

testing per product, based on this industry example. Since this reformulation would be undertaken to keep an existing product, we assume no relabeling or marketing costs. The total reformulation costs are therefore \$440,000 per product, or \$36,520,000 for the 83 meals assumed to be reformulated if adopting the second-tier sodium levels for meals and main dishes under scenario 6a. This cost would be incurred in the first year or two after the introduction of the rule. Assuming 50 percent of the cost is incurred per year for 2 years, and ignoring the time discount, the cost is \$18,260,000 per year.

Regardless of the relative costs of reformulation, FDA believes that a substantial number of market participants will choose to rebrand or relabel their products out of the "healthy" category if it becomes too restrictive. This has already happened under the current first-tier level: The number of "healthy" meals and main dish products dropped from 210 to 148 from 1993 through 1999, and the number of "healthy" brands dropped from 13 to 10. This time period spans the adoption of the current definition of "healthy" in 1994.

In this case, the direct costs of relabeling the product and conducting a marketing campaign would be social costs, since they represent extra investment that will not increase or improve the choice of products for consumers. Although FDA has no information about the costs of this type of rebranding activity to the manufacturer, they are most likely substantial.

However, the market may put a premium on "healthy" brands. This premium is a good measure of what consumers are willing to pay for the "healthy" signal. Since consumers would presumably be paying less for a less valuable product, the total effect of rebranding on consumer utility is negative but limited. However, firms have made an investment in the "healthy" brand based on an expected return closely related to this "willingness to pay" premium, and this investment would now be worthless if the product is unable to use the "healthy" claim. If the new definition of "healthy" with the second-tier sodium level is no more useful a health signal than the old definition, as we argue, this lost investment is a cost to society. In the original analysis of the regulation defining "healthy" (59 FR 24232 at 24247), which was issued in 1994, FDA estimated that the average premium (measured as the selling price difference) that the market placed on

"healthy" brand goods was \$0.57 per 16 oz equivalent. FDA used the Washington, DC store sample of 106 meals and main dishes referred to earlier to reestimate this premium for 2000, with similar results.

According to the analysis in FDA's technical memorandum (Ref. 5), the "healthy" brand competitor has a significant \$0.32 premium over the other major health positioned producer in this market, and at least as high a premium over the other major claims producer. Excluding the specialty organic products, the "healthy" brand is the highest priced product on the market in our sample. FDA believes \$0.32 to be a reasonable estimate of the market premium for the "healthy" brand. At average serving sizes of 10 oz, this translates into a \$0.51 premium per 16 oz, which is very close to the \$0.57 premium estimated in 1994.

In the 1994 analysis, the total value of each brand was based on this premium and average sales volumes. Sales of the brands still in the market were approximately 1.3 million units per product in 1999 (Ref. 2). Under the assumption of 19 percent rebranding in order for meals and main dishes to comply with the second-tier sodium level (scenario 6a), 28 products would be changed, with a total lost premium of \$11,648,000 per year (28 products x \$0.32 premium lost x average sales of 1.3 million units per year).

Adding this to the reformulation costs of the 83 products yields a total cost estimate of \$29,908,000 for years one and two, and a residual of the lost premium of \$11,648,000 for what would have been the rest of the normal life cycle of the lost "healthy" brand. Clearly, these costs are very large for a rule which would lead to little or no health benefit for the population, and avoiding these costs represents a large benefit of option 2b, the proposed rule.

*Option 2c: Retain the First-Tier Sodium Levels for "Healthy" Meals and Main Dishes and Individual "healthy" Foods.* The benefits and costs of option 2c are very close to the sum of the benefits and costs associated with options 2a and 2b. However, as stated in the discussion of option 2a previously in this document, retaining the first tier sodium levels for "healthy" individual foods would significantly decrease the consistency between sodium levels in "healthy" meals and main dishes and the sodium levels in meals put together by combining "healthy" individual foods. The less consistent the sodium levels in "healthy" meals and individual foods, the less consistent, and therefore less useful, is the low

sodium signal conveyed by the "healthy" label.

*Costs of Option 2c.* The cost of this proposed amendment, as with option 2a for individual foods, and option 2b for meals and main dishes, is the increased risk due to higher sodium intake and the diminishing effectiveness of the "healthy" low sodium signal. Since option 2c is essentially combining options 2a and 2b, the costs associated with a higher sodium intake are roughly the sum of the costs associated with options 2a and 2b.

As discussed previously in detail in this document, the average increased sodium intake occurring under option 2b is insubstantial (roughly 22 mg per meal) and the health effects from this low level of sodium increase are negligible. As stated previously, even under the conservative assumption of a linear dose response, the statistical lives saved by decreasing allowable sodium in "healthy" meals and main dishes to tier-2 levels would be less than 1. Furthermore, the effectiveness of the "healthy" low sodium signal would not be diminished since tier-1 levels of sodium for meals and main dishes allow for even less sodium than would appear in a meal composed of tier-2 individual "healthy" ingredients.

However, the potential increase in sodium intake, as discussed in detail under option 2a, due to relaxing the current level of sodium allowable in individual "healthy" foods, as well as the costs associated with the deterioration of the "healthy" signal, is significant.

Therefore, FDA believes the costs of option 2c, due to the reduced effectiveness of the "healthy" low sodium signal and the health risks due to increased sodium intake are significant, but only negligibly higher than those costs described for option 2a.

*Benefits of Option 2c.* The benefits of avoiding reformulation, rebranding, and relabeling costs under this option are roughly the sum of the benefits associated with options 2a and 2b.

FDA estimates, as discussed in the benefits section of option 2a, that the benefits of avoiding reformulation and relabeling costs associated by retaining the first-tier sodium levels for individual "healthy" foods are small.

As discussed in the benefits section of option 2b, the benefits of avoiding reformulation, rebranding, and relabeling costs by retaining first-tier sodium levels for "healthy" meals and main dishes are substantial. FDA estimates the total cost of reformulation and relabeling avoided in option 2b is \$29,908,000 for years one and two, and \$11,648,000 per year thereafter.