low calorie"). HHS also proposes that certain claims on a menu be exempt, such as "light fare" as a description of a category of menu items.

USDA proposes that mitigating measures be added to the HHS proposal. USDA urges adoption of a small business exemption for menus, so that the rules would not apply to the menus of single-location restaurants or chains of ten or fewer restaurants. While the NLEA provides a small business exemption for the requirement to place a nutrition label on all food products, it contains no such exemption for the nutrient claims provisions at issue here. This suggests that no such exemption was intended for nutrient claims, although it should not preclude granting a limited, de minimis exemption, such as an exemption for menus of small restaurants.

As an alternative to a small business exemption, USDA proposes that the "reasonable basis" test of HHS should be only a general guideline, not the sole means of avoiding a violation for small businesses. To the extent of its enforcement discretion, FDA would take action only if the menu is materially misleading and the restaurant personnel preparing

the menus knew that the descriptions were materially inconsistent with the guidelines, or knew the actual composition of the food items described in the nutrient claim was materially different from the item's description. This enforcement guideline would provide some mitigation for small business; however, FDA laws are primarily enforced by state and local governments that would retain discretion to enforce the law in a manner that could weaken the mitigating effect of the standard. HHS opposes a small business exemption and mitigating enforcement measures, even for chains of ten or fewer restaurants. HHS maintains that even such small chains or single location restaurants should be required to demonstrate a reasonable basis for nutrient claims on a menu.

Decision:

✓ ——— USDA: exempt restaurant menus (to the extent permitted by law)

————— HHS: regulate restaurant menus

To the extent menus are covered:

————— USDA: ((a) include small restaurant exemption for menus, or

————— ((b) include mitigating enforcement provisions as described above.

————— HHS: do not include small restaurant exemption or mitigating enforcement provisions.

Issue Three: Nutrition Label Format

Under the NLEA, every food product (except food served in restaurants) must carry a nutrition information panel. The NLEA also specifies the nutrient items that must appear on the panel, e.g., total fat, carbohydrate, cholesterol, etc. The statute requires that the label must be designed so that (a) the public can readily observe and comprehend the information on the label, and (b) the relative significance of the nutrients can be understood in the context of a total daily diet. USDA and HHS agree that the panel should state the amount of each of the listed nutrients that is found in the food, e.g., 13 grams of total fat. There remain two fundamental differences between the agencies, however.

HHS proposes that, in addition to listing nutrients and amounts, the panel should state the total daily amount a person should have of each nutrient (called the "daily value") and the percentage of that daily total found in the food. (The HHS proposed format is shown at attachment 1.) USDA contends that the total daily amount and the percentage for each nutrient should not be listed on the panel; instead, only general dietary guidelines would be stated in a footnote. (The USDA proposed format is shown at attachment 2.)

The two differences between HHS and USDA are thus whether a daily reference value should be shown, and, if so, whether the percentage of the value should also be shown. HHS argues that showing a total daily amount and a percentage that the food supplies of the total daily amount enables consumers to understand the relative value of a serving of the product to their total diet. Without this relative value information, HHS maintains, the consumer would not know the significance of a particular amount of a nutrient.

Moreover, according to HHS, public health research demonstrates that percentages have a utility to the consumer. Use of a percentage, HHS believes, allows consumers to take advantage of the information provided in a practical way, permitting them to make their own choices quickly and effectively.

USDA believes, however, that the HHS approach excessively regulates or prescribes the diet, and that the USDA proposed label is less confusing and more informative. USDA argues particularly that by requiring that a single percentage of daily value be shown for a nutrient, HHS must base the daily value on a single average diet (set by HHS at 2,000 calories per day). USDA asserts that any one daily value level is incorrect for most of the population, as shown by the fact that only 25 percent of the population has a dietary need at or below the 2,000 calorie level.

HHS replies that the 2,000 calorie level is justified because it errs on the side of a lower, rather than a higher intake of fat. HHS also asserts that it would be inappropriate to use a range of calorie intake levels, rather than a single level (such as 2,000 calories). While use of a range would take account of the range of dietary needs in the population, HHS believes that consumers would, unjustifiably, tend to place themselves in a higher part of the range, and thus to consume higher amounts of fat and calories.

During discussions on this issue, a third compromise option was developed. It is shown at attachment 3. Under the

compromise option, daily values are indicated, as HHS seeks. However, instead of a single value (as proposed by HHS), a range of daily values is shown. A percentage of daily value is not shown, so all information is in the same unit, making it easier to follow. (The format also uses the HHS footnote that explains daily value and the USDA format information showing equations of grams of a nutrient and calories.) This proposal combines the USDA proposal to eliminate the percentage and the HHS proposal to include daily values, and resolves the one-size-fits-all, single daily value problem by showing a range of values. Inclusion of daily values would permit consumers to evaluate the food product in terms of their total daily intake of food. Elimination of the percentage enables a range of daily values to be displayed, allowing consumers to more adequately relate the information to their own situations.

