

Therefore, FDA believes the benefits of option 2c, due to the avoided reformulation and relabeling costs associated with implementing the tier-2 sodium levels for both “healthy” meal and main dishes and “healthy” individual foods, are substantial but only slightly higher than those benefits described for option 2b.

*Net Benefits of Option 2c.* The net benefits of option 2c, retaining the first-tier level of sodium for both “healthy” meals and main dishes and individual “healthy” foods, are roughly the sum of the net benefits of options 2a and 2b.

The net benefits of option 2a, retaining the first-tier level of sodium for individual “healthy” foods are negative. The costs due to the health risk associated with increased sodium intake and the lost consistency and meaning of the “healthy” low sodium signal outweigh the benefits due to avoided reformulation, rebranding, and relabeling costs.

The net benefits of option 2b, retaining the first-tier level of sodium for “healthy” meals and main dishes are positive. The benefits in avoided reformulation, rebranding and relabeling costs substantially outweigh the negligible costs due to a very small potential increase in average daily sodium intake.

Since the net benefits of retaining the first-tier sodium level for “healthy” meals and main dishes are so substantial, FDA believes the net benefits of 2c, roughly the sum of the net benefits associated with 2a and 2b, are positive, but lower than the net benefits of the proposed rule, which would adopt as permanent the first-tier sodium limits for meals and main dishes only.

### 3. Net Benefits of the Proposed Rule

This analysis attempts to take limited data to illustrate in some detail what would actually take place in the market under the proposed rule. First, the costs to the “healthy” signal’s meaning and consistency outweigh the benefits of retaining the first-tier sodium level for individual foods. However, the meal and main dish analysis shows that while the benefits of retaining the first-tier sodium level (the costs foregone) are substantial for companies that would need to reformulate to comply with the second-tier sodium level or rebrand and relabel themselves out of the “healthy” market, the health costs associated with retaining the first-tier sodium level are both unquantifiable and most likely quite insubstantial or nonexistent. Therefore, the net benefits of the proposed rule, which would allow the second-tier sodium level to go into

effect for individual foods but would adopt as permanent the first-tier sodium level for meals and main dishes, are positive.

### B. Small Entity Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic effect of the rule on small entities. FDA finds that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would make permanent the less restrictive first-tier sodium level that meals and main dishes must meet to make a “healthy” claim. Without this proposed rule, the more restrictive second-tier sodium level would raise the costs of making a “healthy” claim on such products. If a small business were to market a “healthy” meal or main dish, it would be able to do so at lower cost under the proposed rule than if FDA left the current rule unmodified.

This proposed rule does not modify the current rule for the sodium content of “healthy” individual foods, under which the second-tier sodium level for those foods will take effect in 2006. Although the proposed rule does not impose a cost on small businesses over and above the rule that would otherwise be in place, FDA could lower the cost to small businesses of making a “healthy” claim by adopting as permanent the first-tier sodium level for individual foods.

As stated in the preliminary regulatory impact analysis discussed earlier, manufacturers of “healthy” foods in three categories—cheeses, soups, and some meats—are likely to be affected by the implementation of the second-tier sodium level. These foods are discussed in this document. As FDA has no information concerning costs for other individual foods and has received no comments indicating that manufacturers of these other foods would have difficulty meeting the second-tier sodium level, the agency tentatively concludes that the impact on small entities producing other types of “healthy” individual foods is not significant. FDA invites comments regarding small entities producing other “healthy” individual foods that may be adversely impacted by this proposed rule.

Of the affected individual food categories, meat is regulated by the

USDA and is not part of this analysis. The Small Business Administration (SBA) considers a cheese manufacturer small if it employs 500 or fewer workers, but no small or large business currently produces “healthy” cheese. The SBA considers a miscellaneous food manufacturer (neither SBA nor the Census Bureau specifically tracks soup producers) small if it employs 500 or fewer employees. According to the 1999 survey of foods used for this analysis, six companies produce “healthy” soups (Ref. 2), but none of these companies qualifies as a small business according to the standard SBA criteria. According to the 1999 Statistics for Businesses from the United States Census Bureau, over 90 percent of food manufacturers are small by the standard SBA criteria, so new entries into this industry in the future are likely to be small businesses. FDA tentatively concludes that this proposed rule will not have a significant impact on small entities.

### VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has tentatively determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has tentatively concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### VIII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.