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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Food Labeling; Nutrient Content Claims, Definition of Sodium Levels For The Term "HEALTHY"; Docket Nos. 91N-304H AND 96P-0500.

ConAgra Foods, Inc. ("ConAgra") is the second largest food company in America, with approximately \$20 billion in annual sales to retail, wholesale, mass merchandisers, club and foodservice channels. ConAgra Foods employs nearly 67,000 people. Major brand names include *Healthy Choice, Banquet, Armour, Chef Boyardee, Butterball, Reddi-Wip, Egg-beaters, Orville Redenbacher, Hunts, Hebrew National, PAM, Gulden's, Swiss Miss*, and many others.

Even before the Nutrition Labeling Education Act of 1990 ("NLEA"), Healthy Choice was in the market with nutritional information on its product labels, and a "healthy" product line. Since its launch in 1988, Healthy Choice has played a pivotal and critical role in FDA's nutrition labeling policy, and continues to be the most successful healthy product line sold nationally.

Healthy Choice began as an idea in 1986, when then ConAgra CEO Charles "Mike" Harper suffered a mild heart attack. His doctor told him to exercise; avoid stress, tobacco and alcohol; and to eat foods lower in fat, cholesterol, and sodium. The first two prescriptions were easy to fill, but much to Harper's surprise, there were almost no foods on the market that fit the third prescription and had any taste.

There were the low calorie, but high sodium "diet" items, and there were "low" sodium products like the Pritikin Diet soups that had no flavor and were virtually uneatable. Soups were especially hard to find, so hard, in fact, that Harper's wife had to come up with homemade recipes - forming the basis of the first Healthy Choice soups.

During 1987 and 1988, ConAgra looked for food scientists who could help create foods that were balanced nutritionally and tasted good. Working with nutritionists and specialists from across the country, ConAgra developed the first line of nutritionally balanced meals, and in the fall of 1988, Healthy Choice products entered the market. The consumer response was such a huge success that Healthy Choice meals began national distribution in January of 1989.

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Unlike today, in the late 1980's food companies were not required to print their nutritional information on food product packages. But two years prior to the NLEA, and **six years** prior to mandatory labeling regulations, Healthy Choice did put nutritional information on its packaging. The Healthy Choice packages educated consumers through the use of simple pie charts to demonstrate how the food fit into a daily diet consistent with such nutritional authorities as the American Heart Association, the National Institutes of Health, and the National Heart, Lung and Blood Institute, and following guidelines established by the Surgeon Generals.

Because of its work in food and nutrition, and its experience with nutritional labeling, Healthy Choice met with FDA frequently between 1990 and 1994 as that agency was developing labeling regulations consistent with the mandate of the NLEA. By the time the 1994 implementing regulations came out, Healthy Choice had already been in the market six years with voluntary nutritional labeling on a wide variety of products.

Healthy Choice was there first. Before Congress saw a need, before FDA drafted regulations, before competitors created "me-too" products, Healthy Choice was there filling a real need for palatable, healthy products.

After Healthy Choice created the "healthy" category and publicized it, soup giant Campbell's, whose sodium line average at the time was around 975mg per serving, eventually launched their Healthy Request soup line to compete with Healthy Choice.

More Healthy Choice products came along as ConAgra Foods utilized it's expertise to develop healthier versions of popular, yet nutritionally inferior food products such as hot dogs, hamburger and deli/lunch meat. However, the original "healthy" regulations published in 1994 killed a very popular "healthy" product at the time – a nutritionally controlled and tasty hamburger – leaving consumers with no "healthy" hamburger alternative on the market.

ConAgra Foods is concerned that FDA's current Proposal will do a similar disservice to consumers by causing the disappearance of whole categories of healthy food products from the market, and thus further limit consumers' choices. While the Proposal makes what appears to be an impressive showing of statistics, biomedical analysis and business predictions, the truth is that none of the rhetoric can overcome the facts –

- Healthy Choice foods remain the stalwart "healthy" products in the marketplace in the categories in which these products are sold. FDA should not use regulations to erode the progress that has been made in healthier food alternatives. Nor should FDA allow manufacturers of non-healthy products to use labeling regulations to prevent consumers from having healthy alternatives, or impede FDA's health policy; especially when one of those

- manufacturers is selling a “healthy” labeled soup in Canada with far more sodium than “healthy” regulations allow in the United States;
- Obesity is the number one contributing factor for terminal diseases, yet FDA is focusing resources pursuing already low levels of sodium contained in less than 1/10th of one percent of the food supply;
 - The FDA has *not* focused on the much higher fat and sodium levels in the other 99.9% of the food supply;
 - Taste receptors inside the human tongue require the shape and size of the sodium chloride ion in order to register a salty taste, and in that respect the salty taste is physically unique as there are no substitutes the tongue will accept;
 - These physical limitations in human taste perception make creating palatable, lower sodium versions of some products impossible, no matter how much one would wish it were otherwise;
 - Public health policy (and FDA’s own stated goals) forbids FDA from depriving the public of “healthy” product offerings that are, in many cases, up to 50% less in sodium than their unregulated counterparts, simply because those products *cannot* get to an arbitrarily set lower sodium limit; and
 - The Proposal is arbitrary, capricious and unfairly discriminates against those companies who pioneered “healthy” eating, and those companies who persevere and continuously strive to consistently provide consumers a wide range of healthy alternatives to less healthy product offerings.

ConAgra Foods agrees with FDA that blood pressure levels in this country are too high for many people. As noted above, even before FDA began to think about a definition for “healthy”, and before the NLEA mandated labeling regulations, Healthy Choice was already advocating for, and creating, healthier versions of popular, but nutritionally inferior products. Today, the roles apparently have not changed -- FDA is still focused on sodium, while Healthy Choice recognizes that the best way to combat obesity, high blood pressure and disease is by offering a reasonable level and balance of all of the nutrients of concern, and ensuring a variety of such products to tempt the palate of a populace generally unconcerned with nutritional issues. The FDA claims that its intentions are to provide health based options for the consumer, but instead these actions will result in the opposite. As a result of this Proposal, consumers will have even fewer healthy options because many Healthy Choice products will be regulated out of existence.

We respectfully request that FDA withdraw the second tier sodium levels for individual foods, just like it did for meal type products, because such levels are counterproductive for society. To jump off a thought from CSPI, this brand does not promise to be the “perfect choice”. Just the healthy one.

In this Proposal, FDA seeks comments on lowering the sodium level required for "individual" foods to be labeled "healthy", and seeks comments on its proposal to maintain meal-type products at 600mg, among other issues. ConAgra Foods agrees with FDA's extensive analysis and outcome on the meals' sodium level, but respectfully submits that the same in-depth analysis was not done on individual food products. Based on our research and analysis, had FDA gone through the same rigor and compiled the most current data, FDA would have concluded that individual products must also remain where they are – at 480mg per serving. A summary of our comments and analysis follows.

COMMENT SUMMARY

1. In 1994, FDA and USDA published consistent Final Rules regarding a definition for the alleged implied nutrient content claim "healthy". FDA's stated goal was to develop criteria that would allow for a sufficient number and variety of products to be called "healthy", yet stringent enough so that "healthy" products could fit within dietary guidelines. (See page 7 herein.)

2. However, even under current sodium levels, production and consumer acceptance are difficult, and the number of manufacturers willing to produce and market healthy labeled products has dropped precipitously. For the most part, Healthy Choice has persevered in spite of the production difficulties created by to the low nutrient requirements, and as a result, is the only legitimate healthy product line serving consumers in 8 of the 9 categories in which it competes. (See pages 8-9.)

3. FDA states there are over 800 products that have a "healthy" claim on them. To prove its point, however, FDA relies on products like chewing gum and sugar substitutes. Labels for these products were counted in the "healthy" list because they contain ingredient warnings that saccharin and phenylalanine are bad for your "health". Certainly FDA would not permit these manufacturers to use "healthy" as a nutrient content claim, so why would FDA permit this kind of misleading "data", which is repugnant to the serious business of creating truly healthy products for consumers, to be used to "prove" that "healthy" products exist? (See pages 13-15.)

4. Taste, food safety and manufacturing issues preclude hot dogs, processed meats, cheeses and soups to be made to consumer's expectations at a sodium level of 360mg. Hot dogs fall apart at this level, processed meats have significant textural issues and reduced microbial protection (in fact, recent USDA regulations *require* an increase in antimicrobial substances such as sodium lactate), and consumers have repeatedly demonstrated with their pocketbooks and through taste tests that they will not eat these products at 360mg. (See pages 15-27.) Furthermore, attempting to set one sodium maximum for the huge variety of products ranging from single carrot sticks to breakfast sandwiches to soups is not logical.

Because consumers will not buy products at the lower sodium levels, companies cannot sell them because retailers will not stock failing products and so will take them off the shelf. The net result is that companies will be forced to discontinue selling these products. Several of the Healthy Choice products fall into the "impossible to make foods" at the 360mg level (e.g., soups and processed meats). These products represent almost half of the Healthy Choice product line.

