

July 5, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
12420 Parklawn Drive
Rockville, MD 20852

Re: Docket Nos. 91N-384H and 96P-0500
Food Labeling: Nutrient Content Claims, Definition of Sodium Levels for the Term
"Healthy"
68 Fed. Reg. 8163 (February 20, 2003)

The Center for Science in the Public Interest (CSPI)¹ submits these comments in response to the Food and Drug Administration's proposed rulemaking on sodium limits for foods that make "healthy" claims.

I. Reducing sodium levels in the food supply is crucial to the public's health.

Hypertension is a public health problem of epidemic proportion in the United States. The Joint National Committee on the Detection, Evaluation, and Treatment of Hypertension recently released new guidelines expanding the pool of people whose blood pressure increases their risk of cardiovascular disease.² These guidelines classify as "prehypertensive" 45 million people whose blood pressure was previously considered normal. In addition, the guidelines classify 50 million Americans as hypertensive, including more than one out of two adults over age 60. Because blood pressure rises with age in the U.S., virtually all Americans are at risk of becoming hypertensive as they grow older. People who have normal blood pressure at age 55 have a 90 percent lifetime risk of developing hypertension. Furthermore, 30 percent of people who have hypertension are unaware of their condition, and 66 percent of hypertensives do not have their blood pressure under control. High blood pressure raises the risk of stroke, heart attack, heart failure, and kidney disease.

The National Heart, Lung, and Blood Institute has concluded—based on decades of clinical, epidemiological, and animal research—that reducing sodium intake can lower the risk of high blood pressure and cardiovascular disease. The evidence linking sodium intake to blood pressure is indisputable, despite efforts by the food and salt industries to convince the American public that sodium is harmless. However, processed foods

¹ CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

² <http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf>

contribute more than 75 percent of the average American's sodium intake, making it difficult for the public to follow the advice of health officials to consume less sodium. It is therefore absolutely essential that the food industry lower the sodium content of its products.

II. “Healthy” foods provide an extremely valuable lower-sodium alternative.

The FDA’s definition of the term “healthy” has given food companies an incentive to market lower-sodium products. The number of healthy products on the market is not extensive, in part because food processors have resisted efforts to reduce the sodium content of their foods. However, ConAgra’s lines of Healthy Choice canned soups, frozen meals, and processed meats are currently among the few lower-sodium alternatives on the market.

Our own brand-name ratings reveal that, in these product categories, there are limited lower-sodium options:

*** Canned soups.** In a survey of soups published in the December 2002 issue of *Nutrition Action Healthletter*, Healthy Choice soups dominated the “Best Bites”— soups that contain no more than 480 milligrams of sodium (and one gram of saturated fat) in a one-cup serving [Attachment 1]. With roughly one-fifth of a day’s worth of sodium, these products are not low in salt. However, they contain roughly half of the sodium of typical canned soups. If the second-tier sodium level were to shrink or eliminate the Healthy Choice line of canned soups, consumers would have no sizeable line of widely available alternatives to canned soups with 800 to 1,000 mg of sodium.³

*** Processed meats.** In the November 2001 issue of *Nutrition Action Healthletter*, Healthy Choice was the only major brand of ham, roast beef, and pastrami slices with 450 mg of sodium per two-ounce serving [Attachment 2]. Oscar Mayer, Louis Rich, and other brands typically had 600 to 800 mg of sodium per serving. Only one brand of processed poultry (Empire Kosher Turkey Breast and Turkey Pastrami) reported sodium levels of 360 mg or less, suggesting that the second-tier sodium limit might not be feasible for processed meats. If Healthy Choice and other brands were unable to reach the second-tier sodium limit, consumers would have no widely available alternatives to processed meats with 600 to 800 mg of sodium per serving.

ConAgra argues that it cannot lower the sodium levels of its soups and meats to the second tier. As a result, CSPI is faced with the same dilemma that occurred in May 1998, when we filed the following comments: “If stricter sodium limits led to the disappearance of “healthy” products from the supermarket, the modest progress towards lowering

³ If Healthy Choice soups were to disappear, people who are conscientiously trying to lower their sodium intake might avoid all canned soups or buy only the few, relatively expensive, low-sodium soups on the market. However, the popularity of the Healthy Choice line of soups effectively reduces the sodium intake of a greater number of consumers who buy Healthy Choice soups for other reasons. The reduction in sodium intake in this larger group of consumers would therefore be lost.

sodium consumption could be lost. Even the disappearance of “healthy” versions of a few categories of foods—like canned soup and hot dogs—would be detrimental because it would leave consumers with no lower-sodium versions of those foods to choose from.”

