

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

21 CFR Parts 5, 20, 100, 101, 105, and 130

[Docket No. 91N-0219]

RIN 0905-AD08

### Regulatory impact Analysis of the Final Rules to Amend the Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Regulatory impact analysis statement.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing the final regulatory impact analysis (RIA) that it has prepared under Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). This study presents the costs and benefits of the food labeling regulations that FDA is issuing. FDA is issuing these final rules (published elsewhere in this issue of the **Federal Register**) in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and as part of the Secretary of Health and Human Services' (the Secretary's) food labeling reform initiative. The agency has prepared this comprehensive RIA document for these regulations because, when taken together, they constitute a major rule.

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#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60366 et seq), FDA published a number of proposed food labeling regulations to implement the provisions of the 1990 amendments (Pub. L. 101-535). In the same issue of the **Federal Register** (56 FR 60856, November 27, 1991), FDA published an RIA (hereinafter referred to as the 1991 RIA proposal) which preliminarily estimated the costs and benefits of the various proposed regulations and on which FDA asked for comments. Interested persons were given until February 25, 1992, to comment. FDA received approximately 350 letters, each containing one or more comments, from health professionals, trade associations, Federal and State Governments, foreign governments, consumer advocacy

organizations, consumers, professional societies, food manufacturers and distributors, and academia. Many of the issues addressed in the 1991 RIA proposal are covered in the separate final rules issued concurrently with this document.

Comments have not altered FDA's preliminary finding that the food labeling reform initiative, taken as a whole, will have associated costs in excess of the \$100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291, FDA has developed one comprehensive final RIA that presents the costs and benefits of all of the food labeling proposals taken together.

In addition, FDA is publishing elsewhere in this issue of the **Federal Register** a final rule to announce its decision to delay the application of the nutrition labeling and nutrient content claims provisions of the Federal Food, Drug, and Cosmetic Act (the act). In that rule FDA concluded that requiring compliance with section 403(q) or (r)(2) of the act (21 U.S.C. 343(q) or (r)) on May 8, 1993, would cause an "undue economic hardship" on the food industry in that there would be costs to the food industry that are excessive and more than Congress intended. All comments regarding the applicability date are addressed in that document.

FDA also published, as a component of the 1991 RIA proposal, a preliminary regulatory flexibility analysis which addressed the issue of small businesses. The 1990 amendments granted an exemption from mandatory nutrition labeling for small businesses. Under section 403(q)(5)(D) of the act, a small business is defined as a business with less than \$500,000 annual gross sales or a business with annual gross sales of more than \$500,000 but less than \$50,000 in food sales. The exemption does not apply to those products that make nutritional claims or voluntarily provide nutrition information.

Comments concerning this exemption stated that this exemption was too low and are discussed more thoroughly in the mandatory nutrition labeling final rule published elsewhere in this issue of the **Federal Register**. FDA, in response to these comments, participated in a series of public forums that had been scheduled by the U.S. Department of Agriculture (USDA) to discuss the small business issue. In addition, FDA published a notice in the **Federal Register** asking for comments on this issue. As of publication of these rules and the final RIA, the exemption has not been changed. FDA will discuss in more detail the affect of the 1990 amendments on small businesses in a final

Regulatory Flexibility Analysis published subsequent to these final rules.

##### II. Regulatory Options

Under the Regulatory Flexibility Act, FDA is required by law to consider ways to reduce the regulatory burden on small businesses. One conceivable regulatory option would be to allow product lines with fewer than 500,000 unit sales annually produced by small firms (firms with less than 500 employees) to make reasonable estimates of mean nutrient content rather than complying with the 80/100/120 rules.

Under the regulatory option currently selected, class I nutrients (added nutrients) including vitamins, minerals, protein, dietary fiber, and potassium are required to have at least 100 percent of the listed value within specified variances. Class II nutrients (naturally occurring), including vitamins, minerals, proteins, total carbohydrates, dietary fiber, other carbohydrates, polyunsaturated or monounsaturated fat, or potassium must have at least 80 percent of the value for the nutrient declared on the label within specified variances. Finally, a food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium is misbranded under section 403(a) of the act if the nutrient content of the composite sample is greater than 20 percent more than the declared amount, again within the variance specified for the appropriate test. In addition, in new § 101.9(g)(6), reasonable excesses over or under the labeled amounts are allowed where current good manufacturing practices (CGMP's) are used. This option would replace these values with a requirement to list the mean value within variances established for specific nutrient tests and allowing reasonable excesses over or under the labeled amounts where CGMP's are used. This option could either exist as a blanket exemption for small firms or one that is made by special request on a per firm basis to the agency.

Thus small firms could determine nutrient levels by analysis, by calculation using nutrient data bases of ingredients and recipes, or by other reasonable means that provide assurance that the value declared is the mean value of a particular nutrient in the food product. This option would reduce the burden on small business by allowing the use of means rather than values determined by analytical testing in the declaration of nutrient content.