5. Healthy Choice products make up less than 1/10th of one percent of all food sales, and less than 2/10th of one percent of all grocery sales. (See **Exhibit 3-A**.)

These facts demonstrate at least three things:

- Consumers overall buy relatively few "healthy" products even at the present sodium levels.
- Lowering the sodium 120mg for a product line with already reduced sodium will have no positive affect on public health.
- Reducing the sodium levels on Healthy Choice products even further will force a number of healthy products off the shelf, leaving only higher sodium alternatives, thus actually *increasing* the levels of sodium consumed because of the lack of alternatives.

6. When Healthy Choice is forced off the shelves in these categories by regulatory action, consumers are left with much higher sodium alternatives. Consumers look to Healthy Choice for a balance of a number of nutrients. With Healthy Choice no longer on the shelf, consumers cannot be expected to take the time to search through hundreds of product offerings, looking for the next best sodium alternative ... assuming there even is one. Instead, consumers can be expected to take the path of least resistance and go back to what is readily available; i.e., whatever is typical in the market. For some of these product categories, "typical" is upwards of 800, or even 1,000mg's per serving; more than double Healthy Choice's current sodium level. (See **Exhibit 18**.)

7. Healthy Choice has had an incentive affect on the market. A number of competitive "me too" products were created specifically to compete with Healthy Choice, but companies found manufacturing such items a difficult task. When the anchor brand is drummed out by regulation, there will no longer be an incentive for less health-conscious suppliers to compete for nutritionally responsible consumers, or to enter the competitive set. The impact on public health and consumer choice is more dramatic than simply considering the impact of Healthy Choice exiting the market as a singular event.

8. There are no viable salt substitutes. Food scientists working in this arena have repeatedly told ConAgra Foods that there are no viable salt substitutes, and they do

not expect to find any for a long time. These experts have also advised the FDA of the same issues on numerous occasions. (See pages 15-17.)

9. Achieving current standards is a difficult task. Future proposed standards are impractical, and potentially impossible while maintaining palatability. Contrary to FDA's assertions, there have not been a significant number of truly "healthy" product introductions in the past 5 years. Since 1998, 76% of new "healthy" product offerings have been Healthy Choice. During that time, there were less than 80 new "healthy" product offerings, or about 16 a year, but in that same time frame there were approximately 20,000 "non-healthy" product offerings *every year*. (See page 9.)

10. Tier 1 sodium levels appear to have succeeded in lowering the overall sodium levels in foods; at least in the categories in which Healthy Choice competes, and in spite of the relatively low volume of "healthy" labeled products. For example, in the case of ready-to-serve soups, the *average* sodium content/serving of soup was reduced by 32mg/serving from roughly 882mg/serving prior to the implementation to the current 850mg/serving. Dropping even lower to Tier 2 levels, however, will backfire, forcing some Healthy Choice products off the market, causing sodium levels in non-regulated products to increase, and thus create an overall **increase** in sodium consumption. (See pages 9-13, and 21.)

11. Healthy products like Healthy Choice balance all nutrients of concern, plus have required "positive" nutrients, unlike products touting "lean" or "low-fat". For example, Lean Cuisine has no sodium requirement, nor any positive nutrient requirement. Products like Weight Watchers, Campbell, and Oscar Mayer have no criteria at all. Balancing low fat and greatly reduced sodium is extremely difficult and food products that balance all nutrients should be protected, nourished and encouraged. FDA should not make rules to drive products that fit into a "healthy" diet off the market, or allow unregulated manufacturers to undermine FDA's health goals. This is especially important **when a major U.S. manufacturer is selling "healthy" labeled soup in Canada at sodium levels far exceeding what is legal in the U.S.**, and with sodium far exceeding what that manufacturer claims is "palatable" (See page 19.)

12. The Surgeon General has stated that obesity is an epidemic in this country and costs billions of dollars annually. The U.S.A is not a country of unlimited resources, yet this target on sodium appears out of touch with the efficient use of resources, inasmuch as society should be spending its resources on:

- a. Educating society on balanced nutrition;
- b. Educating consumers regarding, and controlling, obesity; and
- c. Impacting high sodium products instead of attacking products with already lowered sodium that are also low in fat.

13. To be sure that resources are used effectively, Tommy Thompson, Secretary of Healthy & Human Services, has stated that food companies should be encouraged and rewarded for creating healthy products – yet this Proposal would do exactly the opposite and force products that are low in fat, saturated fat and cholesterol, and already lower in sodium, from the market by setting impossible sodium standards.

14. Consumer's are not privy to the nuances of regulatory actions, and are confused when standards are arbitrarily changed.

15. Finally, given the facts stated above, this proposed regulation unfairly discriminates against one company; the company that pioneered "healthy" products and which currently has the only healthy branded products in several food categories, as it will cause ConAgra Foods to lose nearly half of its Healthy Choice product line. FDA has no scientific or legal basis to effect such an unlawful taking.

I. INTRODUCTION

In the May 10, 1994 Final Rule defining "healthy" (59 FR 89; pg. 24232), FDA stated that its...

"...goal in defining 'healthy' is to define the term in such a way that it will highlight foods that, because of their nutrient content, will be most helpful to consumers in constructing a diet that is consistent with dietary recommendations." *Id.* at 24233.

When creating the definition, however, FDA stated "the agency would consider it inappropriate if the definition of "healthy" were to exclude an entire category of foods that is recommended in dietary guidelines." *Ibid.*

Furthermore, the FDA concluded ... "that a definition that required 'low' sodium would be too restrictive because such a requirement would disqualify many products that would be useful in maintaining a diet that conforms to current dietary guidelines.... The agency believes that for the claim to be useful, foods that are able to bear the claim should be of sufficient number and variety to help consumers achieve a total diet that is consistent with dietary guidelines." *Id.* at 24239.

Finally, in the FDA's partial Stay of the Final Rule on April 1, 1997 (62 FR 62, pg 15390), FDA stated:

"If the petitioner is correct that the technology does not yet exist that will permit manufacturers to produce certain types of low fat foods that will contain lower levels of sodium required by January 1, 1998, and still be acceptable to

consumers, then the possibility exists that 'healthy' will disappear from the market for such foods. **If this situation comes to pass, FDA will have squandered a significant opportunity.**" Id. at 15390.

II. A SQUANDERED OPPORTUNITY

FDA may well have "squandered a significant opportunity." According to data obtained from Information Resources, Inc. ("IRI"), Healthy Choice is the only healthy product offering in fully 8 of the product categories in which it competes, and is 1 of only 3 offerings in the remaining category, soup. This means that of the thousands of products making up luncheon meats, ice cream and ice cream novelties, frozen meals, popcorn, spaghetti sauce, hot dogs, and precooked sausages, only one company has a healthy labeled product among the products tracked by IRI (which is based on census scanner data collected weekly from more than 32,000 supermarket, drug and mass merchandising outlets across the U.S.).

Critics will contend that the absence of healthy labeled products does not automatically mean that all of the previously healthy labeled products that are now gone have disappeared solely due to the sodium requirement – a statement which would be true.

However, this commenter's vast experience with healthy labeled products, and a case history of the product offerings over the last 8 years, indicates a strong correlation between sodium levels and product failures.

In our March 31, 1997, Supplementary Comments to our 1996 Petitions to FDA and USDA (the "Supplementary Comments"), we tracked the development, and the demise, of products competitive to Healthy Choice. Those Supplementary Comments, attached as **Exhibit A**, clearly demonstrate on pages 3-10 that major competitors such as Oscar Mayer in meats and Progresso in soups, dropped "healthy" brand names after the 1994 "healthy" definition went into effect, and kept their sodium at higher, but far tastier levels.

For example, Oscar Mayer Healthy Favorites hot dogs had 550mg of sodium pre-healthy definition, but in May of 1995 dropped the Healthy Favorites name in favor of Oscar Mayer Free. The product claimed "no fat", but had 509mg of sodium.

Then in 1997, sodium levels of Oscar Mayer Free hot dogs went up to 539mg. Healthy Choice hot dogs, the lowest sodium hot dogs on the market and still low in fat, are at 440mg. FDA wants them even lower, at 360mg.

Kraft also found it could not sell "healthy" cheese after sales of its Healthy Favorites line had declined 100% by February of 1997. However, Kraft "Free" products, with sodium levels above Healthy Choice, soared by 83% in the same time frame.

Moreover, as indicated in the Supplementary Comments, in 1994 there were at least seven (7) "healthy" brands of frozen entrees or dinners – today there is only one -- Healthy Choice, and Healthy Choice is still the lowest sodium brand of any competitive product line.

Soups tell the most impactful story. In the early 1990's, Progresso introduced a Healthy Classics line of soups at a line average of 476mg. Even at that level, which is slightly below the current "healthy" definition of 480mg, but significantly higher than the proposed 360mg, Progresso could not make it. By March of 1997, sales volume was down to a couple of million dollars a year, when Progresso introduced its 99% Fat Free line, which had a whopping 649mg sodium line average. Today, Progresso's health positioned ready-to-serve soups have sales of over \$29 million, and grew at a rate of over 11% in the last 52 weeks. And the sodium? Progresso's Classics, 99% Fat Free line averages **950mg of sodium**.