III. FDA should retain the first-tier sodium levels to avoid jeopardizing the viability of lower-sodium “healthy” foods.

To ensure the viability of the current lower-sodium alternatives on the market, CSPI urges FDA to retain the first-tier sodium levels (480 mg/serving) for individual foods.⁴ The potential benefit of lowering sodium in “healthy” foods to the second-tier level is simply not worth the risk of losing the current alternatives to the high-sodium selection of canned soups and processed meats that dominate the market.

According to the FDA, at least one company—presumably Campbell Soup—indicates that it sells several soups that can meet the second-tier sodium level. However, the number of soups in this line is quite small, giving consumers only a limited selection. Furthermore, Campbell also sells a far larger number of canned soups with 800 mg to 1,000 mg of sodium. Unlike ConAgra, which is tied to a brand name that includes the word “healthy,” Campbell could easily shrink or eliminate its “healthy” line in the future. In fact, Campbell has an incentive to eventually eliminate its “healthy” line because the name implies that the company’s larger selection of saltier soups is unhealthy. While it may appear that Campbell seeks to offer lower-sodium alternatives, its true intention may be to eliminate its competition from Healthy Choice.

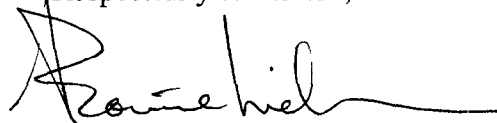
It is impossible for CSPI or the FDA to know whether Campbell ultimately intends to shrink or expand its “healthy” line. Nor can CSPI or the FDA know whether ConAgra has made every effort to lower sodium in its products, as the company claims. However, it is clear that Healthy Choice has the only large, readily available, heavily advertised lower-sodium lines of canned soups and processed meats. Furthermore, it is clear that the risk of losing these alternatives far outweighs the potential benefit of lowering sodium in “healthy” foods to the second-tier level. Therefore, we urge FDA to maintain its current limit on sodium in “healthy” foods.

This position may, at first glance, appear to contradict CSPI’s efforts to lower sodium intakes. In fact, CSPI’s studies of supermarket and restaurant foods have revealed that unnecessarily high sodium levels are rampant throughout the food supply. Ideally, the FDA would target its sodium-lowering regulations at this vast majority of foods, not the “healthy” foods that constitute a small fraction of the food supply and, in some cases, the only lower-sodium alternatives available.

⁴ If the FDA were to propose an alternative plan for reducing the sodium content of “healthy” foods without jeopardizing the viability of “healthy” canned soups and processed meats already on the market, CSPI would consider supporting it. For example, the FDA could exempt not only frozen meals, but these two categories of food, from the second-tier sodium levels. However, CSPI questions the usefulness of such a regulation, given that it would establish second-tier sodium levels only for categories of foods—such as cereals, ice cream, and cookies—that tend to already meet the second-tier level.

It has been more than two decades since the National Heart, Lung, and Blood Institute, the Surgeon General, the National Academy of Sciences, the American Heart Association, and other health authorities first urged Americans to cut back on sodium to reduce the risk of high blood pressure and its deadly consequences. It is appalling that the federal government has failed to regulate or motivate the food industry to substantially reduce sodium levels. It is unconscionable that, despite these recommendations, the food industry continues to dump large quantities of sodium into processed and prepared foods. Despite scientific evidence that has grown stronger over the years, the food and salt industries have mounted a major public relations campaign to convince Americans that high sodium levels are not a danger. The FDA—indeed, the federal government—has to counter that message with its own campaign. Moreover, it has to use its regulatory powers to force the food industry to stop putting millions of Americans at risk of hypertension by loading the American food supply with excessive and unhealthy levels of sodium.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bonnie Liebman", with a long horizontal flourish extending to the right.

Bonnie Liebman
Director of Nutrition

Of counsel:
Sandra Eskin

Attachment 1

Among our favorites from the "healthy" lines: Healthy Choice Vegetable Beef, Garden Vegetable, and Split Pea and Ham.