Approximately 59 percent of all food products have fewer than 500,000 units sold annually and are produced by

small firms. This option would significantly reduce analytical costs by between \$235 and \$600 million depending upon the rate of retesting that would otherwise be done. In addition, this option will prevent small business failure which may occur for small firms with very low product volume. This option would result in virtually no loss in benefits because the occasional errors in labeling may offset one another. In addition, although this type of exemption would represent a large number of products, it represents only about 2 percent of the diet. Thus, for example, if these manufacturers were to approximate wrong (or intentionally misrepresent their products) concerning the amount of total fat in their product such that all of the products in this category underreported the amount of fat by 50 percent, and if all consumers were 100 percent misled by such underreporting it would only result in a 1 percent error in fat consumption. Given that such errors in reporting are: (1) Likely to balance out; (2) will probably be corrected by enforcement over time; and, (3) that it is unlikely that all consumers would be misled by gross errors, a significant loss of benefits as they have been calculated in this regulatory impact analysis seems unlikely.

An alternate standard for coverage of this option, such as exempting small firms (500 or less employees) with less than 100,000 units could also be chosen. This would exempt 51 percent of the products covered by the 1990 amendments, but it would exempt less than 2 percent of the diet.

Although FDA is allowing the "reasonable basis" standard in food service establishments making nutrient content claims and health claims, FDA believes that there is a significant difference between the criteria used to determine whether or not a claim is justified, and the criteria used to determine the quantified level of a nutrient to be reported on a food label. In addition, FDA believes that the option that it has chosen is also consistent with the other relevant sections of the act including sections 402(b) and 403(a) (21 U.S.C. 342(b) and 343(a)).

### III. Costs of the Regulations

#### A. General

In the 1991 RIA proposal, FDA determined that about 17,000 domestic food manufacturers and 260,000 labels would be affected by the regulations promulgated in response to the 1990 amendments. Of these, approximately

160 dietary supplement manufacturers would alter approximately 3,400 unique dietary supplement products. In addition, 96,000 food service establishments would also be required to alter their menus if they are not in compliance with nutrient content and health claims regulations.

Categories of costs include administrative, analytical, printing, inventory disposal, and reformulation. In all cost categories, except administrative costs, the costs of relabeling products produced and labeled in foreign countries cannot be separated from those products produced and labeled domestically. Thus, the administrative costs considered are domestic costs only, whereas the printing, inventory, and analytical costs considered are multinational.

In the 1991 RIA proposal, mandatory ingredient labeling for standardized foods and certified colors were separated from the other actions because it was to take effect in November of 1991. Costs for these provisions, as proposed, were \$128 million.

In the **Federal Register** of July 2, 1991 (56 FR 30452), FDA published a proposal on the declaration of percentage juice. FDA determined that the costs which would occur as a result of those proposed requirements would be \$40 million, based on an effective date of November 8, 1991. When the 1991 RIA proposal was published, the proposed requirements regarding the declaration of percentage juice were to become effective concurrently with the requirements for mandatory nutrition labeling which would have resulted in lowering the incremental costs to \$1 million. However because those provisions are subject to being enforced 9 months before the agency will enforce the requirements for mandatory nutrition labeling, the costs are appropriately determined to be the original assessment of \$40 million. FDA received no comments to the original proposal, objecting to its determination of the costs. Therefore, the agency is not amending its original estimate of the costs of declaring percentage juice.

Voluntary nutrition, labeling of raw fruit, vegetables, and fish is also separable from all other provisions of the 1990 amendments because it affects supermarkets, not food manufacturers. The agency estimated those costs to be between \$117 to \$155 million.

The costs to food manufacturers for all other labeling regulations, including percent juice labeling, mandatory nutrition labeling, nutrient content claims definition, health claim labeling, format changes, and others, were estimated in the 1991 RIA proposal to

be as high as \$1.3 billion, depending on the compliance period chosen.

In addition, FDA estimated that the costs, to restaurants and other food service establishments to reprint menus not in conformance with nutrient content or health claim proposed regulations would be \$116 million.

FDA estimated that total costs of the proposed rules to implement the 1990 amendments, excluding voluntary supermarket labeling, would be approximately \$1.5 billion. The agency also determined that if the agency opted to allow an additional 6 months or an additional year to the compliance period provided for by the statute, total costs would decrease to \$.8 billion and \$6 billion, respectively.

In October 1992, Congress passed the Dietary Supplement Act of 1992 (DS Act). This act prevents the agency from implementing the 1990 amendments as they apply to dietary supplements until December 1993. This act requires the agency to issue proposed regulations applicable to dietary supplements by June 15, 1993. Because this document is intended to determine the costs and benefits of all regulations implementing the 1990 amendments, the agency is responding to the comments regarding dietary supplements with tentative conclusions and is presenting preliminary estimates of those costs. The agency will address any alterations to these estimates when it issues regulations on the 'labeling of dietary supplements.