Other product categories and examples are in the Supplementary Comments. Clearly, current sodium policy, and the threat that healthy products will have to go down to 360mg yet still maintain good flavor, has had a "chilling" effect on food manufacturers' desire to create healthy products, and they have stopped doing so. According to data archived by Mintel Corporation, during the last five years there have been less than 80 new "healthy" product introductions, and about 75% of those were Healthy Choice. This means new "healthy" product introductions were less than 1% of all new product introductions every year. In addition, new products with low sodium claims have dropped significantly in the last three years, while still higher than "healthy" claims, which are far harder to make. (Mintel data available on request.)

This same "chilling effect" also prevents ConAgra Foods from entering new product categories. For example, we have been attempting to enter the frozen breakfast aisle for a number of years, but some individual breakfast items cannot be made with 360mg or less of sodium. Not knowing whether products between 360mg and 480mg will be allowed to remain on shelf has prevented ConAgra Foods' management from agreeing to the investment required to launch a new product line.

III. FDA’S GOAL ACHIEVED

A. Lower Sodium Levels

The health policy underlying FDA’s defining of “healthy” was to assist consumers in identifying products that would fit into dietary guidelines for healthy living. The goal was twofold – to have a “sufficient number and variety” of healthy products to choose from, and to reduce the sodium levels of all products with a sort of “halo effect”. The first part of the goal appears to have failed, we believe because of the constant threat that healthy sodium levels will be forced to go to impossible levels. At the current 480mg for individual products, however, the second part of the goal appears to have succeeded.

Data compiled and kept by independent nutrition organizations indicate that sodium levels, at least in the product categories in which Healthy Choice competes, are down overall from pre-healthy definition levels. As an example, the leading soup varieties and hot dogs are charted below.

<u>Product</u>	<u>Sodium Line Averages Pre-1994 Healthy Definition</u>	<u>Today (3/03)</u>
Campbell’s Chunky (19oz)	975mg	888mg
Campbell’s Home Cooking (19 oz)	939mg	787mg*
<small>*Sub-brand name changed to Simply Home.</small>		
Oscar Mayer Wieners	640mg	566mg

Clearly some individual products’ sodium levels have come down since the “healthy” implementation. The chart at **Exhibit 1** demonstrates how the entire soup category has come down as well.

However, as discussed below, attempting to lower “healthy” sodium levels to 360mg will cause this downward trend to backfire.

B. Dietary Guidelines

In the above quoted statements, FDA indicates “healthy” foods should fit into a diet based on dietary guidelines. In fact, the Agency states in the Proposal that it “selected the 480mg level because it was low enough to assist consumers in meeting dietary goals....” (Proposal at 8163). In discussing its rationale for the 360mg level,

FDA states: “the Agency derived at this 360mg sodium level by applying a 25% reduction to the original sodium disclosure level of 480mg for individual foods.” (Ibid.) Clearly there was no scientific or health based facts pointing to 360mg as the “healthiest” limit.

Health organizations, including FDA, have set the recommended daily maximum sodium level at 2,400mg. The menus attached as **Exhibit 2** demonstrate that individual products at 480mg can easily fit into a diet with 2,400mg daily sodium maximum.

Furthermore, in the current Proposal, the Agency states that “minor adjustments”, such as the lower sodium level the Agency is proposing for “healthy” individual foods would be sufficient to bring a daily menu within dietary guidelines. There are two issues with that supposition. First, as discussed at length within these Comments, lowering the sodium levels in individual foods by 25% is NOT a minor adjustment. And second, FDA may be surprised to learn that, in fact, not only do Healthy Choice items currently fit into daily meal plans consistent with dietary guidelines, Healthy Choice products also fit easily into a DASH diet. As demonstrated below, the National Heart, Lung and Blood Institute, in their publication *Facts About the DASH Diet* (NIH Publication No. 01-4082, Revised May 2001), provide “a week of menus from the DASH eating plan.” Following is “Day 4” from sample menus, altered to include Healthy Choice individual foods. Note that the menu includes three Healthy Choice individual foods and one main dish, yet is still under the recommended daily sodium maximum.

DASH/HEALTHY CHOICE MENU

Serving Size	Food Item	Calories	Protein (g)	Carbohydrate (g)	Fiber (g)	Total Fat (g)	Sat Fat (g)	Sodium (mg)
Breakfast								
3/4 cup	Corn Flakes	77	1	18	1	0	0	223
1/4 cup	Skim Milk	21	2	3	0	0	0	32
1 tsp	Sugar	16	0	4	0	0	0	0
4 oz	Fruit Yogurt, Fat Free	64	4	11	0	0	0	50
1 each	Apple	80	0	22	5	0	0	0
1 cup	Grape Juice	154	1	38	0	0	0	8
1 cup	Coffee	5	0	1	0	0	0	5
Lunch <i>Ham and Cheese Sandwich</i>								
1.8 oz	Healthy Choice Honey Maple Ham	60	9	3	0	2	1	450
3/4 oz	Cheddar Cheese, reduced fat	37	5	0	0	1	1	130
2 Slices	Healthy Choice Soft Honey Wheat Bread	120	6	24	4	1	0	240
1 lrg leaf	Romaine Lettuce	1	0	0	0	0	0	1
2 Slices	Tomato	6	0	1	0	0	0	3
2 tsp	Honey Mustard	34	0	5	0	2	0	25
1 cup	Carrot Sticks	52	1	12	4	0	0	43
1 cup	Skim Milk	86	8	12	0	0	0	127
Dinner <i>Healthy Choice Solos/Southwestern Style</i>								
1 each	Rice & Beans	330	9	59	10	6	2	600
1/2 cup	Green Peas	62	4	11	4	0	0	70
1 cup	Cantaloupe	55	1	13	1	0	0	14
1 Slice	Healthy Choice Soft Honey Wheat Bread	60	3	12	2	1	0	120
1 cup	Skim Milk	86	8	12	0	0	0	127
1 tsp	Margarine, soft	20	0	0	0	2	0	37
Snack								
1/3 cup	Almonds, raw, sliced	187	6	6	3	16	1	0
1/2 cup	Fruit Cocktail, packed in juice	55	1	14	1	0	0	5
1 cup	Apple Juice	117	0	29	0	0	0	7
Totals:		1785	72	311	36	33	6	2316
% DV			144%	104%	145%	50%	31%	96%
Breakfast Totals		417	9	97	6	0	0	318
Lunch Totals		397	30	58	8	7	2	1018
Dinner Totals		613	26	107	18	9	3	968
Snack Totals		358	7	49	5	16	1	12

There is no doubt that a consumer could fit about one more individual food into this diet if the Healthy Choice product was 360mg, but adding one or two more foods a day at the expense of wiping out whole categories of foods from being called “healthy” defeats FDA’s goals.

IV. THE REAL NUMBER OF “HEALTHY” BRANDS AND PRODUCTS

The Proposal provides a series of statements, unsupported except by FDA’s own internal memoranda, to attempt to prove that, while there are fewer “healthy” meal type products than before the healthy definition was published, there are *more* individual “healthy” food products on the market. (Proposal, pg 8165.) We have not been able to obtain from FDA the raw data it utilized. Moreover, their conclusions are based on a 1997 Flaps Study, and 1999 IRI data (Ibid.). Therefore, ConAgra Foods asked IRI to provide raw data of current sales of key product categories, using 52 week sale figures ending March 30, 2003 – four years later than FDA’s data.

The IRI data is attached hereto as **Exhibit 3**. What we learned about the following individual food categories in which Healthy Choice competes is a staggering contradiction of FDA’s claim ... that in 8 of the 9 categories in which Healthy Choice competes, there are no other healthy branded products.

Other than the government, there are no health experts, doctors, nutritionists, or dieticians, who have stated that “healthy” means 360mg of sodium. FDA’s current sodium criteria for individual foods is not based on science or sound nutrition, but on a survey FDA performed of labels of individual food products that have some form of the word “health” on them. (Ibid.) FDA’s Proposal indicates that the number of products with “health” or “healthy” on their labels has risen since the inception of the “healthy” definition 10 years ago. **FDA’s premise is not that 360mg is the healthiest number, but an achievable one.**

“... with the possible exception of cheese, the overall impact of permitting the second-tier sodium level to take effect for individual foods appears to be limited to minor reductions in the number of ‘healthy’ products in some food categories....

Accordingly, the Agency tentatively concludes **that the second-tier sodium level is the appropriate sodium requirement for the “healthy” definition of individual food products.**” (Id. at 8167)

FDA’s premise, which is not even science-based, is seriously flawed. When the FDA did its survey of “healthy” products for purposes of supporting the 360mg level of the Proposal, **FDA included products that were illegally using “healthy” claims**, as well as labels that had “health” or “healthy” on them, even if the words were not used as nutrient content claims.¹ For example, a perusal of Exhibit B to the Proposal indicates

¹ Yablunsky Conversation with FDA on June 10, 2003

that FDA counted the following as products containing “healthy” for purposes of their individual product analysis.