Campbell's Healthy Request soups are also a good bet, especially the "Hearty" ones, which contain more food than some of the company's condensed soups. And Health Valley works wonders with the 250-or-so milligrams of sodium in its Fat Free line, especially the Minestrone, 14 Garden Vegetable, and (out-of-this-world) 5 Bean Vegetable. Its Fat Free Vegetable Barley and 99% Fat Free Chicken Noodle didn't taste so wonderful.

Some small companies also got Best Bites, but were less reliable tastewise. Pritikin's seasonings (or lack thereof) left us cold. Tabatchnick's Barley & Mushroom was tasteless, while its Split Pea was scrumptious. Hain went from good-tasting (Mushroom Barley) to anything but (Vegetarian Lentil). ShariAnn's Spicy Green Lentil gives lentil soup a new twist, but her Indian Black Bean & Rice is far too heavy on the cloves. And comments on Amy's No Chicken Noodle went from "tastes like gravy" to "dead ringer for real chicken soup."

Some lines were more consistent. Imagine's cartons of organic soups—like Creamy Broccoli or Creamy Butternut Squash—were dependably delish.

SINGLE-SERVING SOUPS

What better way to stir up a hot lunch when you're stuck at the office with only hot water to cook with?

Just watch which brand you choose. Fantastic knows how to make a Country Lentil, Jumpin' Black Bean, Minestrone, and Split Pea. But its Creamy Asparagus and Cha-Cha Chili appealed to some taste buds more than others.

Likewise, Dr. McDougall wowed us with his Tortilla Soup and Split Pea with Barley. (His Minestrone and Ramen Noodles weren't as popular, though ramen fans should give the doc's a try, given the sky-high levels of sodium and saturated fat in large brands like Nissin and Maruchan.)

Other winners: Kettle Cuisine's Carrot Ginger was spectacular...and its homemade richness came through whether we ate it hot or cold. Nile Spice makes a dynamite Split Pea, and its Red Beans & Rice has a welcome kick. Opinions on Nile's Tomato Herb ranged from good to so-so.



Can't blame these ramens. They look innocent, but most ramen noodles are loaded with saturated fat (usually thanks to their palm oil) Not these babies. They're low in fat and are low enough in sodium—and rich enough in nutrients—to get a Best Bite.

PHOTOS: Nick Waring



Healthy means less salt. If you see the word "healthy" on a label, a serving of the food can't contain more than 480 mg of sodium (that's 20 percent of a day's worth). Bonus: "Healthy" foods must also be low in saturated fat. While some "healthy" soups didn't meet our nutrient minimums, they still beat salty soups, hands down.

Health Valley's line has no knock-outs, but it has no losers either. Overall, a disappointing soup-in-a-cup still beats a lousy soup-in-a-can. The only exception: Teapot Soups. The company hasn't quite gotten the hang of making instant soups.

Just don't assume that one cup is one serving. Those just-add-boiling-water cups can make anywhere from six ounces of soup (Lipton) to 15 ounces (Fantastic Big Soup Noodle Bowls, Health Valley, and a few other brands). Since most labels list calories, sodium, etc., for eight ounces, you'll have to double the numbers if you eat the whole cup of the biggies. That's what we've done in our chart.

The information for this article was compiled by Tamar Genger.

In the Soup

To earn a Best Bite, an eight-ounce serving of soup could have no more than 480 milligrams of sodium (600 mg for single-serving soups that make more than eight ounces). It also had to have at least 50 percent of a day's worth of any combination of vitamins A and C, calcium, iron, protein, and fiber. Within each category, soups are ranked from least to most sodium, then most to least fiber, then least to most calories.

Multi-Serving Soups (1 cup)	Calories	Sodium (mg)	Fiber (grams)
✓✓ Health Valley Organic No Salt ¹	90	40	4
✓✓ Tabatchnick No Salt ¹	140	60	6
✓✓ Health Valley Fat Free ¹	100	250	6
✓✓ Pritikin ¹	110	290	4
✓✓ Tabatchnick Barley Mushroom, Cabbage, Creamed Spinach, Lentil, Minestrone, Split Pea, Tomato Rice, Vegetable, Vegetarian Chili, or Yankee Bean ²	120	320	6