In response to its assessment of the costs in the 1991 RIA proposal, FDA also received several comments regarding costs from firms whose products are regulated by USDA, not FDA. The agency has forwarded these comments to USDA for consideration in their RIA.

1. One comment stated that FDA's cost analysis could not be correct because it is impossible to accurately estimate costs.

The agency disagrees with the comment. The agency recognizes that costs of regulation are complex and often difficult to measure with 100 percent accuracy. However, after studying the industries affected and considering the comments, FDA is confident that it has determined the costs of the regulations with reasonable accuracy. The agency will not amend its cost estimates based on this comment.

2. One comment stated that because it would take up to 30 years to see the benefits of the regulations, FDA should calculate the costs of nutrition labeling for 30 years. The comment criticized FDA for limiting the costs to a 5-year period.

FDA disagrees with this comment. FDA has determined that the benefits will occur sooner than 30 years. For calculation purposes, FDA assumed that the lag time for cancer is 10 years. Beyond 20 years, the discount rate drives the benefits too low to be significant. FDA, therefore, calculated benefits over 20 years for ease of computation. For the sake of consistency, FDA also calculated the costs over 20 years. FDA did not limit its determination of costs to 5 years as the comment mistakenly understood, FDA is calculating the final costs and benefits similarly.

#### *B. Administrative Costs*

In the 1991 RIA proposal, FDA determined that administrative costs would be approximately \$177 million, of which \$15 million are attributable to mandatory ingredient labeling of standardized foods and certified colors. FDA received one comment from an industry association that stated that FDA provided a fairly reasonable assessment of the administrative portion of total cost. This judgment was based on the association's evaluation of such costs for the firms it represents. However, FDA received several other comments criticizing its estimates.

3. Two comments stated that administrative costs are more closely related to the number of products or labels than to the number of firms. One firm stated that administrative costs will be high because of the number of units involved and the fact that the product is packaged at many different locations by third-party vendors. This situation, the comment stated, will necessitate additional administrative costs in the nature of man-hours for coordination.

FDA acknowledges that the comment may be correct but has no additional information to support this claim. In its original analysis, FDA assumed that administrative costs differed based on firm size. In part, this assumption is based not only on the bureaucratic difficulties inherent in larger companies, but also on the assumption that larger firms produce a greater number of products. The comment did not state nor supply data as to whether changing this assumption would increase or decrease administrative costs. Thus, FDA is not amending its final administrative cost estimates based on this comment.

4. Several comments stated the cost of increased errors should be included in administrative costs, especially for smaller firms. The comment stated that error rates will increase because of: (1) The unreasonably short timeframes in which all label changes will be made,

(2) inexperienced short-term personnel hired to relieve the enormous strains on capacity, and (3) the novelty and magnitude of the changes themselves.

FDA agrees that firms may experience increased error rates which may increase administrative costs. FDA also agrees that these costs will be significantly reduced by allowing firms additional time to comply with labeling regulations. However, FDA is not amending its final cost estimates to account for increased errors because the final rule allows additional time, and the comments did not provide information regarding either the rate at which errors would be increased or the cost of such errors. Also, FDA believes that the cost of increased errors would not significantly increase total costs. Finally, by delaying the date that it will apply section 403(q) and (r)(2) of the act, the agency is relieving the time pressures that the comments said would contribute to the error rates.

5. Several comments provided estimates of administrative costs, FDA received only one estimate for small firms, \$3,000 per firm. Estimates for medium to large firms range from approximately \$6,500 to over \$1 million per firm. One manufacturer of both FDA and USDA regulated products stated that additional man-hours and a part-time consultant would be required to implement the proposed label requirements at a total cost of \$53,300. Some comments provided separate estimates for internal administrative costs and external administrative costs. Internal administrative costs include travel expenses, overtime expenses, and payroll expenses and benefit costs for added employees. External administrative costs include such items as legal fees, temporary help, and consultants.

FDA recognizes that the factors that determine administrative costs are very complicated. In the 1991 RIA proposal, FDA estimated that administrative costs for intricate regulations would be \$9,000 for small/medium firms and \$68,450 for large firms, assuming a compliance date of May 8, 1993. Administrative costs would be less with longer compliance periods. Final administrative estimates are based on a compliance period ending in May 1994. Administrative costs would be \$3,375 for small/medium firms and \$25,700 for large firms. The range of administrative cost estimates submitted in the comments was extremely broad. Also, there were no identifiable patterns to the estimates given. Therefore, FDA is not altering its original estimates. In the future, FDA would be interested in obtaining more detailed data concerning the nature and

level of the marginal administrative costs of regulation.

6. One comment stated that the cost of reading, analyzing, and commenting on the proposals should be addressed. The comment stated that thousands of people are spending many hours reading, analyzing, discussing, and explaining FDA proposals and writing, typing, copying, collating, and sending comments.

FDA recognizes that many resources are spent in the process of reviewing and responding to proposals. Whether these costs should be attributed to the regulation or considered normal costs of doing business in a regulated industry is debatable. Nevertheless, FDA has no information to determine the amount and value of resources spent in reviewing regulations and is, therefore, not amending its estimates based on this comment.