PRODUCT	CLAIM
Life Savers carefree Spearmint Big Pack Stick (Gum)	“Phenylketonurics; contains Phenylalanine. Use of this product may be hazardous to your health. ”
Sweet ‘n Low Sugar Substitute	Saccharin Hazard Warning
Garden Burger Meatless Patty 10 oz (560mg sodium)	“In the book...learn about Paul’s approach to dieticians and healthy eating and healthy environment. ”
Popsicle Stick Ice Single Assorted Sugar Free	“Eat healthy, Eat well”
Lean Cuisine Microwave Potatoes Deluxe Cheddar Box 10.37 oz (630mg sodium)	“...fits easily into a healthy diet...”
Jimmy Dean Tastefuls– Baked Honey Ham and cheddar Sandwich Regular/Dessert 6.45 oz* *This product has since been discontinued—a Jimmy Dean 5.66oz sandwich with ham, turkey, and cheese. today is 23 grams of fat; 9 grams sat fat, and 1050mg sodium	“...can be part of a healthy diet.”

Absolutely amazing is FDA’s lack of diligence when counting “healthy” products. How can chewing gum, popsicles, and full-fat ham sandwiches be healthy?? These products make a mockery of the serious business of nutrient content claims, and demonstrate how little enforcement there is of current rules – rules Healthy Choice would never even dream of subverting. Yet FDA is using these misleading statements to “prove” there are “healthy” products on the market.

Because we were unable to obtain from FDA the raw data, we can only surmise from their chart how many products are legitimately healthy. Moreover, FDA used 1999 IRI data to “prove” the number of healthy individual products, data that is over 4 years old. It is also interesting to note that the 1997 FLAPS Study never mentions healthy, although FDA indicated it used the Study to determine how many products used a “healthy” nutrient content claim. See Reference 4, attachment A to the Proposal. Moreover, FDA did an in-depth analysis of brand names containing “healthy” for meals and main dishes, but did not do the same analysis for individual foods. See Reference 2, Attachment I to the Proposal. Why didn’t they?

ConAgra commissioned IRI to run current sales numbers for “healthy” products, and further ran all products in the categories in which Healthy Choice competes. The conclusions are shocking ...in 8 of the 9 categories in which Healthy Choice competes; Healthy Choice is the only “healthy” offering. (See **Exhibit 3.**) The FDA’s conclusion, therefore, that the 480mg level has not been a deterrent to having “healthy” products is not accurate. And if 480mg is already a deterrent, 360mg surely would be. In fact, as discussed at length in ConAgra’s 1996 Citizen’s Petition and 1997 Supplementary Comments, certain food products cannot be made at the 360mg level either due to manufacturing constraints, taste issues, food safety, or all three.

Although meats will be discussed later, it is worth noting that the FDA asked if cheese should have a different level because salt is required in cheese making, and FDA noticed that all of the “healthy” cheese offerings have disappeared from the shelf, and sodium is required for manufacturing. Cheese should not have its own category because none of these individual products should be forced into a lower sodium level to begin with. Take the hot dog: if Healthy Choice hot dogs are forced off the market, which they will by this Proposal, the next “healthiest” sodium level is 548mg, nearly 20% more than Healthy Choice. In formulating a health policy then, isn’t FDA working against all of the experts who recommend lowering sodium intake?

V. SOUP

A. Refuting Proposal Conclusions

Over the last dozen or so years, ConAgra Foods has provided the FDA with taste tests, NPD reports, studies, letters from flavor experts and related data and materials supporting the fact that there is a flavor threshold below which certain foods cannot go or people will not buy them. (See 1996 Citizen’s Petition, at **Exhibit B**, and 1997 Supplementary Comments, at **Exhibit A**.) Updated reports and tests are provided herein to refute the premises on which FDA bases its 360mg level for soup:

1. *Consumers will eat 360mg soup products;*
2. *Viable sodium substitutes are available; and,*
3. *That a major soup manufacturer that has been able to create a soup at 360mg (Proposal at 8166).*

MYTH #1. “Consumers will eat 360mg soup products.”

There is no market based or consumer test evidence to suggest that consumers will purchase or eat soups containing only 360mg of sodium. Consumers vote with their pocketbooks. While the term “healthy” has a certain amount of draw for consumers and may inspire a one-time purchase, the food must taste good! Consumers will not buy products that do not meet their organoleptic expectations. The assumption that the vast majority of consumers will purchase soups at 360mg is unequivocally false, according to the following:

(i). According to National Eating Trends 2003 data, no/low salt or sodium foods represent 1.5% of all food consumed, down from 3.3% in 1994.

(ii). Data collected by Food Marketing Institute corroborates that taste is king (*Food Marketing Institute, Eating in America: Perception and Reality, Prevention Magazine*, 1994). Eighty-nine percent of those participating in the FMI survey of 597 shoppers said that taste was the most important factor in food selection.

(iii) The Healthy Choice brand has conducted numerous studies over the past 9 years to determine the optimal soup formulations that would keep the high nutritional standards that have come to symbolize the Healthy Choice brand, while optimizing flavor and other organoleptic qualities. ConAgra Foods’ soup taste test, April 22, 2003, indicates that, even with modern “salt enhancers” and bitter blockers, the 360mg Chicken Noodle soup was not liked by consumers. Even a 480mg salt enhanced product was not well liked, indicating that salt enhancers themselves may create flavor issues. (See **Exhibit 4.**)

(iv). IRI data of low sodium alternatives indicate very low sales in direct correlation to levels of sodium. Of the total soup category, which is roughly \$2.7 billion in sales, only \$19 million currently falls under the proposed 360 mg sodium level. This is approximately 1.7% of the entire Ready to Serve soup category. There are no condensed soups that meet the criteria. Of the RTS soups, only one – Campbell’s Low Sodium soup line – meets the low sodium claim requirements at less than 100 mg sodium. The market share on this product line, which is under .4% of the Ready to Serve Soup Category, continues to decline – last year falling 37.5%. These abysmal market shares provide further proof that there is a threshold for sodium content that is higher than the FDA’s proposed second tier of 360 mg. Even though the products can technically be produced, consumers have not converted to nor will they buy the lower sodium products. (See **Exhibits 5 and 5-A.**)

(v). Mintel Corporation study of new products marketed by year, by nutrient claim, indicating low or reduced sodium claims are merely 15% of low fat claims, and have decreased significantly over the last three years.

(vi). Taste tests and studies provided to FDA as exhibits to the 1996 Citizen's Petition (**Exhibit B**) and 1997 Supplementary Comments (**Exhibit A**), indicating that for a variety of foods, including soups, consumer acceptance drops off dramatically in relation to sodium content. In addition, as described in the previously submitted Comments, the sodium chloride ion is the only ion that will fit into the salty taste receptors. (See, for example, work done by the Monell Chemical Senses Center, papers from which are exhibits 165 and 166 of the Citizen's Petition, **Exhibit B**.)

The bottom line of all this data is that consumers will NOT EAT products that have fallen below a flavor threshold, especially when the other flavor enhancers, like fat, are so limited.