Decision:

- _____ USDA format: content disclosure alone
(with dietary guidelines).
- _____ HHS format: content disclosure, single
daily value and percentage of daily value.
- _____ Compromise format: content disclosure,
range of daily values, all in the same unit
(but with no percentage).

HHS PROPOSAL

Nutrition Facts

Serving Size 1/2 cup (114g)

Servings Per Container 4

Amount Per Serving**Calories** 260 **Calories from Fat** 120

	% Daily Value	Daily Value* for 2,000 calorie diet
Total Fat 13g	20%	Less than 65g
Saturated Fat 5g	25%	Less than 20g
Cholesterol 30mg	10%	Less than 300mg
Sodium 660mg	28%	Less than 2,400mg
Total Carbohydrate 31g	11%	300g
Dietary Fiber 0g	0%	25g
Sugars 5g		
Protein 5g		

Vitamin A 4% • Vitamin C 2% • Calcium 15% • Iron 4%

*This Daily Value is a reference only. Your Daily Value may vary depending on your calorie needs. Typical intakes for women are 1600-2200 calories, for men 2000-3000 calories and for children (ages 4-14) 1800-2500 calories. More information can be obtained from, Dietary Guidelines, Consumer Information Center, Pueblo, CO 81002.

USDA PROPOSAL

Nutrition Facts

Serving Size 1 cup (253 g)

Servings Per Container 1

Amount Per Serving

Calories 260

Calories from Fat 75

Total Fat

(1g=9 calories)

8.5g

Saturated Fat

3.5g

Cholesterol

35mg

Sodium

1010mg

Total Carbohydrate

(1g=4 calories)

22g

Complex Carbohydrate

18g

Sugars

4g

Dietary Fiber

9g

Protein

(1g=4 calories)

25g

Vitamin A 20% • Vitamin C 2% • Calcium 8% • Iron 45%

*Use this nutrition information to help you plan your total daily diet. The Dietary Guidelines recommend that Americans: Eat a wide range of foods. Choose a diet with plenty of vegetables, fruits, and grain products. Choose a diet low in fat (30% of calories or less), saturated fat (less than 10% of calories), and cholesterol. Use sugar, salt and sodium only in moderation.

COMPROMISE PROPOSAL

Nutrition Facts

Serving Size 1 cup (253 g)

Servings Per Container 1

Amount Per Serving

Calories 260

Calories from Fat 75

Daily Value*

Total Fat (1g=9 calories)	8.5g	53-93g
Saturated Fat	3.5g	18-31g
Cholesterol	35mg	300mg
Sodium	1010mg	2400mg
Total Carbohydrate (1g=4 calories)	22g	240-420g
Complex Carbohydrate	8g	
Sugars	4g	
Dietary Fiber	9g	18-32g
Protein (1g=4 calories)	25g	40-70g

Vitamin A 20% • Vitamin C 2% • Calcium 8% • Iron 45%

*This Daily Value is a reference only. Your Daily Value may vary depending on your calorie needs. Typical intakes for women are 1,600-2,200 calories, for men 2,000-3,000 calories and for children (ages 4-14) 1,800-2,500 calories. More information can be obtained from, Dietary Guidelines, Consumer Information Center, Pueblo CO 81002

RBZ copy

THE WHITE HOUSE
WASHINGTON

November 10, 1992

NOTE FOR SECRETARY BAKER

RE: Food Labeling Regulations

As I mentioned, this is one of the outstanding issues I've been working to resolve.

I've attached Secretary Sullivan's memo to you and my reply of the same day.

We're close to completing an options memo for POTUS, as we discussed. I'll give you an update when you return.

RBZ

THE WHITE HOUSE

WASHINGTON

November 9, 1992

MEMORANDUM FOR SECRETARY SULLIVAN

RE: **Food Labeling Regulations**

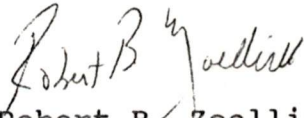
Thank you for sending me a copy of your memo to Secretary Baker of this date on the Food Labeling Regulations.

I share your disappointment that the interested parties have not resolved their differences to permit publishing of the regulations today. (I spoke to Secretary Madigan today after receiving your memo, and he is maintaining his position as well.) And as we discussed at our meeting, I know you appreciate that the draft regulations involve both the serious health issues you outlined and questions relating to the economics of the restaurant, grocery, and food production industries (and their related employment).

I also thought it was unfortunate that we could not agree to publish the final rule except for the few areas of disagreement. Under that approach, we could have proceeded with the numerous revisions in the proposed rules that HHS/FDA has decided to make. In the few, albeit important, areas of disagreement, we might have published either brief neutral language (drawing from the statute) or even the language FDA used in its notice of proposed rulesmaking (NPRM). We would have been no worse off than we will be once the NPRM becomes final today, and in fact would have been able to incorporate a large number of FDA's revisions. I understand there was some concern that this "interim final" approach would have been hard to draft or appeared unwieldy, but it does seem a shame not to have been able to try.

At this point, as we discussed, the only way I can see to resolve the remaining differences is to prepare an options memo for the President. We are doing that expeditiously, as I have discussed with your staff.