7. One comment argued that FDA should consider the cost that the implementing regulations would have on the Government, e.g., extra FDA personnel, laboratory supplies, and tax increases to the American consumer.

FDA agrees with this comment. FDA estimates that approximately 85 Full-Time Equivalents (FTE's) have been utilized in the 2 years of development of the implementing regulations. In addition, FDA estimates that 135 FTE's will be used each year during the next 20 years in recurring activities related to the implementing regulations, e.g., enforcement and petition review. Each FTE is currently valued at \$75,000. Therefore, FDA's labor costs are about \$6.4 million for start-up and \$127 million in recurring costs (discounted at 5 percent). In addition, FDA estimates that other costs to the Government to implement the 1990 amendments are approximately \$4.4 million in start-up costs and an additional \$2 million per year over the next 20 years, or \$25 million (discounted at 5 percent). Therefore, total estimated costs to the Federal Government are \$163 million. FDA notes, however, that these costs do not constitute increased cost to either consumers or industry in that they do not represent an increase in funding to the Federal Government. The development and enforcement of these regulations is funded primarily by replacing other Government programs.

8. One dietary supplement manufacturer stated that FDA should take into account the total cost of administrative time rather than incremental costs associated with the regulatory action being taken.

FDA disagrees with this comment. Executive Order 12291 requires that FDA calculate the cost of this regulatory

action. Therefore, only incremental costs—those costs associated with the additional administrative effort required to comply with the implementing regulations—are relevant. Accordingly, FDA rejects the comment on this point.

9. One dietary supplement manufacturer stated that FDA's estimate of administrative costs for supplement manufacturers was incorrect. The comment suggested that if one mid-level executive spends 1 week trying to read and understand these regulations, the cost would be in excess of the \$850 per firm estimated by FDA.

FDA neither agrees nor disagrees with this comment. Although the assumptions FDA made regarding administrative costs for dietary supplements may have resulted in underestimates, comments did not provide FDA with information with which reasonable estimates could be made. FDA will continue to study the supplement industry and will alter its estimates, if necessary, when the regulations regarding dietary supplements are issued. FDA is not currently altering its original estimate based on this comment.

#### C. Analytical Costs

In the 1991 RIA proposal, FDA estimated analytical costs to be \$195 million, of which \$112 million are initial one-time costs. Although one firm stated that its cost estimates verify the numbers reported by FDA in its 1991 RIA proposal, several other comments argued FDA's estimates were too low.

10. Several comments questioned FDA's assumption that some products are already tested. These comments stated that the agency's assumption that 20 percent of products are already performing all newly required tests and would require no additional testing is arbitrary and not based on survey or other data. These firms argued that no products are currently undergoing all testing that would be necessary for compliance because the definitions for some nutrients or food components will significantly change.

FDA is persuaded by this argument. In its final estimate, the agency is assuming that all products will undergo at least some analytical testing and is adjusting the costs for analytical tests accordingly. FDA is assuming that the 40 percent of foods that currently provide nutrition information will require testing for only the newly required nutrients. The remaining 60 percent of foods are not currently undergoing testing for any nutrients. Therefore, the incremental costs for this 60 percent of foods will be the cost of

performing all required tests. This change in assumptions also affects administrative costs because the regulation will be complex (requiring testing) for all firms, rather than for 80 percent of firms as originally assumed.

11. One comment requested that FDA make its laboratories available for testing at a small or no fee in order that firms may offset at least some of the cost of the regulations.

FDA does not have the resources to make its laboratories available to do testing, nor can FDA charge a fee to do testing. Therefore, FDA rejects this request. Although the choice may affect the company's expenses, whether testing is performed in-house, by independent laboratories, or by FDA laboratories, the societal costs of the regulation are the same.

12. Many comments stated that testing costs per product may increase because of the increased demand on laboratories. One firm estimated that analytical work on a priority basis will add about \$2,000 per product. Similarly, many commenters suggested that an increase in demand for printing services would create additional costs.

FDA agrees that the price of testing may increase in the short run because of increased demand. However, because firms will have 15 months to comply, not six months as assumed by the comments, any increase in costs will not be significant. FDA is not considering these costs in its final estimate.

13. One comment argued that FDA's estimate of the cost of analytical testing is wrong because it is based on the number of products, rather than the number of labels. The comment stated that it is not clear that a correlation exists between the number of labels needed to test and the number of products. For example, the comment stated that "manufacturing for private labels may require more testing of essentially the same product due to ingredient demands for retailers."

FDA believes that the comment did not understand FDA's definition of products and labels. FDA defined a product as an individual formulation regardless of size of container. Any change in ingredients constitutes a separate product formulation. When a private label manufacturer changes a product's ingredients in order to meet different demands of retailers, a different product is created, and additional testing is required. However, if the manufacturer merely changes the packaging for different retailers but does not change the product formulation, there is no new product, only a new label. FDA concludes after consideration of thy contractor's

(Research Triangle Institute (RTI)) report and comments to the 1991 RIA proposal, that for each distinct product formulation a separate analytical test must be performed. Tests for each individual label are unnecessary. Therefore, FDA is not modifying its estimate of analytical testing in response to this comment.