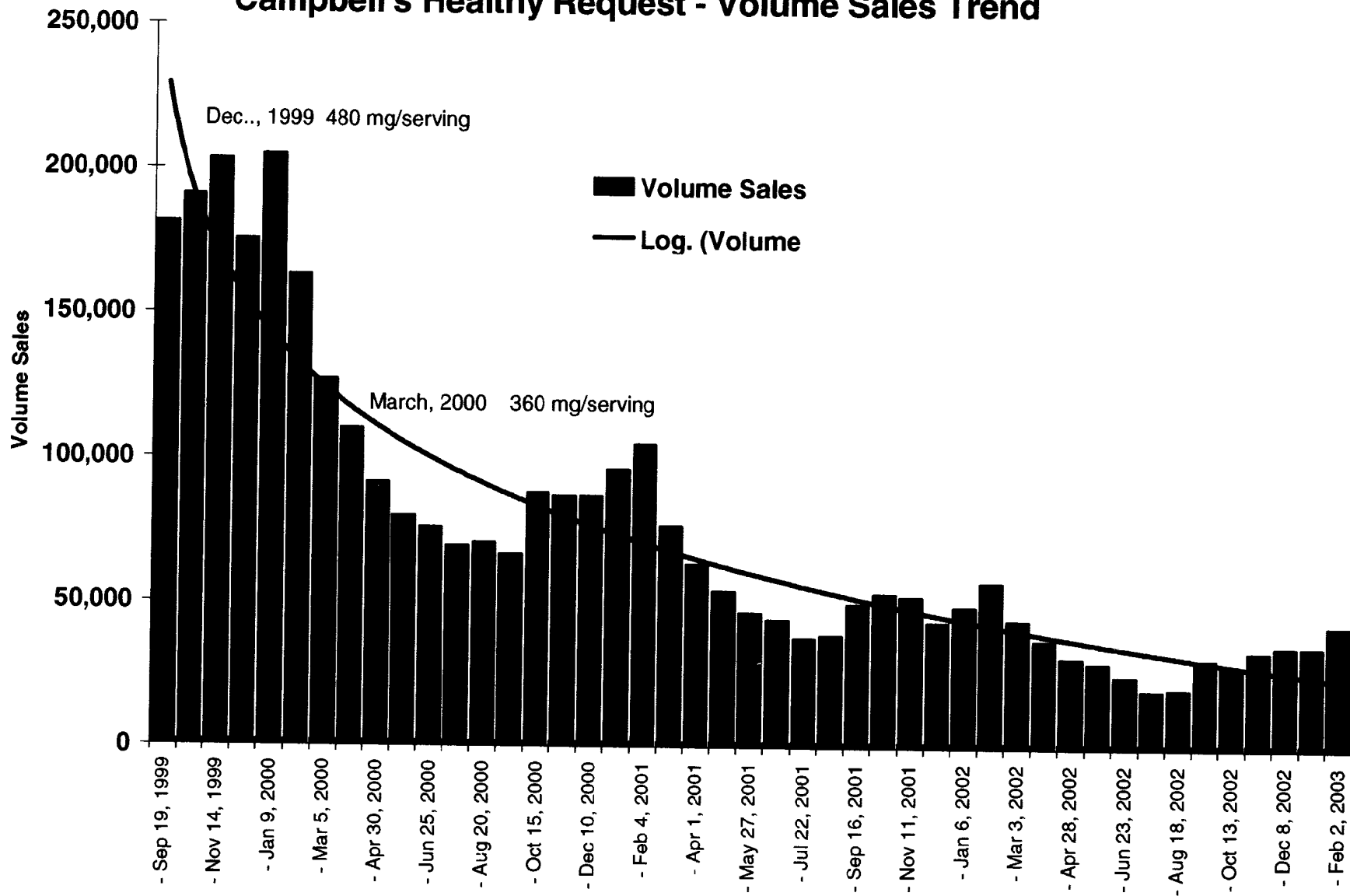
MYTH #2. "Viable Sodium Substitutes Exist."

Ten ingredient companies, including the world's two largest, sent Comments to the FDA pursuant to the Citizen's Petition, indicating that there were no viable salt substitutes nor effective bitter blockers when using potassium as a salt substitute. Another one of those companies, Quest International, has already commented this year to FDA, indicating there still has been no success in this area. Our experience with these companies indicates that more will comment similarly.

MYTH #3. "There is a major soup manufacturer that has created a soup at 360mg...that is palatable to consumers"

Campbell may have recently created a soup at 360mg, and we at ConAgra Foods know that this is possible. In fact, we could produce a similar product. However, very few people will eat it. There is a fairly close correlation between level of sodium and level of sales, as demonstrated by the chart on the next page. Lower sodium soups have lower sales, a good indication those soups are not popular. The taste tests mentioned above also demonstrate a lack of consumer acceptance. In fact, we taste tested the current Healthy Request Chicken Noodle soup at 360mg, and it was not well liked by consumers. (See **Exhibit 4**.) On the next page we have included a chart that graphically demonstrates the correlation between salt levels and sales of Campbell's Healthy Request as the line has gone from 480mg of sodium down to 360mg. Sales of Healthy Request have plummeted from approximately 181,000 cases in 1999, (when sodium was 480mg) to approximately 43,000 cases in February of 2003 (360mg of sodium). Consumers vote with their pocketbooks, and the outcome could not be clearer...consumers will not buy soup at 360mg of sodium.

Campbell's Healthy Request - Volume Sales Trend



Health Valley, whose fat free soups line average hovered around 227mg for years, recently raised the sodium in these products by about 150mg. for a line average of 378mg. Coincidentally, sales of Health Valley are also up. Health Valley must have realized what ConAgra Foods realized...that Campbell can keep its Healthy Request line of soups on the shelf regardless of consumer acceptability because, as the market leader with about 66% of the shelf space, Campbell can demand that retailers accept Healthy Request if they want Campbell's other, very popular products. Neither Health Valley, nor Healthy Choice has that kind of leverage in the soup aisle, so we must make our soups acceptable to consumers.

What is really fascinating about Campbell's claim to have a palatable 360mg soup is the fact that Campbell is currently selling its Healthy Request Condensed Soup in Canada, which has no "healthy" definition, at levels far above the legal limit in the United States. Product information attached as **Exhibit 6** show a Healthy Request Clam Chowder at 636mg per serving, and a Healthy Request Hearty Bean and Vegetable at **680mg of sodium!** If their Healthy Request is so good at 360mg, why do they need to nearly double the sodium for sales in Canada??

B. Furthering a Public Health Policy

If FDA truly wanted to affect the health of the nation through labeling, why not force the soup market leader to reduce the sodium in all of its soups by just 10mg per serving? This action would have roughly the same effect numerically as forcing Healthy Choice to drop 120mg, but would impact hundreds of thousands more consumers, and would be far less noticeable to consumer's taste buds. In fact, if FDA forced the higher sodium products to reduce their sodium levels by 120mg, think of the difference that would make to consumers' consumption. With Campbell's Household Penetration of 65%, FDA could truly affect health policy by effecting the higher sodium soups.

Instead, FDA wants to remove the already lowest sodium, palatable national brand of soup from the market. Certainly when attempting to define "healthy", wouldn't a product that has a line average of 40% less than the leading competitor qualify as "healthy"?

One of FDA's suppositions is that if "healthy" soups reduce their sodium levels, consumers who eat them will eat less sodium. While this is an apparently logical conclusion, it assumes as a fact something ConAgra Foods has successfully refuted time and time again--the vast majority of consumers will not eat soups at 360mg per serving, especially when there are other, much tastier, alternatives. Generally speaking, if consumers won't buy it, supermarkets won't stock it. So consumers will be forced to make other choices.

Should consumers chose other soups, the chart at **Exhibit 7** indicates that the most popular soup, Campbell's Chunky, with a market share of 30.4%, has 888mg/serving, or 85% higher (nearly double!) that of Healthy Choice.

Should consumers choose some other product to replace soup because of the high sodium levels, the chart attached as **Exhibit 8** provides some more popular choices. Briefly, if a consumer chooses a typical sandwich for lunch, sodium will range from 600mg to over 1,000mg sodium, with fat from 6 grams to 25 grams. Pot pies are approximately 735mg in sodium to 1030mg/serving, and 15 to 30 grams of fat. Consumers could also chose a Healthy Choice meal, such as Roasted Chicken at 600mg, and 8 grams of fat. The conclusion is that almost any other alternative is higher in sodium, and in many cases much higher, and, except in the case of the Healthy Choice entrée, also much higher in fat.

Moreover, should Healthy Choice Ready to Serve Soups be forced off the shelf because they cannot compete at the 360mg range, the average sodium consumption/serving of soup will actually increase by 4mg per serving. If, as we predict, not only will Healthy Choice soup, but also Healthy Request Condensed soup be forced to die or reformulate to the proposed 2nd Tier, 360mg level, then the loss of market share from both brands would cause the average sodium consumption/serving of soup to actually **increase by 16mg**. (See **Exhibit 9-A**.) The consequence is that FDA would lose practically all of the overall beneficial impact from implementing the 1st Tier sodium levels, which drove sodium/serving of soup down 17mg/serving from 864mg/serving to 847mg/serving. (See **Exhibit 9-B**.)

FDA is attempting to effect health policy by focusing on one nutrient, sodium, as opposed to the overall diet, and by focusing on a very narrow segment ("healthy") of the food industry. Using soup as an example, the entire soup industry is roughly \$2.7 billion in sales. Of this total market, there are only \$166 million in sales from that meet the current first tier, or 480 mg, sodium requirement. Of that \$166 million, only 11% (\$19 million) of the sales come from products that meet the proposed second tier of 360mg. Further limiting the playing field is the fact that \$11 million of the \$19 million in sales of product meeting the second tier come from soups that are marketed as organic and generally not sold in mainstream markets. This culminates to a total of \$8 million out of \$2.7 billion in sales that can meet the FDA's proposed sodium level. Therefore, the FDA is basing their entire proposal on .3% of the soup market. Adding further issue to using this as a base for public health policy is the fact that this .3% market share is eroding each month. (See chart next page.)