I know this issue is extremely important, appreciate the efforts of you and your staff, and hope that we can solve it rapidly so you can proceed.


Robert B. Zoellick
Deputy Chief of Staff
to the President



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D. C. 20201

NOV 9 1992

MEMORANDUM FOR THE CHIEF OF STAFF TO THE PRESIDENT

Re: Food Labeling Regulations

As you know, Secretary Madigan and I have met with Bob Zoellick to discuss differences Ed and I have over food labeling regulations. Based on those discussions, I am convinced our differences are not resolvable. While it would be desirable for our Departments to simultaneously issue consistent regulations, we are under no legal duty to do so. To the contrary, I am under a statutory mandate to have issued final food labeling regulations by November 8. If I do not act today, rules that we proposed last year take effect. These rules are strenuously opposed by industry and are more costly and regulatory than the rules I want to issue today. Furthermore, if I fail to act, our Administration will, as a practical matter, have forfeited this issue to the next Administration.

I initiated food labeling reform in 1990 by proposing regulations to require basic nutrition information on food labels, define such terms as "light" and "low fat", and permit claims linking diet with disease prevention benefits. In November 1990, President Bush signed the Nutrition Labeling and Education Act, which confirmed the general direction of my initiative and mandated promulgation by my Department of the detailed regulations now in dispute. Secretary Madigan issued a parallel set of labeling proposals covering meat and poultry products, but without a specific statutory mandate or deadline for final rules.

Food labeling reform is an integral part of Healthy People 2000 - our landmark disease prevention and health promotion initiative. We have learned over the past two decades that the incidence of heart disease and cancer in our country are strongly influenced by what we eat and can be significantly reduced if the intake of fat, saturated fat, cholesterol and sodium is brought within recommended dietary guidelines and fiber intake is increased.

My Department has developed final regulations that will provide consumers with reliable information they can use to select healthier diets. Our regulations are based on our specific statutory mandate, extensive research, and over 40,000 comments from consumers, industry and the public health community. It is not possible to please everyone in an undertaking of this complexity, but, on the key issues in dispute, our rules have broad public support. On the most important issue -- the nutrition label format -- the public health and nutrition communities strongly support our approach.

Page 2 - Memorandum for the Chief of Staff to the President

These rules are important to the public health and of fundamental importance to me as the Nation's chief public health officer. It is imperative I issue them immediately. My failure to do so places me in violation of my statutory responsibility, will cause enormous hardship for the food industry, and will likely mean that the final rules will be controlled by the next Administration. I simply must act. Secretary Madigan should be free to make his own decision about USDA's rules when he is ready to do so.

I genuinely believe the issuance of these regulations will be a proud and important legacy for the President and his Administration.

A handwritten signature in cursive script, reading "Louis W. Sullivan".

Louis W. Sullivan, M.D.

cc: ✓ Mr. Robert Zoellick

FDA/USDA Food Labeling
Positions and Possible Compromises

FDA

1. Light

1/3 less calories or 50% less fat; except that when > 50% of calories from fat -- then 50% less fat required

- 1. Lt in Sodium
- 2. diff %?
- 3. ~~Limit on total~~ No info below certain text

2. 3rd Party Endorsement

Health endorsements allowed if truthful and not misleading

3. Restaurants

FDA regulates menus; small business (under 11) gets 1 year delay; "reasonable basis standard"

4. Format

DRVs with % of a set daily value based on 2000 calories

Health Claim

Legal Basis

- Restaurants: - choice
- Legal Enforcement

- Male vs Female
- Unit 2000, 2500
- Give range

A

FDA and USDA use FDA guidelines to 20% meat; but if product > 20% meat, then USDA uses USDA guidelines; and for all USDA products, 50% less in sodium allows "light in sodium"

B

FDA regulates <2% meat; USDA regulates >2% meat (Go their own way")

C

1/3 less calories or 50% less fat; except that when 75% of calories from fat -- then 50% less fat would be required; and for all USDA products, 50% less in sodium allows "light in sodium"

USDA

1/3 less in calories; or 50% less in fat; or 50% less in sodium

No 3rd party endorsements

No regulation of restaurants

No daily reference values. List information in grams; footnote on dietary guidelines

- 1. OLC (Tim Flanigan)
- 2. Enforcement: Guidelines
- 3. Restaurant Act

Tim Flanigan

(a) Current rule w/o labels (b) 1st

1. Start reg req of restaurants
2. Start reg req of menus
3. ~~Current rule~~ (under labels) + labels need

C

Nutrition Facts

Serving Size 1 cup (253 g)

Servings Per Container 1

Amount Per Serving

Calories 260

Calories from Fat 75

(most of calories from fat)

Daily Value*

Total Fat <i>(19 - 22)</i>	8.5g	53-93g
Saturated Fat	3.5g	18-31g
Cholesterol	35mg	300mg
Sodium	1010mg	2400mg
Total Carbohydrate	22g	240-420g
Complex Carbohydrate	8g	
Sugars	4g	
Dietary Fiber	9g	18-32g
Protein	25g	40-70g

Vitamin A 20% • Vitamin C 2% • Calcium 8% • Iron 45%

*Ranges are based on recommended intakes and food consumption surveys. Advisable calorie, fat, carbohydrate, fiber, and protein intake should vary based on age, sex, height, weight, metabolism, and activity level.