14. Many comments suggested that analytical costs as originally calculated are too low because the number of products on which they were based is too low.

FDA agrees that the estimate of the number of products contained in the 1991 RIA proposal was too low. FDA also agrees with comments that some firms use different formulations of the same product for different geographical areas because of varying ingredient demands. FDA's count of products and labels is based on Universal Product Code (UPC) codes that may not pick up these variations. Also, certain specialty items that are not sold through distribution channels using UPC codes would not be counted. Comments did not provide adequate information from which FDA can amend its original assessment of the number of products based on these considerations. However FDA reviewed its source of the number of products (A.C. Nielsen) and found that its estimate was incorrect.

FDA originally used data collected in 1987 that was derived from grocery store warehouses. Because many products are not distributed through warehouses, FDA undercounted the number of products. A. C. Nielsen has since revised its method of data collection to account for this problem. Therefore, FDA now estimates that there are 196,000 products. The estimate of the number of labels, which was based on an up-to-date count of UPC codes, remains unchanged at 257,000. However, FDA recognizes that these estimates are still understated because Nielsen surveys 3,000 grocery stores and does not extrapolate to the remaining stores. FDA does not have any information with which such an extrapolation could be made. FDA also recognizes that these are still underestimates because: (1) Some firms use different formulations of the same product for different geographical areas due to varying ingredient demands; (2) FDA's count of products and labels is based on UPC codes which may not pick up these variations; and (3) certain specialty items which are not sold through distribution, channels using UPC codes would not be counted. However, FDA does not have any better data, nor did the comments provide

better data. Therefore, the final estimates are based on these figures.

15. One comment argued that FDA's calculation of testing costs for those 32 percent of firms already performing the currently required tests was wrong. This comment argued that subtracting the \$135 for tests not required was wrong because this is a sunk cost that was already being imposed by FDA. The comment did not object to the subtraction of \$135 from the \$354 cost required for analysis under the current regulations because this portion of the \$354 will not be incurred by first-time testers.

FDA disagrees with the first point. FDA is not reimposing the costs for tests no longer required. The marginal cost is the cost of required tests (\$376) less the cost of tests previously required by regulations but not required by these final rules (\$135). FDA agrees with the second point made by the comment. The costs per test is not changed.

16. One comment argued that FDA's analytical cost estimates should have included employee time to prepare samples for testing, review laboratory reports, interpret the results, and determine resulting nutrition values that can be placed on labels. The comment stated an appropriate estimate should be 2-1/2 hours per product at an average salary and benefits figure of \$85.

FDA agrees that the employee's time for preparing samples should be included as part of the analytical costs. However, the other activities cited by the comment are not analytical costs but administrative costs and are considered in that section of the document. Having concluded that the cost of preparing the sample should be added to its initial analysis, the agency, using the average hourly earnings calculated by the Department of Labor, has determined that an appropriate cost would be 1/2 hour per sample at an average salary and benefits figure of \$19 per hour. These costs are included in the agency's final estimate.

17. One comment suggested that analytical costs should include the value of lost products and packages destroyed to run analyses, as well as the cost of freight to ship to the laboratory.

FDA agrees that for those products not undergoing any testing, the cited activities should be included in the analytical costs of complying with these regulations. Although FDA has no specific information on the amount of product and packaging that would be destroyed, or on the cost of that product, FDA can make crude estimates. These estimates suggest that such costs will be small relative to total costs. For example, if the cost of manufactured

food products is approximately \$2 per unit, and approximately 12 units per product are destroyed to conduct analytical testing, the total cost would be \$4.7 million. Because these costs represent less than 1 percent of total costs, FDA is not attempting to accurately determine the cost of lost product and package and is not including these costs in its final estimates.

18. Several comments disagreed with FDA's assumptions regarding the frequency of retesting. One comment stated that partial, if not full, retesting will occur each time a product is reformulated. The comment noted that this occurs more frequently than every 5 years. Another comment stated that retesting would occur quarterly. A third comment was told by a laboratory that FDA would require testing 3 or 4 times a year. This latter comment recommended that FDA recommend laboratory analysis no more than once every 5 years or when the recipe changes.

FDA does not have a set number of times a product must be tested in a year, nor does FDA determine the frequency with which analytical information should be verified. The agency simply requires that the information on the label conforms to the regulations. Therefore, if a product is reformulated, the manufacturer should retest the product. The agency has no information regarding the average frequency of reformulation, nor was such information submitted by the comments. However, FDA is persuaded that many firms may retest their products more frequently than every 5 years. FDA, for its final estimates, calculated analytical costs based on a retesting frequency ranging from annual retesting to once every 5 years.