**SOUP SALES UNITED STATES
(52 Weeks ending 4/27/03 – IRI Data)**

TOTAL CATEGORY	DOLLAR SALES (MM)	SODIUM/SERVING
Condensed/semi condensed and Ready to Serve Soup	\$2,711	847 mg
Healthy Branded Soups – Total	\$ 166	480 mg or less
Healthy Branded Soups – Tier 1	\$ 148	480 mg
* <i>Healthy Choice</i>	* \$71.2	
* <i>Healthy Request (condensed)</i>	*\$76.2	
Healthy Branded Soups – Tier 2	\$ 19	360 mg
* <i>Healthy Request (Ready to Serve)</i>	*\$8.0	
* <i>Healthy Valley (Organic)</i>	*\$10.9	

If healthy soup cannot compete at the 360mg range, the average sodium consumption will actually increase by 16 grams per serving! Today, the line average of sodium in soup is 847mg. If manufacturers are 100% successful in reformulating their 480mg product to 360mg (a proposition not supported by consumer taste tests), the line average of sodium in soup will decline by 5mg/serving. However, if, as we predict based on consumer tastes, the marketplace will force Healthy Choice soups off the market and Campbell's Healthy Request Condensed soups will have a significantly reduced market share, then the average sodium/serving will increase by 16mg. (See **Exhibit 9-C.**)

C. Understanding Soup Consumption

In the nearly 10 years since the implementation of the healthy definition, as a manufacturer we have become increasingly aware of its shortcomings. Rigidity continues as one of those shortcoming and the regulation deserves rethinking and modification. Rules for sodium reductions need a more “common sense” approach. Effective reductions need to be considered in the narrow context of the food category involved and the historical content of regular foods in that same category. Some foods retain their palatability and are acceptable to the consumer even after significant sodium reductions; many others are not. Some foods contain higher sodium content for food safety purposes or shelf life considerations and cannot technically survive mandatory yet arbitrary reductions. However, contrary to FDA’s thinking, this does not mean that lesser sodium reductions should be prohibited at the expense of valuable, palatable products for the consumer who wants to make informed dietary choices.

Almost 10 years ago, when the FDA developed the rationale for “healthy” claims as is currently proposed, it developed an arbitrary progression of sodium reduction on the speculation that business greed would push science to provide the answer. But, as we have repeatedly demonstrated, no amount of wishful thinking will make FDA’s desires “force fit” reality.

Soups are a unique product in the world of “individual foods”, because they are not “individual” foods at all. Usually made up of between 5 and 20 ingredients, soups can be as complex as main dish or meal type products. In fact, over the years, labeling experts at FDA and USDA have agreed that most Healthy Choice Soups meet the regulatory definition of a main dish or meal type product,² but have refused to allow nutritional claims to be calculated using those criteria. Instead the Agencies have insisted that for claims purposes (like “low fat” or “healthy”), soups are individual products. This simply defies logic.

² Soup qualifies as a “main dish product”, which under current FDA regulations, must: Weigh at least 6 oz per labeled serving; contain not less than 40g of food, or combinations of foods, from each of at least two of the listed food groups (21 CFR 101.13(m)). Assuming the serving size is correct, soup also fits into the FDA definition of “meal”; which must weigh at least 10 oz per labeled serving contain not less than three 40g portions of foods, or combination of foods from two or more of the listed food groups (21 CFR 101.13(1)).

Soup, with a RACC of 245g is more similar to, and often exceeds, the RACCs of products considered to be meals and main dishes. For example, pizza has a RACC of 140g, lasagna – 226g, burritos – 140g + 55g for sauce. Contrast the soup RACC with individual foods with RACCs in the 40g-85g range

At the very least, soups meet consumers' definition of a meal and according to NPD, Inc., as of February, 2003, **an amazing 72%** of consumers perceive soup as a meal. (See **Exhibit 10**.) Yet, the "healthy" regulation will not allow soup claim criteria to be based on the meal criteria, which would allow a much greater flexibility in appetite appeal, yet still remain well below current soup sodium levels of around 850mg/serving. Exclusion of soups from the labeling provisions afforded to these categories of food is arbitrary and unwarranted.

Moreover, by far the largest group of consumers of soup as a meal or a meal portion is seniors. (See **Exhibit 11**.) Seniors have their own special needs....losses of taste and smell are common in the elderly and result in part from normal aging. Deficits in these chemical senses cannot only reduce the pleasure and comfort from food, but can increase their risk for nutritional and immune deficiencies. The loss of taste perception is the biggest taste deficit for the elderly. (Schiffman, S. *Journal of The American Medical Association*, 278(16)). Enticing seniors to get enough calories, but yet maintain a diet low in fat and cholesterol, is a real challenge for health experts. Soup is an excellent way to get a variety of food groups into one meal, and, if made healthy, can be low in fat, and lower in cholesterol and sodium than more mainstream products. Should Healthy Choice soup be forced to lower its sodium to 360mg and so be forced off the market, this very valuable nutritional tool will be cut from seniors diet.

In addition, with the lower calorie requirements of older adults, the need for less sodium per calorie is an important consideration. For the roughly 31% of the older population who frequently consume soup, Healthy Choice soups provide an average of 3.8mg of sodium per calorie, whereas the leading brands contain over **12 mg of sodium per calorie**. (See **Exhibit 12**.)

The Center for Science in the Public Interest (CSPI) recognized ConAgra's contribution to the soup category in their *Nutrition Action Healthletter* (December 2002, pages 11-12), stating that, "[t]he trick is finding a soup that won't pack nearly half a day's worth of salt into a modest 150-calorie cup of liquid." CSPI further states, "Among our favorites from the 'healthy' lines: Healthy Choice Vegetable Beef, Garden Vegetable and Split Pea and Ham."

FDA states in the Proposal that the relatively large RACC and serving size of soups is a handicap to attaining the "healthy" criteria. (Proposal at 8166.) But is FDA willing to give up an entire category of foods – soups – from the healthy level? We think not. Instead, FDA's statement should serve as a clear indication that whatever rationale the FDA used to come up with the sodium level for "healthy" does not work across all categories of individual foods.

Even with a 245g RACC, FDA claims that soups have insufficient nutrient density to "allow" reasonably achievable sodium levels. The implication is that Healthy

Choice soups should contain more calories as a justification for higher sodium limits. With all that is currently unfolding with regard to obesity and fat consumption, it defies logic to make it regulatorily impossible to market low fat, controlled sodium, wholesome products. This is especially ironic when the only palatable alternatives are higher in sodium or fat or both.

VI. PROCESSED MEATS

While we understand that the FDA has no jurisdiction over meat products, the agency is clearly aware that meat products will be affected by this Proposal. In fact, FDA and USDA have always worked closely on nutritional regulations, and USDA has followed a policy of nutritional regulations consistent with FDA's. See 59 FR 89, pgs 24235, 24238 and 24245 ("The agency [FDA] believes that such an approach is appropriate because establishment of a consistent definition with USDA will ensure that the term is used in a credible, consistent, useful and nonmisleading manner." See also similar USDA quotes at 59 FR 89, pages 24220, 24223; "FSIS and FDA have jointly reached a decision to establish a uniform definition of the term 'healthy' as it applies to all foods regulated by both agencies." Therefore, this Proposal will affect "healthy" meat products.

A. No "Healthy Choices".

In ConAgra's 1996 Petition, and our 1997 Supplementary Comments, we described at length the difficulties in making hot dogs at 360mg of sodium. (See **Exhibits A and B**.) We also described the difficulties of flavoring meat products at 360mg of sodium – the surprising factor here is that the honey flavor in Honey Ham is lost without the appropriate amount of sodium.

We also provided taste tests indicating that processed meats, like soup, have a flavor profile for sodium beyond which palatability falls off. The amount for meats is strikingly similar to soups -- around 440mg per serving. Recent taste tests continue to support our original conclusion. (See **Exhibit 13**.)

Given these facts, and as stated in previous submissions, should the FDA force "healthy" products down to 360mg, Healthy Choice would be taken off the market by retail customers who cannot sell these products to consumers who still indicate that taste is the primary reason they choose certain foods. (National Eating Trends 2003.)

If Healthy Choice leaves the luncheon meat category, the next best sodium level is approximately 600mg sodium/RACC for turkey products, and even higher for other meats (620-780mg). Oddly enough, the "Lite" or reduced fat varieties are even high, hovering around 700mg. With the popularity of these products all across America, for

FDA to purposefully remove the only “healthy” alternative, one that controls both fat and sodium, is amazingly short-sighted.

In its November 2001 issue of the *Nutrition Action Letter*, CSPI reported on a survey of lunchmeats. Healthy Choice meats won several of the Best Bites awards. In its report, CSPI said:

It’s no coincidence that most of our Best Bites are made by Healthy Choice. The government won’t allow the word “healthy” on a label unless a serving of the food is low in fat (no more than three grams), low in saturated fat (no more than one gram), and not high in sodium (no more than 480 milligrams)....

Luncheon meats that meet the fat cut-offs are a dime a dozen. Oscar Mayer Fat Free, Louis Rich Fat Free, and DAK Lookin’ Lean lines are all low in fat and saturated fat. But few meats—even the lean or fat-free ones—meet the sodium cut-off for “healthy”....