BRAND - NAME RATING

	Calories	Sodium (mg)	Fiber (grams)
✓✓ Health Valley Organic ¹	90	330	4
✓✓ Woodstock Organics Creamy Potato	100	330	3
✓✓ Taste Adventure Minestrone, Navy Bean, or Sweet Corn Chowder ²	160	360	7
✓✓ Campbell's Healthy Request Ready to Serve, except New England Clam Chowder ¹	120	360	3
Campbell's Healthy Request Ready to Serve New England Clam Chowder	110	360	2
✓✓ Imagine Creamy Broccoli or Creamy Butternut Squash ²	100	370	2
✓✓ Westbrae Fat Free Santa Fe Vegetable	160	380	8
Imagine Creamy Portobello Mushroom, Creamy Potato Leek, Creamy Sweet Corn, or Creamy Tomato ²	90	390	2
✓✓ Health Valley 99% Fat Free Chicken Noodle or Chicken Rice ²	130	390	2
✓✓ ShariAnn's Cream of Tomato, Great Plains Split Pea, Indian Black Bean & Rice, Spicy French Green Lentil, Spicy Mexican Bean, Tomato with Red Bell Pepper, or Tomato with Roasted Garlic ²	120	410	3
✓✓ Progresso 99% Fat Free Lentil	130	440	6
✓✓ Campbell's Condensed Healthy Request, except Chicken Noodle or Cream soups ¹	90	440	3
Campbell's Condensed Healthy Request Chicken Noodle or Cream soups ²	70	440	1
✓✓ Healthy Choice Bean and Ham, Chicken Corn Chowder, Chicken Pasta, Country Vegetable, Creamy Potato & Ham, Garden Vegetable, Hearty Chicken, Hearty Chili Beef, Mediterranean Bean with Pasta, Minestrone, Old Fashioned Chicken Noodle, Roasted Chicken with Garlic, Split Pea and Ham, or Vegetable Beef ²	130	480	4
✓✓ Hain ¹	100	480	3
Healthy Choice Baked Potato, Chicken with Rice, Chunky Beef and Potato, Classic Italian Bean and Pasta, Creamy Tomato, Fiesta Chicken, New England Clam Chowder, Turkey with White and Wild Rice, Vegetable Clam, or Zesty Gumbo ²	100	480	3
✓✓ Amy's No Chicken Noodle	90	480	2
Taste Adventure Black Bean, Curry Lentil, Golden Pea, or Split Pea ²	220	540	12
Pacific Creamy ^{1*}	120	540	1
ShariAnn's Italian White Bean, Minestrone, Potato and Cheddar, Vegetable Barley, or Vegetarian French Onion ^{2*}	110	570	2
Amy's, except No Chicken Noodle ^{1*}	100	590	4
Woodstock Organics, except Creamy Potato ¹	130	620	4
Fantastic ^{1*}	120	660	3
Lipton Soup Secrets ¹	80	690	0
Nissin Top Ramen ^{1#}	190	770	1
Campbell's Simply Home ^{1*}	110	790	2
Maruchan Ramen Noodle Soup ^{1#}	190	790	1
Wyler's Soup Starter Soup Mix ¹	100	820	3
Knorr Savory Soups ^{1*}	100	820	1
Campbell's Ready to Serve Classics ^{1*}	110	840	3
Campbell's Select, except New England Clam Chowder ^{1*}	120	840	3

	Calories	Sodium (mg)	Fiber (grams)
Campbell's Condensed 98% Fat Free ¹	70	840	1
Knorr Naturals Hearty Soups ¹	100	840	1
Campbell's Condensed Classics ^{1*}	90	860	2
Campbell's Select New England Clam Chowder [#]	200	870	2
Progresso, except 99% Fat Free Lentil ^{1*}	110	880	2
Campbell's Condensed Special Selections ^{1*}	90	890	2
Campbell's Condensed Fun Favorites ¹	80	890	1
Mrs. Grass Soup Mix ¹	50	890	0
Campbell's Chunky ^{1*}	150	900	3
Pepperidge Farm Lobster Bisque or Vichyssoise ^{2#}	140	1,020	0
Pepperidge Farm, except Lobster Bisque or Vichyssoise ^{1*}	100	1,050	2

Single-Serving Soups

(1 container—about 1 cup unless noted)