19. One comment stated that testing would almost always be duplicated and, in many cases, triplicated.

FDA believes that this comment confirms its assumption in the 1991 RIA proposal that initial tests will be performed three times to confirm the results. Thus, no change in the agency's original assumptions are necessary in response to this comment.

20. One comment suggested that analytical testing for new product introductions under the new proposals would be more expensive than otherwise.

FDA disagrees with this comment. Although initial testing costs to firms may go up because of queuing, FDA is not convinced that demand for testing will ultimately exceed the supply of testing services. However, FDA is including the incremental additional

cost of testing new products in its final estimates of analytical testing costs which the agency did not do in the 1991 RIA proposal.

21. One comment suggested that the added cost of analysis would burden small companies because their work would be done by already overworked commercial laboratories which charge high fees for services, sometimes in excess of \$900 for a full nutritional profile. Another comment agreed, arguing that the cost per product, estimated at \$1,482, represents approximately 3 percent of the gross revenue per product for the average small/medium firm.

FDA agrees that because of the smaller volume under which small firms operates, the additional analytical testing could cause a burden on smaller firms. FDA believes that giving firms a longer time to comply with regulations, until May 8, 1994, will alleviate some but not all of this burden by reducing the impact of queuing costs. In addition, FDA believes that allowing firms the option of using nutritional data bases, instead of requiring analytical testing, will reduce the burden on small firms by providing a low-cost alternative to analytical testing.

22. One large firm stated that all costs incurred would be passed along to consumers almost immediately, not over a 20-year period. That comment explained that the cost of analytical work cannot be financed over a 20-year period.

FDA does not agree with this comment. The comment misinterpreted the agency's calculations. FDA did not state in the 1991 RIA proposal that costs would be financed over a 20-year period. FDA analyzed costs that will be incurred immediately. In addition, FDA also determined that firms would retest their products periodically, even without reformulating, to verify the accuracy of the nutrition information reported on the label and calculated the costs of this retesting over the next 20 years.

23. Several comments provided estimates of the costs of analytical testing. Estimates of analytical testing per product ranged from \$500 to \$2,000.

FDA, in the 1991 RIA proposal, calculated the analytical cost per product to be \$723 for those products that have been tested and \$1,785 for those products that have not been tested. Because these estimates are within the range reported by comments, FDA is using them in the final RIA.

24. One large firm stated that because testing for protein quality would be changed under FDA's proposed rules, the cost of this test should be included

with testing for cholesterol, fiber, fatty acids, and sugars. The comment also stated that under FDA's definitions, analysis for complex carbohydrate content would also be required.

FDA agrees with this comment that the cost of testing for protein quality would increase under FDA's rules. FDA has determined, based on information from existing independent testing laboratories' price lists, that a change in the definition of protein quality will add approximately \$540 per product to the cost of analytical testing. Therefore, total costs would increase by approximately \$159 million over the next 20 years assuming products would be retested every 5 years or \$440 million assuming annual retesting (discounted at 5 percent). (FDA notes that these are maximum estimates. The agency is providing values in the final rule on mandatory nutrition labeling, published elsewhere in this issue of the **Federal Register**, that should significantly reduce the costs of calculating protein quality for many foods.) FDA is not, however, adding complex carbohydrates to the list of nutrients required to be listed in the nutrition label (see final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**). Therefore, no analysis for this nutrient is necessary.

25. One comment stated that the changeover to new Reference Daily Intake (RDI) values will require that all data bases be completely reprogrammed to reflect the new values, and that therefore the cost of reprogramming all data bases should be included as a cost to the regulations.

FDA agrees with this comment. Because RDI's differ from Recommended Dietary Allowance's and Daily Reference Value's, on which the nutrition label is based, data bases would need some new programming if the agency were to switch to RDI's. The comment did not provide any data regarding the additional costs resulting from such changes. FDA is not aware of the number of such data bases but notes that it would take a large number coupled with significant reprogramming costs to affect this cost estimate. Therefore, FDA believes that such costs will be small relative to the total costs of the regulation. However, because the DS Act prevents FDA from adopting revised RDI's at this time, the costs associated with switching to new RDI values will not occur.

26. One large firm commented that for most nutritionally-modified products, and for the foods for which they substitute, it is necessary to conduct a complete nutritional analysis to determine nutritional equivalence. The

comment estimated the cost of testing for complete nutritional equivalence for one product to be \$2,300 for the first lot and \$1,200 for the remaining two confirmatory lots. Also, the comment stated that the agency's proposals require testing for several micronutrients not previously included in nutritional equivalency testing, such as Vitamin K and molybdenum.

The point of the comment is unclear. If the comment is referring to tests conducted when using nutrient content claims, FDA disagrees that such costs have not been considered. The costs associated with the use of nutrient content claims are the costs of obtaining the information to insure that the claim meets the definitions provided by FDA. All firms will obtain that information when performing analyses for the nutrition panel. Therefore, there are no incremental costs for using nutrient content claims. If, however, the comment is referring to substitute products, that policy is not changing, and the comment has no relevance. Finally, because of the moratorium under the DS Act, FDA has not adopted RDI's for Vitamin K or molybdenum. Therefore, no testing for these nutrients is necessary at this time. For these reasons, FDA will not change its estimates based on this comment.