Not that 480 milligrams is not rock-bottom low. There’s no getting around the fact that luncheon meats are full of salt. And luncheon meat *sandwiches* are even saltier, since you’re almost guaranteed an extra 300 mg of sodium from the two slices of bread. **So it pays to minimize the damage by buying Healthy Choice meats.**

CSPI *Nutrition Action Letter*; dated November 1, 2001. page 13. (Emphasis added.) (**Exhibit 14.**)

Again, as with soups, if the FDA is truly concerned about improving the health of the nation through nutrient content policies, then asking Oscar Mayer to lower the sodium in their products by 120mg would have a huge impact. Oscar Mayer has a 26% market share, and sales of \$750 million, or 8 times greater than all of Healthy Choice luncheon meat sales combined. Common sense tells us that if there sodium dropped by 120mg per serving, the country’s sodium consumption would be impacted.

B. Functionality

Salt, and in fact sodium in multiple forms, has multiple functions. Salt:

(1) allows the manufacture of processed meats by extracting muscle protein that coagulates upon cooking, forming the typical appearance and form consumers recognize as hams, franks, and smoked sausage. Without salt these products would simply not exist.

(2) in combination with muscle protein creates the texture consumers expect from processed meats. Without salt the texture of ham would resemble a cooked

pork roast, the texture of franks would resemble a turkey and pork baby food, and the texture of smoked sausage would resemble meatloaf.

(3) is essential in creating the flavor consumers expect.

(4) contributes to the microbial stability of a refrigerated perishable item that is fully cooked and ready to eat. In fact, USDA's recent Final Rule on listeria demands that meat processors use some form of listed antimicrobial, such as sodium lactate. Salt is the oldest and most common preservative used in processed meat products. Salt is still an important ingredient in delaying spoilage and maintaining the shelf life consumers expect (See Exhibits 163-164 from our 1996 Citizens Petition; attached as **Exhibit B.**)

C. Food Safety

Salt is important in preserving perishable refrigerated products such as processed meats and cheese. To further enhance consumer protection, we also use lactate or lactate/diacetate blends in Healthy Choice processed meats. These ingredients have been recognized by the USDA for their anti-*Listeria* properties and are in fact the only antimicrobial ingredients that have been consistently relied upon to formulate processed meats into a low public health risk category [Directive 10,240.3 "*Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program, Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products*" – Final Rule]. Particularly for processed cured meats, these ingredients can be incorporated in product formulations to completely suppress the growth of any *Listeria monocytogenes* that may be present. Because of the current sodium restriction, we are forced to use potassium lactate rather than sodium lactate. The use of potassium lactate instead of sodium lactate presents flavor issues that are discussed below.

D. Competitive Alternatives

There are virtually no other processed meats that meet the "healthy" definition other than Healthy Choice. We are definitely the experts when it comes to healthy processed meats. Other manufacturers have chosen to market "low fat" processed meats instead of "healthy processed meats" to avoid the texture, flavor and microbiological stability challenges of sodium controlled processed meats. Manufacturers of low fat processed meats do not need to reduce sodium versus their full fat version. Healthy Choice has the additional burden of lowering fat and sodium at the same time. The resulting taste compromise is borderline acceptable at the current 480 level and is unacceptable at 360mg of sodium.

As noted above, in order to achieve a low risk processed meat per the current food safety regulations a combination of lactate and diacetate is required. Other manufacturers

use sodium lactate (on labels for Oscar Mayer, Ball Park (Sara Lee), and Hillshire Farms (Sara Lee)), but Healthy Choice is forced to use potassium lactate. The level of potassium in Healthy Choice processed meats is consequently much higher than other non-healthy "better for you" marketed processed meats. When using the required amount of potassium lactate to place products in the low *Listeria* risk category per USDA regulations, the potassium level is the same or a little higher than the sodium level, creating a serious off flavor that must be masked. If we were required to lower the sodium further to 360mg, the potassium level would significantly exceed the sodium level. This high ratio of potassium to sodium presents extreme flavor challenges. Potassium is a common, albeit imperfect, sodium substitute, but at replacement ratios beyond 30%, products become very bitter and metallic tasting.

The use of bitter masking ingredients and flavors systems in processed meats are unsatisfactory as they are not specific to potassium and end up dramatically altering the overall flavor. Campbell commented that our 1995 sodium reduction consumer research on soup, franks, and mac & cheese was flawed because we simply reduced sodium without further formula alterations. Our research on processed meats from 1996 to 1999 **did** include flavor maskers and they were not effective. Potassium had to be increased to help preserve and flavor the product, yet the resulting flavor was not acceptable to consumers.

The bottom line is that we will have to discontinue this product line at the 360mg sodium level, and this is so in part due to food safety regulations demanding the addition of sodium, and nutritional regulations demanding its removal.

VII. OBESITY

A. Our Nation's Number One Health Problem and Largest Epidemic

The impact of overweight and obesity on our nation's health is far greater than any other nutritional disorder. Obesity increases the risk of many causes of death and has been clearly established as an independent risk factor for coronary heart disease (**Exhibit 15**). As stated in *The Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity 2001*:

- Overweight and obesity have reached nationwide epidemic proportions.
- Both the prevention and treatment of overweight and obesity and their associated health problems are important public health goals.

While a one-to-one correlation between sodium reduction and the risk of cardiovascular disease has not been established, maintaining a healthy weight clearly has a direct impact on cardiovascular health (**Exhibit 15**). Obesity/weight gain not only increases risk of death from heart disease, certain cancers, and other diseases, it also

increases risk of death and serious injury from motor vehicle crashes (Mock, et al., *Accid Anal Prev*, 2002). In women, increased body mass index (BMI) is associated with major depression, suicide ideation, and suicide attempts (Carpenter, Hasin, et al, *AJPH*, 2000). Additionally, overweight and obesity significantly affect the quality of life and have a negative impact on psychological parameters (Carpenter, Hasin, et al., 2000; Frank, Dingle, 1999). Schwimmer and colleagues (2003) found that the quality of life scores in obese children and adolescents are similar to children who have been diagnosed with cancer.

The burden of obesity to our society manifests itself in premature death and disability, in health care costs, in lost productivity, and in social stigmatization. Obesity accounts for approximately 300,000 deaths every year (Surgeon General's Call To Action, 2001). Morbidity from obesity is at least as great as poverty, smoking, and problem drinking (Sturm R, et al. 2001). The toll of overweight and obesity are not due only to premature death and an increased risk of numerous chronic diseases, but it also imposes a financial burden. As stated in *Healthy People 2010*:

“Many diseases are associated with overweight and obesity. People who are overweight or obese are at increased risk for high blood pressure, type 2 diabetes, coronary heart disease, stroke, gall bladder disease, osteoarthritis, sleep apnea, respiratory problems, and some types of cancer. The health outcomes related to these diseases, however, often can be improved through weight loss or, at a minimum, no further weight gain. Total cost (medical cost and lost productivity) attributable to obesity alone amounted to an estimated \$99 billion in 1995.”

The negative impact of overweight and obesity on hypertension is irrefutable. What's more, weight loss itself, even if ideal weight is not achieved, reduces blood pressure. Losing as little as 10 or 20 pounds improves blood pressure levels (*JNC IV*, 2003). Not only has no progress been made in reducing the incidence of overweight, the proportion of overweight and obese adults and children have increased substantially, with no indications of the trend reversing. As stated by U.S. Department of Health and Human Services (*HP 2010,19-8*), the proportion of adults and children who are overweight or obese represents one of the biggest challenges for *Healthy People 2010*.

B. Consumers Need Help

We are reminded daily via magazines, the internet, in books, advertising, and television, that overweight and obesity is a major problem in our society and that American's are looking for help. Weight loss is at least a \$50 billion a year industry, not including medical procedures. Some 50 million people attended *Weight Watchers* meetings in 2002 (*MSN website*; March 4, 2003). *Weight Watchers*, *Jenny Craig*, and

LA Weight Loss Centers do more than \$1 billion a year in business. Moreover, Jared Fogle has even become a star by losing weight and touting the benefits of Subway sandwiches.

Interestingly, many of the foods purported to be useful for weight reduction are contraindicated for salt reduction. For example, one 6-inch BMT Classic Subway sandwich has 480 calories (24% DV) and 1,900 mg of sodium (79% DV). Ordering the reduced sodium version (without cheese, salt, olives, and pickles) reduces the sodium to 1430 mg sodium (60% DV). (**Exhibit 16.**)

Contrarily, a ham sandwich made with Healthy Choice bread and lunch meat (three servings of Healthy Choice individual foods) and the same components added to a Subway sandwich, has only 204 calories (10% DV) and 744 mg sodium (31% DV) (**Exhibit 17**). As shown in **Exhibit 17**, a full day's menu using Healthy Choice items, which includes a ham sandwich, has 2171 mg of sodium for the entire day. The average amount of sodium in one 6-inch subway sandwich is 1,321mg or a little more than half an entire day's worth of the Healthy Choice diet sodium. (See **Exhibit 16.**) It appears that Healthy Choice is being penalized for providing consumers with a product that considers all of the desired nutritional parameters, reduced calories, reduced fat, reduced saturated fat, and reduced sodium.