✓✓ Kettle Cuisine Carrot Ginger	120	230	3
Teapot Soups Potato Leek	130	350	1
Thai Kitchen Rice Noodle Bowl ¹	180	400	0
✓✓ Teapot Soups, except Potato Leek ¹	180	440	7
✓✓ Dr. McDougall's ¹	170	480	4
✓✓ The Spice Hunter Black Bean, Navy Bean, Split Pea, or Szechwan Noodle ²	170	490	8
✓✓ Fantastic, except Creamy Broccoli Cheddar, Creamy Garlic Mushroom, Creamy Potato Leek, or Vegetable Miso Ramen Noodles ¹	190	510	8
✓✓ Kettle Cuisine Gazpacho	110	510	2
Lipton Cup-a-Soup ¹	60	530	0
Fantastic Vegetable Miso Ramen Noodles	130	540	2
✓✓ Health Valley (2 cups) ¹	220	550	6
Fantastic Creamy Broccoli Cheddar, Creamy Garlic Mushroom, or Creamy Potato Leek ^{2*}	150	550	2
✓✓ Nile Spice Black Bean, Gazpacho, Lentil, Minestrone, Red Beans & Rice, Split Pea, or Tomato Herb ²	150	580	7
The Spice Hunter Bowl Size (2 cups) ^{1*}	190	780	4
Knorr TasteBreaks ¹	160	940	3
Campbell's Soup to Go ¹	130	960	2
Campbell's Soup at Hand ^{1*}	140	970	3
Birds Eye Hearty Spoonfuls ^{1*}	190	1,130	4
Nissin Cup Noodles (2 cups) ^{1#}	300	1,140	2
Fantastic Big Soup Noodle Bowls ¹	220	1,230	2
Maruchan Instant Lunch (2 cups) ^{1#}	290	1,310	2

✓✓ Best Bite. ¹Average of the entire line (excluding broths).

²Average of the soups listed. *Some soups in the line have more than 1 gram of saturated fat. #Contains 3 or more grams of saturated fat.

Notes: Some large line averages may not include every soup in the line. Numbers don't include milk for soups that call for it (using fat-free milk shouldn't change the numbers appreciably).

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Source: Manufacturers.

No Matter How You Slice It

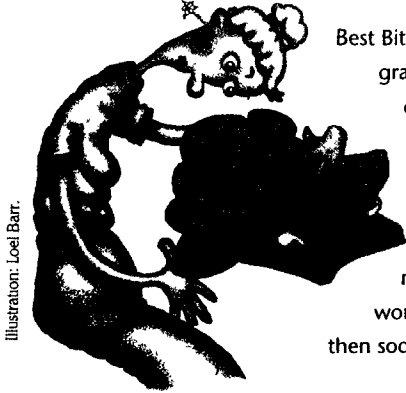


Illustration: Loel Barr.

Best Bites contain no more than three grams of total fat and 480 milligrams of sodium in a two-ounce serving. The number of slices that weigh closest to two ounces is in parentheses following each product's name. Within each category, the meats are ranked from best to worst—from least to most total fat, then sodium, sat fat, and calories.

Calories
Total Fat (grams)
Saturated Fat (grams)
Sodium (mg)

Bryan Classic Deli Honey or Smoked Ham (6) ¹	60	2	1	610
Hillshire Farm Deli Select Ham (6) ²	60	2	1	630
DAK Lookin' Lean Premium Ham (2)	60	2	0	760
Oscar Mayer Ham (2-4) ²	70	2	1	760
Louis Rich Carving Board Ham (5) ²	60	2	0	800
Bar-S Extra Lean Cooked Ham (2)	80	2	0	840
✓✓ Empire Kosher Turkey Pastrami (3)	50	3	1	360
✓✓ Danola Black Forest Smoked Ham (3)	90	3	2	480
Carl Buddig Premium Lean Slices Ham (6) ²	70	3	1	600
Louis Rich Turkey Ham and Smoked Chopped Turkey Ham (2) ¹	80	4	1	700
Carl Buddig Ham (10) ²	90	5	2	650
Butterball Lean Turkey Ham (2)	90	6	2	700
Oscar Mayer Ham & Cheese Loaf (2)	120	9	5	700
Bar-S Traditional Chopped Ham (2)	160	12	6	820

Sliced Luncheon Meat

(No. of slices in 2 oz.)