27. Manufacturers of dietary supplements objected to FDA's assumption that, because of the nature of the product, full analytical testing is already performed on supplements. Comments stated that because full analytical testing is not currently done on dietary supplements, all dietary supplement products will undergo full nutrient content analysis.

FDA is persuaded by the comment. In the 1991 RIA proposal, FDA conceded that this assumption was merely supposition and requested information from industry sources on this point. FDA will develop an appropriate estimate of cost of analytical testing for dietary supplements as part of the rulemaking that the agency will complete in accordance with the DS Act.

28. Several dietary supplement manufacturers also stated that FDA's estimate of analytical costs was understated because the number of products was understated.

The agency's original analysis was based on a count of the number of unique supplement products reported in use during a small survey of consumers. Because of the small number of consumers sampled, FDA agrees that this was not an accurate source to determine the number of dietary supplement products. In comments to

the 1991 RIA proposal, one association reported 25,000 products and 75,000 labels in use in the supplement industry. The association was unclear as to how these numbers were calculated, and how "supplement" was defined in order to arrive at these numbers. The agency believes these estimates seem large. However, because no better information currently exists, FDA's using these figures in calculating costs to dietary supplement manufacturers. FDA will further study the supplement industry and make any necessary changes to its estimates when regulations are issued in accordance in the DS Act.

#### *D. Printing Costs*

In the 1991 RIA proposal, FDA preliminarily determined that firms would spend approximately \$112 million on printing costs to comply with mandatory ingredient labeling of standardized foods and certified colors, and approximately \$750 million to comply with all other provisions, except labeling of raw fruit, vegetables, and fish. FDA received several comments criticizing the agency's calculation of printing and redesign costs.

29. One comment was concerned that FDA assumed that changes will occur only to the principle display panel (PDP) and to the information panel.

FDA is aware that mandated changes are so significant that the entire label will be changed. FDA accounted for this fact in the 1991 RIA proposal. In the model supplied by the contractor and used by FDA, label redesign was denoted as a "complex" label change which was used for all labels.

30. Several comments stated that capital costs associated with label printing are underestimated. The comments stated that for many firms, new labeling devices will be needed. One comment, for example, stated that food manufacturers may have to install new packaging or labeling systems if existing labels are not large enough to accommodate the new information. Comments stated labeling equipment would cost approximately \$65,000.

FDA agrees that some firms may require new labeling devices but does not have enough information to determine how many new devices will be needed. Whether firms will need to increase package or label size to accommodate the new information will depend largely on the format selected. FDA is allowing a reduced format for small packages and very small packages may be exempt from nutrition information. The decision to purchase new machinery will also depend on how lengthy health claims are. FDA

does not believe that health claims will cause many firms to increase package size because health claims are voluntary. If a firm must increase package size and order new packaging equipment to accommodate a claim, many firms will not make the claim. Although FDA does agree that capital costs may be significant, inadequate information regarding the number of devices needed prevent the agency from quantifying these costs.

31. Several comments stated that FDA should include the cost of the first labels ordered under the new requirements because these initial label orders replace those labels that will not be in compliance.

In determining the impact of regulations, FDA is only concerned with incremental costs only. The cost of initial label orders is incremental only in the sense that labels are ordered to replace existing labels that are no longer in compliance. FDA included these costs in its calculation of the cost of label inventory disposal because disposed label inventory is valued at its replacement cost. To include both initial label orders and inventory disposal costs would be double counting. Therefore, FDA rejects these comments on this point.

32. One comment claimed that, as the compliance date nears, additional costs will be incurred as firms find it necessary to request smaller, less efficient print runs.

FDA agrees with this comment. However, the agency does not have information with which it can estimate these costs nor does it believe they will significantly add to the costs. FDA believes that giving firms a longer time to comply with these regulations will alleviate this burden.

33. Several comments provided estimates of printing costs ranging from \$500 to \$5,500 per label.

FDA believes its calculation of printing costs fits within this range. FDA calculated the cost of redesigning 257,000 labels within a 6-month compliance period at \$862 million, or an average of \$3,400 per product. FDA is using these same estimates, adjusted for a longer compliance period, in the final RIA.

34. Manufacturers of dietary supplements objected to FDA's analysis of printing costs as described in the 1991 RIA proposal. One manufacturer estimated redesign costs for all of its products to be \$363,250 but did not provide the agency with the number of products that would be covered under this estimate. Other firms estimated relabeling costs per product to be between \$400 and \$5,000.