Subst

Nutrition Facts

Serving Size 1/2 cup (114g)

Servings Per Container 4

Amount Per Serving

Calories 260 Calories from Fat 120

		% Daily Value	Daily Value* for 2,000 calorie diet
Total Fat	13g	20%	Less than 65g
Saturated Fat	5g	25%	Less than 20g
Cholesterol	30mg	10%	Less than 300mg
Sodium	660mg	28%	Less than 2,400mg
Total Carbohydrate	31g	11%	Less than 300g
Sugars	5g		
Dietary Fiber	0g	0%	25g
Protein	5g		

Vitamin A 4% • Vitamin C 2% • Calcium 15% • Iron 4%

*This Daily Value is a reference only. Your Daily Value may vary depending on your calorie needs. Typical intakes for women are 1600-2200 calories, for men 2000-3000 calories and for children (ages 4-14) 1800-2500 calories. More information can be obtained from, Dietary Guidelines, Consumer Information Center, Pueblo, CO 81002.

Mixed with
3 types of
unb

No range

Patented

Overcontrolled
eating
disorders

OK
w/ USDA

X

USDA FORMAT

DESCRIPTION:

- **Provides basic information about nutrient value of product.**

RATIONALE:

- **Meets the minimum obligations spelled out in the NLEA, disclosing information which enables consumer to calculate their intake.**
- **Does not excessively regulate or prescribe the diet.**
- **Solves the "any single value is wrong for most of the population" problem that comes with a single daily reference value.**

PROBLEMS:

- **Does not include information to allow consumers to make calculations to show relevance of disclosed information to the individual consumer's circumstances.**

A *v*Other Format Options

List grams with gram range
in daily footnote for
1,600/2,800 calories

B *e*

List grams with % DRV in
footnote for 1,600/2,800
calories

C *F*

List grams with a % of
median female diet and
median male diet

D *G*

List daily value at 1900 for
women, 2500 for men

INTERIM APPROACH

Cites are to current FDA draft preamble.

Preamble: FDA recognizes that it is not legally required to regulate claims on restaurant foods in a manner identical to that proposed for packaged foods. (p.460) Moreover, regulation of the restaurant industry must recognize that packaged foods and restaurant foods differ markedly in the way they are prepared and sold. (p.461) It is also true that the agency does not have the resources to adequately enforce its regulations in restaurants. (p.469)

Therefore, the agency will consider establishing regulations specifically for restaurant foods. (p.470) Those regulations will be forthcoming shortly and may recognize that there are other definitional criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, terms used for restaurant foods as compared to the same terms used on packaged foods. (p.469-470) The agency is also concerned that, at this time, a requirement for full nutrition labeling could be a significant barrier to the transfer of information about favorable nutritional characteristics of restaurant foods. (p.474)

Accordingly, as an interim final rule, the agency is adopting an approach whereby the statutory language of the NLEA is merely incorporated in the rule, but which leaves open the question of what constitutes restaurant "labeling" (ie, whether and to what extent menus are regulated as "labeling"). Further elaboration will be provided presently. FDA will also be working with USDA regarding parallel treatment of meat and poultry products.

Comments may be submitted for 30 days from the date of publication of this rule in the Federal Register. Comments previously submitted on the subject of restaurant labeling will be considered and need not be resubmitted.

Rule: "Restaurant Foods. Labeling used by restaurants is subject to 21 USC 343 (r) regarding nutrient claims, except that subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments."

purpose of such terms would be to help the consumer achieve a total diet that conforms to current dietary guidelines.

IV. Restaurant Foods

FDA received many comments regarding the proposed nutrient content claims criteria as they would apply to restaurant foods and to foods sold in other establishments in which food that is ready for human consumption is sold (e.g., institutional food service, delis, catering). In this discussion, such foods will be referred to as "restaurant foods," firms selling such foods will be referred to as "restaurants," and responsible individuals in these firms will be referred to as "restaurateurs." However, the concepts and policies discussed are intended to apply broadly to the foods covered by sections 403(q)(5)(A)(i) and (ii) of the act. *

#274. Several comments stated that because the 1990 amendments are silent with respect to requiring restaurant foods to comply with the requirements for nutrient content claims, FDA is not legally required to regulate such claims for restaurant foods in a manner identical to that proposed for packaged foods. See p 16

FDA disagrees with the comments that the 1990 amendments do not apply to nutrient content claims made for restaurant foods. As explained in the general principles proposal (56 FR 60428), >

the 1990 amendments, read together with the very explicit statements in the legislative history (136 Congressional Record H5841 (daily ed. July 30, 1990)), fully support the agency's proposal in § 101.13(o)(5) (redesignated as § 101.13(p)(5)) that a nutrient content claim may not be used for food that is served in restaurants or other establishments in which food is served for immediate human consumption, or for food that is sold for sale or use in such establishments, unless the claim is used in a manner that is authorized by a definition that FDA has adopted.