Weight Watchers, another company that targets those desiring to lose weight, is perceived to be a healthy approach to weight loss, and in fact, is a program recommended by many health-care professionals. Of interest however, is that the menus provided to a Weight Watchers member do not include any of the packaged foods sold by Weight Watchers under the Smart Ones brand name. The average sodium level for 53 Smart Ones products is 682 mg of sodium (**Exhibit 18**).

Recently Tommy Thompson, Secretary of Health and Human Services, faced with a new study underwritten by the U.S. Center for Disease Control stating that obesity costs America over \$93 billion per year, pleaded in a public speech for food companies to do their part in this stopping this epidemic. In fact, Mr. Thompson indicated to reporters that food companies who make positive contributions to health would be rewarded (Associated Press, May 8, 2003).

So why is Healthy Choice being punished? Clearly one of the nation's leading health oriented product lines, Healthy Choice has continuously since 1994 struggled with government's attempts to run the line out of business by establishing practically impossible sodium limits on "healthy" products, while ignoring the vastly higher sodium products not labeled "healthy"! Thompson has called on the "entire food industry" in its battle against obesity. Why not call on the entire food industry in the identical battle against hypertension?

Thompson also called upon industry to help educate the American public on obesity prevention. But wasn't that the government's responsibility under the NLEA? And yet despite the government's failure to educate the populace, food companies have not failed. A recent Reuters article (May 19, 2003) lists a number of food company-health organization alliances aimed at educating the public re: the food-health connection, including Healthy Choice, with its alliances with the American Dietetic Association, American Heart Association, and others.

Even the new FDA Commissioner, Mark McClellan, has stated that the FDA must do more to help consumers get good information and improve labels so they can make smarter choices. (Speech before the National Food Policy Conference, May 8, 2003.) What better way to assist consumers in achieving a healthy diet than to offer more "healthy" products.

Yet FDA's actions will result in reducing the number of healthy products by forcing a too low sodium level for low fat products. It is beyond dispute that fat and salt add flavor to food. Healthy Choice takes out enough fat to call its food products healthy under federal guidelines, which requires lower fat limits than any other claim—including "lean". But Healthy Choice goes even further – Healthy Choice products also limit sodium, saturated fat, and cholesterol, and all products have 10% of the DRV of 1-3 positive nutrients. Unlike its competition, Healthy Choice does not increase the sodium levels to make up for the loss of taste when fat is removed: Healthy Choice also has to lower the sodium.

But now FDA wants to lower even further sodium limits *on the only product line in the market that already has lowered limits*. We have told FDA consistently since 1990 that some products simply cannot be made at those restrictive salt levels and to have even the number of healthy products that we have is something short of a miracle. And we have had a halo effect on the industries we are in—forcing competitors like Lean Cuisine, and Weight Watchers to make their products healthier overall. Other competitors, like Oscar Meyer and Kraft, tried to make healthy meats and cheeses, but left the marketplace after a few years of failure.

Even Healthy Choice sales are down considerably and the brand management team is continuously regarding new brand names in order to make their products appealing to consumers as their competitors. But ConAgra is convinced this is a necessary niche for products and dog-facedly continues to try to tempt consumers' pallet in a way that is good for them.

C. Alternatives for an effective health policy

Like the recent call to action by the British government, the FDA should be encouraging all food companies to reduce their sodium levels in all of their products. Other organizations already have. For example, the National High Blood Pressure Education Program (NHBPEP) in 1993 issued their first report. The Report called for changes in the food industry, specifically:

Manufacturers should be further encouraged to produce food products that are lower in sodium and calorie content, as well as lower saturated fat and cholesterol content.... To have a major impact on sodium consumption, it is critical that the food industry reduce the content of sodium in processed foods, especially convenience foods, such as frozen dinners and soups, but also in cereals, breads, and dairy products, such as low-fat cheese. National High Blood Pressure Education Program working Group Report on Primary Prevention of Hypertension, Arch. Intern. Med, 153, 1993.

This has been the goal of Healthy Choice since 1988, and to this day is still the only product line on the market that offers products meeting ALL of these recommendations.

Furthermore, attempts at reducing the sodium consumption of the country are woefully lacking a strategic plan. To determine viable approaches to such a goal will require a far better understanding of current sources of sodium, dietary patterns, and consumer behaviors. To begin with, the amount of salt/sodium actually consumed, and more importantly, by whom, would allow for more targeted and effective approaches. The sources of sodium/salt and the real contribution of prepared foods need to be delineated. Other contributing factors, and roadblocks, need to be determined.

In the Proposal (pg 8164), FDA states "...that it would be interested in exploring different options for maximizing the public health gains expected from reducing dietary sodium levels." And, we believe, there is good reason for FDA to pursue alternatives to this Proposal. One might say that focusing on the reduction of 120mg in a very small number of products while ignoring the fat and sodium levels of the top market sellers is similar to choking on a gnat while swallowing an elephant.

Of the 27 Healthy People 2000 nutrition objectives, five have been successful, including the one calling for the availability of reduced fat foods (Healthy People 2010, Vol. II, pp 19-8). Although the targets have not been met, progress has been made towards increasing the intake of fruits, vegetables, and grain products. Progress has also been made in reducing total fat intake, reducing saturated fat intake, and increasing the availability of nutrition labeling on food. However, other objectives such as consumer

actions to reduce salt intake have shown little or no progress. While blame has been cast on the food industry for the lack of progress, research shows that individual compliance is a major roadblock. (See **Exhibit 15.**) Industry can only drive changes that the U.S. population demands and finds palatable.

VIII. Economic Impact

Under Executive Order #12866, FDA must analyze the economic impact of any significant regulatory action. E.O. 12866 “classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million or adversely affecting in any material way a sector of the economy, competition or jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues.” (Proposal at pg 8171.) It is interesting to note that while OMB does not find this regulation economically significant (a finding disputed below), it does find this regulation to be “significant”, apparently due to legal or policy issues.

This regulatory proposal *is* significant under E.O. 12866 for the following reasons:

A. Economic:

This Proposal, if enacted, will cause certain “healthy” labeled products to be forced off the shelf due to a lack of consumer acceptance. Just in the categories in which we compete, we anticipate the following losses³:

1.	Soup	
	Healthy Choice lost sales	\$71.2 MM annually
	Health Valley lost sales	\$10.1 MM annually
	Healthy Requests RTS	\$ 2.6 MM annually ⁴
	Healthy Request Condensed ⁵	\$54.7 million annually

Total Soup Impact \$138.6 MM annually

2. **Lunchmeat** \$180 MM

3. **Hot Dogs** \$ 15 MM

³ All numbers are rounded.

⁴ Predicting a continued erosion of 33% a year or \$2.5MM each year for 3 years, with total discontinuation end of year 3.

⁵ With a predicted market share drop from 5.3% to 1.5%

4. **Sausages** \$ 5 MM

Total Product Sales Lost Annually \$338.6 MM

This loss is far in excess of the \$100 million per year threshold.

B. Jobs

Total ConAgra Foods jobs lost would be approximately 245 employees, representing nearly \$10 million in salary and benefits impacted. And many of these jobs are in small town rural America where few alternative jobs exist, as seen from the chart below:

Archbold, OH –	40 jobs (soup)
Junction City, KS –	40 jobs (meat)
Kansas City, KS –	35 jobs (meat)
St. James, MN –	65 jobs (meat)
St. Charles, IL –	20 jobs (meat)
Britt, IA –	15 jobs (meat)
Quincy, MI –	10 jobs (meat)
Jonesboro, Arkansas –	<u>20 jobs (meat)</u>

Total Jobs Lost **245 (Approximately)**

C. Competition

Clearly a major competitor in whole categories of foods would be wiped out, causing sodium levels overall to rise.

D. Legal or Policy Issues

ConAgra Foods has substantial time, capital and human resources invested in its Healthy Choice brand. Faced with an arbitrary and capricious regulatory taking of nearly 50% of the brand's product line would force ConAgra Foods to use all legal means to protect the interests of its shareholders and consumers. Moreover, data indicates that the public health policy of reducing disease by reducing sodium consumption is not served by this Proposal, and, in fact, has been shown to have the opposite effect.

IX. CONCLUSION

ConAgra Foods appreciates the opportunity to comment on this Proposal. We agree with FDA that main dish and meat type products cannot successfully reduce sodium levels to 480mg and still be palatable and so "healthy" main dish and meal type products should remain at 600mg of sodium per serving. In addition, however, analysis of current data clearly demonstrates that certain categories of popular food products cannot be successfully lowered to 360mg and still be acceptable alternatives for consumers. Therefore, at 360mg, these products will be forced off the supermarket shelf, resulting in an immense impact of this Proposal economically and from an employment perspective. In addition, the Proposal will backfire on the FDA's rationale for the Proposal...that of lowering sodium consumption, as it will limit the availability of whole categories of "healthy" products. As the data demonstrates, the end result of this Proposal will be an *increase* in sodium consumption, not a decrease. ConAgra Foods respectfully submits that current data demonstrates that all individual products cannot be produced at 360mg and be acceptable, and that the nation's health will be better served by maintaining the status quo.

Respectfully submitted,



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