Turkey & Chicken

	Calories	Total Fat (grams)	Saturated Fat (grams)	Sodium (mg)
✓✓ Empire Kosher Turkey Breast (3)	50	0	0	260
✓✓ Butterball Fat Free Honey Roasted & Smoked, Oven Roasted, and Smoked Turkey Breast (6) ¹	50	0	0	470
✓✓ Butterball Fat Free Oven Roasted Chicken Breast (5)	50	0	0	480
✓✓ Oscar Mayer Fat Free Oven Roasted Chicken Breast (4)	50	0	0	480
Thorn Apple Valley Turkey Breast (2)	50	0	0	560
Louis Rich Fat Free Turkey Breast (2) ²	50	0	0	640
✓✓ Hebrew National Oven Roasted Turkey Breast (5)	50	1	0	430
✓✓ Louis Rich Carving Board Grilled Chicken Breast (2)	50	1	0	480
✓✓ Healthy Choice Chicken Breast (2-6) ²	60	1	1	480
Danola Black Forest Smoked Turkey Breast (3)	80	1	0	570
Hillshire Farm Deli Select Turkey Breast (6) ²	60	1	0	590
Louis Rich Carving Board Turkey Breast (2-3) ²	50	1	0	620
Oscar Mayer Turkey (2-4) ²	70	1	0	660
DAK Lookin' Lean Turkey Breast (2)	50	1	0	680
✓✓ Healthy Choice Turkey Breast (2-6) ²	60	2	1	470
✓✓ Jennie-O Extra Lean Smoked White Turkey (2)	70	3	0	480
✓✓ Carl Buddig Premium Lean Slices Turkey (6) ²	60	3	1	480
Butterball Lean Oven Roasted White Turkey (2)	90	6	2	580
Carl Buddig Turkey (10) ²	90	6	2	630
Land O' Frost Chicken (8) ²	100	6	2	740
Land O' Frost Turkey (8) ²	90	6	2	790

Ham, Corned Beef, Pastrami, etc.

Oscar Mayer Fat Free Ham (3)	40	0	0	550
Hillshire Farm Deli Select Corned Beef, Oven Roasted Cured Beef, Pastrami, Roast Beef, and Smoked Beef (6) ¹	60	1	0	620
✓✓ Healthy Choice Ham (2-6) ²	60	2	1	450
✓✓ Healthy Choice Roast Beef and Pastrami (2-6) ¹	60	2	1	450
Thorn Apple Valley Cooked Ham (2)	60	2	0	560

Bologna & Salami

Oscar Mayer Fat Free Bologna (2)	40	0	0	500
✓✓ Jennie-O Extra Lean Turkey Bologna (2)	70	2	0	460
Jennie-O Extra Lean Cooked Turkey Salami (2)	70	3	0	640
Hebrew National Lean Beef Bologna (4)	90	5	3	440
Hebrew National Lean Beef Salami (4)	90	5	3	480
Louis Rich Turkey Cotto Salami (2)	80	5	2	560
Louis Rich Lower Fat Turkey Bologna (2)	100	8	2	540
Oscar Mayer Light Bologna (2)	120	8	2	600
Oscar Mayer Light Beef Bologna (2)	120	8	3	620
Oscar Mayer Beef Cotto Salami (2)	120	9	4	720
Oscar Mayer Cotto Salami (2)	140	12	4	560
Hebrew National Beef Salami (3)	150	13	6	420
Bar-S Chicken Bologna (2)	180	14	4	740
Oscar Mayer Bologna (2)	180	16	6	600
Oscar Mayer Beef Bologna (2)	180	16	7	620
Oscar Mayer Hard Salami (6)	200	16	6	1,020

Vegetarian

✓✓ Lightlife Smart Deli Bologna, Ham, Pastrami, and Turkey (4) ¹	60	0	0	400
✓✓ Yves Veggie Cuisine Deli Slices, Bologna, Ham, Salami, and Turkey (4) ¹	80	0	0	450
✓✓ Tofurky Deli Slices (4) ²	160	2	0	400

✓✓ Best Bite.

¹Average of the varieties listed. ² Average of all varieties and/or cuts.

Daily Values (DV's—limits per day for 2,000 calories):

Total Fat—65 grams. Saturated Fat—20 grams. Sodium—2,400 milligrams.

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Source: Manufacturers.