on
require

However, FDA agrees that it is not legally required to regulate claims on restaurant foods in a manner identical to that proposed for packaged foods. In fact, Congress recognized that special provisions were necessary by explicitly exempting restaurants from section 403(q), the referral and disclosure requirements in section 402(r)(2)(B), and certain of the requirements in section 402(r)(2)(A). FDA's regulations incorporate these exemptions. While it is not required that the regulatory criteria governing claims for restaurant-type foods be identical to those governing other foods, it is only logical that, if claims on foods are to be useful for consumers, the criteria for those claims must be consistent.

recog difference

Therefore, the agency has determined that additional flexibility is needed to facilitate the helpful provision of nutrition information on restaurant foods, but that there must be

assurance that the claims being made are valid. How FDA intends to achieve this degree of flexibility with appropriate assurance is discussed in the agency's responses to the following comments.

#275. Several comments stated that restaurant menu items should be required to comply with the proposed requirements for nutrient content claims. Some comments stated that many menu items are centrally manufactured and conform to system-wide composition and quality standards. Therefore, many restaurants and restaurant chains, especially the larger ones, already have access to the nutrition information necessary to verify claims about their products. Finally, these comments stated that portion control of foods is practiced by many restaurants to control their food costs, and that this control will facilitate compliance by the industry.

Include?

Some comments stated that the proposed regulations governing nutrient content claims would be impracticable for the restaurant industry because packaged foods and restaurant foods differ markedly in the way they are prepared and sold. For example, variability in the nutrient level of individual foods sold in restaurants foods occurs as a result of: (1) seasonal, regional, and market variations in ingredients; (2) differences in preparation methods of similar foods; and (3) consumer preferences in terms of how food is prepared. The comments pointed out that these variabilities would require repeated

costly analyses to determine if each menu item meets the criteria for the content claim. The comment cited additional, complicating factors such as: performance of 100 gram calculations for meal-type products; inadequacy of current databases on nutrient levels in many foods for validating nutrient content claims; and variations in recipes for restaurant foods. One comment estimated the cost of compliance in terms of redoing printed menus in the commercial sector of the foodservice industry to be more than 500 million dollars. Additionally, the comments assert that costs associated with product development, testing, preparation, marketing, and staff training will be required. For these reasons, these comments requested that FDA exempt restaurant foods from the requirements for nutrient claims it is establishing in this rulemaking.

Several comments stated that the proposed regulation for nutrient content claims for restaurants is not the least restrictive alternative available to FDA, in accordance with Executive Order 12291, because it would essentially eliminate a foodservice operator's ability to communicate meaningful nutrition information to consumers and create a disincentive for foodservice operators to develop healthful foods. These comments said that substantial costs of compliance with the new regulations would be passed on to consumers, and the small business segment of the industry would be especially adversely affected. The alternatives suggested by the comments are: (1)

develop definitions for foodservice oriented descriptors; (2) develop voluntary guidelines for foodservice that specify how foodservice operators should provide nutrition information, or (3) establish a standard set of criteria concerning a recommended daily diet so foodservice operators could flexibly and reliably design meals that may be promoted as healthful.

Several comments specifically addressed the use of the term "light" on restaurant foods. One of these comments said that "light" used on a restaurant food or meal should have the same meaning as when placed on a packaged food. Another comment said that "light" should mean only a reduction in calories and that it should be restricted for meal-type products, salt substitutes and for describing physical or organoleptic attributes. One comment said that "light" as used in a restaurant can mean a wide variety of things from lighter texture, color or consistency or overall healthiness than another menu item and that the current definition is too restrictive. A comment from a restaurant chain recommended that "light menus" refer to total meal packages that have at least 25 percent less fat, cholesterol, sodium, or calories than the traditional menu selections. This comment contended that a restaurant meal will take the place of at least three servings, and that a 25 percent reduction would be significant in terms of total diet.

Other comments were less specific in addressing the issue of

restaurant foods or meals bearing relative claims. One of these comments said that relative claims should be permitted for total meal packages at restaurants. Another of these comments said that for relative claims, a restaurant should compare a product to the restaurant's own product.

Given that almost half of the American food dollar is spent on food consumed away from home, and that perhaps as much as 30% of the American diet is composed of foods prepared in food service operations, FDA believes that, from an overall public health perspective, this important segment of the diet can not be ignored. Further, FDA believes that dietary information provided to consumers at point of purchase in restaurants and other food service operations can be useful in helping Americans in maintaining healthy dietary practices. FDA wants to encourage the provision of such information. However, FDA firmly believes that consumers expect, and deserve, that the claims made at point of purchase are truthful and not misleading. The act requires that labeling be truthful and not misleading and information, including claims, provided at point of purchase is labeling.

RL
Some >
(vs half)

FDA advises that not all claims made for restaurant foods are necessarily the type of claims that are covered by the 1990 amendments. For the sake of clarification, the agency offers the following observations. Statements such as "lightly breaded," "light crust," or "light sauce" are not nutrient content claims

At this time

covered by the 1990 amendments. Moreover, because of the importance of context, statements such as "Light Fare," "Lite Bites," or "Light Entrees" on a restaurant menu will not be considered nutrient content claims, provided the menu offers an explanation of the basis for the terms that make clear that they are not intended to characterize the level of a nutrient. For example, a term such as "Lite Menu" followed by an asterisk referring to a note that makes clear that in this restaurant "Lite Menu" means smaller portion sizes than the normal menu would not be considered a nutrient content claim under section 403(r) of the act. In most cases, a prominently displayed disclaimer or information that clearly explains the basis for the use of the term and does not characterize the level of a nutrient in the explanation will be sufficient to remove that use of the term from the coverage of the 1990 amendments.

Cut?

Similarly, a restaurant may be able to use symbols next to menu items where the symbols are clearly explained in terms that would not subject the claim to the 1990 amendments. For example, the use of a star symbol next to entrees, where the symbol is explained in a footnote stating that these items are broiled with no added oils instead of fried, would not be subject to the 1990 amendments.

Menu

Also, a menu may use symbols or make reference to the criteria of a health professional organization or accrediting

Menu

group and explain that the entree or meal is consistent with the general dietary guidelines of that group and not be subject to the 1990 amendments. For example, use of a heart symbol with reference to a note that explains that this entree is consistent with the dietary guidelines of the American Heart Association will be considered dietary guidance, and not a nutrient content or health claim subject to section 403(r), provided the explanation does not characterize the level of a nutrient.

Finally, a restaurant may be able to devise menu items or complete meals that are formulated in complete accordance with the Dietary Guidelines for Americans (e.g., moderate calories, less than 30% calories from fat, less than 10% calories from saturated fat, emphasis on vegetables, fruits, and grain products, moderate use of sugars and sodium, etc.). FDA encourages such actions, because a meal, especially a restaurant meal, represents a significant portion of the day's consumption, as compared to an individual food product. A restaurateur may signal to customers that the meal is formulated in accordance with Dietary Guidelines and FDA will consider such signals to be dietary guidance, and not nutrient content claims under the 1990 amendments. The agency will evaluate the validity of such claims on the basis of their being truthful and not misleading under section 403(a) of the act. However, if the restaurateur went on to characterize the level of nutrients in the food, it would subject the food and the claims for the food to the nutrient

Intros

content claim regime. When a restaurant uses a defined term such as "low calorie", or uses the term "light" without further explanation, or uses a term or symbol that is explained in such a way that states or implies levels of nutrients in terms defined by FDA, it must comply with FDA's definitions of those terms.

How the restaurant demonstrates compliance with those definitions is a difficult matter. FDA recognizes that, as detailed in the comments, there are variations in the nutrient values for restaurant foods. Some of these variations are not unique to restaurants; manufacturers of packaged foods also have to deal with differences in nutrient levels due to seasonal, regional, and supplier variations. FDA has been able to develop workable criteria that take into account these variations. However, the agency acknowledges that there are variations unique to restaurant foods (methods of preparation, etc.). Moreover, FDA recognizes that there are difficult questions, as demonstrated by the comments, as to how exactly to analyze restaurant foods in a reasonable and cost effective manner.

While there are difficulties associated with restaurant foods, FDA concludes that the difficulties are not so great as to preclude restaurants from making claims or to prevent the agency from being able to assure consumers that the nutrient content claims that appear on restaurant foods reasonably reflect the nutrient content of the food. Thus FDA is providing in §

101.13(p)(5) that a restaurant food may bear a nutrient content claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the definition for the claim that FDA has established under section 403(r)(2)(B)(i) of the act. Thus, if a restaurateur labels a fish dish as "low fat", he or she must have a reasonable basis for believing that the product complies with FDA's definition for "low fat," that is it contains less than 3 grams of fat per 100 grams. The reasonable basis can be provided in a number of ways. The restaurateur can show, for example, that FDA's guidelines on nutrition labeling of seafood shows the fish to contain less than 3 grams of fat per 100 grams in the serving and the method of cooking and other foods used in the main dish would not add fat. In addition, the restaurateur could show that he or she relied on a reliable cookbook that gave values for fat in the finished food that were less than 3 grams per 100 grams. Certainly other methods are possible. If a restaurateur uses recognized data bases for raw and processed foods to compute nutrient levels in the foods or meals and then does not use methods of preparation that violate the appropriate use of data bases (e.g., uncontrolled addition of ingredients, inappropriate substitutions of ingredients, etc.), FDA will consider this to be a reasonable basis for assuming that the food meets the criteria for a defined nutrient content claim. Upon demand, the restaurateur will be expected to present to appropriate regulatory officials information on the pertinent nutrient levels in the foods and the

basis on which these levels were determined. In addition, the firm must be prepared to provide reasonable assurance of operational adherence to the reasonable basis criteria, such as recipes, types and amounts of ingredients used, preparation methods, etc. on which the claim is based. The agency will then determine whether the basis of calculation reasonably supports the restaurateur's use of a nutrient content claim such as "low calorie" or "low fat".

This reasonable basis for nutrient content claims will provide regulatory officials, especially State and local authorities, with an effective standard for verifying that claims made for restaurant-type foods are truthful and not misleading and in accordance with FDA regulations. While nutrient content claims used in restaurants are under FDA's jurisdiction, the agency does not have resources to adequately enforce its regulations in restaurants. State and local authorities have traditionally carried out this responsibility. In addition, section 4 of the 1990 amendments provides that state and local authorities may enforce section 403(r) of the act in Federal Court.

Produce

Although it has arrived at an approach that will provide for nutrient content claims on restaurant foods on the date that section 403(r)(2) will be applied, FDA does not consider the problem of restaurant food to be solved. It is possible that

there are other definitional criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, terms used for restaurant foods as compared to the same terms used on packaged foods. If this is the case, a different glossary of terms for use in restaurants may be appropriate. However, at this time, the agency simply does not have the data or knowledge on which to base such determinations. FDA is working, and will continue to work, with the restaurant industry to determine how terms are used on restaurant foods and whether such terms are appropriate. For example, with FDA's cooperation, the National Restaurant Association has undertaken a survey of industry use of nutrition information on menus and of consumer knowledge, practices, expectations, and understanding of various terms and symbols on restaurant menus. [sentence will have to be dropped if NRA does not come through.] FDA is open to petitions for different criteria for nutrient content claims for restaurant foods and, if data warrant, the agency will consider establishing regulations specifically for restaurant foods.

Check

FDA also recognizes that there are a number of significant issues concerning the adequacy of currently existing data bases for use to compute nutrient levels in restaurant meals. However, the agency is working, and will continue to work, with the restaurant industry to assess the adequacy of these data bases

and to encourage the development of additional or newer data where those data bases are found to be lacking.

In developing more specific policies, FDA will also consider whether restaurant foods should be afforded greater latitude in the compliance criteria than the criteria that are currently applied to nutrient variations in processed foods. FDA regulations state that, for naturally occurring vitamins, minerals, and protein, the nutrient content must be at least 80 percent of the value declared and for calories, carbohydrate, fat, and sodium the level must not exceed the declared value by more than 20 percent. The agency recognizes that all data bases have inherent variabilities and a computed nutrient level for a food with several ingredients may have an accumulated variability that exceeds the agency's criteria for packaged foods. FDA is concerned about the accuracy of nutrient level estimations, but pending the development of better data, the agency will accept, as a reasonable basis, claims verification based on nutrient levels from recognized nutrient data bases, without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses. The agency is open to comments and suggestions on how nutrient variability issues should be addressed for restaurant foods and will continue to work with the industry on this issue.

Shif
CCir
deudo

#276. One comment stated that the use of the terms "healthy" or

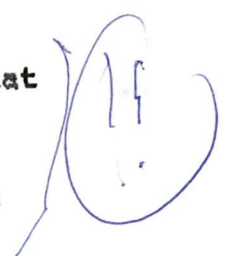
"healthful" on meal-type products is necessary for restaurants to assist the consumer in identifying the choices that fit an eating pattern consistent with general chronic disease prevention. This comment further stated that disqualifying levels for fat, saturated fat, sodium and cholesterol should be set in order to prevent inappropriate foods from bearing this descriptor.

As with the other issues involving "healthy," the agency requests comments and information with respect to whether the agency's tentative definition of "healthy" is appropriate for restaurant meals and main dishes. In order to consider whether there should be separate provisions for the term "healthy" for restaurants, the agency requests information on the extent to which restaurant meals, main dishes or individual foods provide more calories than do meal, main dish, or individual food products in supermarkets. The agency also requests comments on whether consumers would be confused by separate criteria.

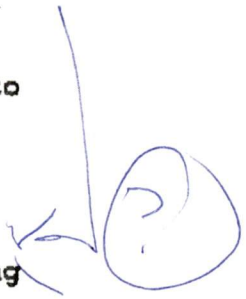
Include

#277. Several comments agreed that FDA has authority to require nutrition labeling when nutrient content claims are made on restaurant foods and stated that nutrition labeling should be required on restaurant foods bearing claims. These comments generally contended that restaurants should be required to follow the same nutrition labeling requirements as food manufacturers when nutrient content claims are made.

Many comments expressed the opinion that FDA does not have authority to require nutrition labeling when nutrient content claims are made on restaurant foods, and stated that nutrition labeling should not be required on restaurant foods bearing nutrient content claims. These comments generally contended that since the act exempts restaurant foods from nutrition labeling, FDA should allow for the nutrition labeling of restaurant foods on a voluntary basis.



FDA finds nothing in the comments to persuade the agency to adopt a position different from that stated in the general principles proposal (56 FR 60427). The agency continues to believe that it has the authority to issue regulations requiring restaurants that make nutrient content claims to adhere to the requirements for such claims including nutrition labeling. However, based on considerations discussed in the response to the previous comments, FDA has decided not to require nutrition labeling at this time.



#278. A few comments stated that, if nutrition labeling were required for restaurant foods bearing nutrient content claims, restaurants would not make such claims because restaurant foods are not standardized, and it would be too costly to provide accurate nutrition information for these foods. The comments also stated that mandatory nutrition labeling (when a claim is made) would inhibit restaurants from making frequent and more

healthful menu changes.

Full nutrition labeling provides the consumer with a way of evaluating a claim within the nutrient context of the food or meal and, therefore, is advantageous in allowing more informed comparisons. However, in the general principles proposal (56 FR 60427) the agency recognized the difficulty of providing nutrition labeling for restaurant foods and asked for comment. The comments have persuaded the agency that, at this time, a requirement for full nutrition labeling could be a significant barrier to the transfer of information about favorable nutritional characteristics of restaurant foods. Therefore, FDA is not requiring that full nutrition labeling be provided when a nutrient content claim is made for restaurant foods. However, the agency is adopting a slightly different approach to the provision of nutrient information to the consumer, as explained in the response to the next comment. The agency does, however, encourage the voluntary provision of full nutrient information for restaurant foods, even when claims are not made.

#279. Some comments stated that if nutrition labeling were required for restaurant foods bearing a claim, restaurants could utilize available nutrition software programs and recognized databases to provide the necessary information for the nutrition label. One comment stated that FDA should develop educational materials for restaurants that explain their obligation not to

make nutrient or health claims on their menus without providing nutrition labeling. A few comments stated that before requiring mandatory nutrition labeling of restaurant foods bearing nutrient content claims, a pilot study should be done to determine the cost and feasibility of such labeling, and that more study is needed before the agency requires labeling on restaurant foods.

FDA believes that consumers should have information about the nutrient content of restaurant foods for which nutrient content claims are made. At a minimum, for example, if a meal is characterized as being "low fat," the consumer should know the fat content of that meal. Therefore, the agency will require that if a restaurateur claims that a meal is "low" or "high" in a nutrient or uses other defined nutrient content claims, he or she must be prepared to advise the consumer about the nutrient amounts that are the basis for the claim, (e.g. "low fat", this meal provides 10 grams of fat). For the interim, the agency will consider that the provision of this limited amount of information to consumers will serve as the functional equivalent of nutrition labeling.



FDA agrees with the comments that educational programs and further study will be helpful. However, the statutory timeframes imposed on the agency by the 1990 amendments do not afford FDA the luxury of deferring, until some future time, all rulemaking on restaurant foods. The agency recognizes the limitations in

the approach it is taking and encourages the restaurant industry to continue to work with FDA to devise a program that will provide consumers with truthful and accurate nutrition information, without at the same time inhibiting the flow of such information or the development of healthier foods. The agency points out that the conduct of feasibility and consumer studies in this area is more properly the responsibility of the regulated industry, and that FDA is currently working with the industry to do such studies.

#280. One comment stated that § 101.10 should be deleted because it would be outdated if nutrition labeling requirements are imposed for restaurant foods bearing claims.

The agency agrees that § 101.10 is outdated and is revising these provisions to reflect its determinations concerning application of 403(r) of the act to restaurant foods. The agency believes that information in § 101.10 was useful in advising firms that wished to voluntarily declare full nutrition information and revised § 101.10 will continue to provide this advice. The new provisions reflect the agency's determinations about use of nutrient content and health claims on restaurant foods through a reasonable basis determination of the nutrient levels that qualify a food for a claim and the requirements for the presentation of nutrition information to the consumer when a nutrient content claim is made.

#281. Other comments addressed specific issues of nutrition labeling for restaurant foods, such as whether the requirement for nutrition labeling of restaurant foods should apply only to large restaurants with fixed menu items, and whether the content or format of nutrition labeling should be different for the foodservice industry than for packaged foods.

FDA will address these issues in its further deliberations and in its continued interactions with the regulated industries. The agency is likely to seek comment on a number of these issues in the future.

V. Petitions

In the general principles proposal (56 FR 60458), FDA proposed to establish procedural regulations to govern the submission, content, and agency review of the three types of petitions authorized by section 403(r)(4) of the act (i.e., petitions for nutrient content claims, for synonymous terms, and for the use of an implied claim in a brand name). The agency also proposed to redelegate to the Director and Deputy Director of the Center for Food Safety and Applied Nutrition (CFSAN) all of the functions of the Commissioner relating to petitions for label claims under section 403(r) of the act involving non-controversial issues. Further, the agency reiterated its interim

- Take an effort to work out : 4 or 5 left
- Really difficult : ~~Unfortunately I have diff rules for meat + non-meat~~
- See if we work thru, find common ground
- One-by-One

- Def'n of Light
- 3rd Party endorsement
- Restaurant
- Format

- Comparative Claims,
Disclaimer
DTRA

• Non-Non 9/9 NPRM

- Doesn't go into effect for 18 mos!