FDA tentatively concludes that its assessment of the redesign cost per label for dietary supplements was underestimated. FDA assumed that labels on supplement products were more similar to drug labels than conventional food labels. However, the comments were successful in convincing the agency that supplement labels are more similar to conventional food labels and would incur a similar cost of printing and redesign. FDA will revise its estimates for redesign cost per label for dietary supplements as part of the rulemaking that FDA will complete in accordance with the DS Act.

#### *E. Label Inventory Disposal Costs*

35. Many comments stated that FDA's estimate of inventory disposal costs were too low. One very large firm estimated its own cost of inventory disposal to be in excess of \$10 million. Another comment estimated disposal costs for the dairy industry to be approximately \$125 million. This comment stated that if the dairy industry represents 15 percent of food sales, then FDA's estimate must be understated.

FDA does not believe that it is possible to extrapolate disposal costs from one firm or industry to the aggregate. Inventory disposal costs are subject to too many different variables to make such comparisons. For example, smaller firms are known to hold larger inventories than large firms. However, large firms hold smaller inventories for a greater number of labels. The cost of inventory disposal is the value of replacing inventories. Costs will be higher per label for products for which the package is the label than for products with stick-on labels. Also, costs will be higher for those labels that are produced using expensive printing processes. Therefore, although an industry or firm may represent a certain percentage of food sales, that industry or firm will not necessarily represent the same percentage of label inventory disposal costs. FDA does not believe it understated label inventory disposal costs except in the case of dietary supplements as described below. Therefore, FDA is not amending its final estimates based on this comment.

36. One comment from a food manufacturer disagreed with the assumption that industry label inventories would not exceed 6 months.

The comment misunderstood FDA's calculations. Although FDA did make such an assumption in regard to manufacturers of dietary supplements. FDA used data provided in a study conducted by RTI to calculate inventory disposal costs applicable to

conventional food manufacturers. These data showed that most firms would require longer than 6 months to deplete label inventories. Therefore, FDA is not changing its final estimates based on this comment.

37. Dietary supplement manufacturers objected to the assumption that existing label stock could be used up within the proposed compliance period. An association of supplement manufacturers stated that "the on-going recession has meant that production levels have been cut, resulting in greater than normal stocks of labels." The association stated that the cost of discarding inventory would be over \$25 million in order to implement the new requirements by May 1993. \$15 million by November 1993, and \$8 million by May 1994.

FDA tentatively concludes that its estimates of inventory disposal for dietary supplement manufacturers were incorrect. FDA, in the 1991 RIA proposal, made an ad hoc assumption regarding disposal of dietary supplement labels. Based on information supplied by comments, the cost of inventory disposal for dietary supplement manufacturers is valued at \$11.5 million for a compliance period ending May 1994. However, because the DS Act imposed a moratorium on implementation of the 1990 amendments with respect to dietary supplements. FDA is not including these costs in the final RIA.

#### *F. Reformulation*

38. Several firms criticized FDA for not including the costs of evaluating and executing changes in marketing strategies, searching and testing new brand names, and reformulating products. One association for supplement manufacturers estimated reformulation costs at \$20,000 per product but did not state how many products would be reformulated. Another comment stated that new product introductions, of which there were 12,000 in 1991, typically cost between \$5 and \$7 million.

In the 1991 RIA proposal, FDA acknowledged that reformulation would take place because of these regulations but stated that it could not determine the costs of reformulation because of a lack of adequate information. FDA agrees that because of the changes in the market that these regulations induce, some products will be reformulated. However, FDA is not estimating either the costs or the benefits of such reformulation. The comments did not provide the agency with enough information to calculate the marginal costs of reformulation caused by these

regulations. Although it is known that new product introductions have grown at an annual rate of 15 percent since 1986, FDA cannot predict how these regulations might affect that rate. However, it seems likely that these regulations will encourage firms to offer more nutritious foods to consumers. FDA also questions the cost of \$5 to \$7 million as an average cost of new product introductions. FDA notes that many small gourmet and confectionery products reformulate often during the year and may have annual sales much lower than these figures. FDA believes the costs and benefits of reformulation will be significant but is unable to estimate either based on the comments received.

#### G. Costs to Food Service Establishments

39. One comment stated that the cost of providing nutrition information in food service establishments would be prohibitive. The comment stated that for a typical establishment offering 80 items, the cost of analytical testing would be \$136,000.

FDA agrees that providing nutrition information in food service establishments would be costly and prohibitive for many firms. The 1990 amendments exempt food service establishments from providing nutrition information. However, the 1990 amendments do not exempt food service establishments that use nutrient content claims or health claims from meeting FDA definitions for nutrient content claims or health claims. FDA is not amending its final cost estimates based on this comment because the agency is not requiring nutrition labeling in food service establishments.

40. FDA received several comments stating that the estimates of costs to the food service industry is understated for the following reasons: (1) The number of establishments affected is understated, (2) the number of menus and menu boards is understated, and (3) the cost per menu is underestimated. An association for the restaurant trade stated that approximately 262,000 commercial establishments and 36,000 institutions have approximately 406,384 printed menus. The association determined that, based on analysis of entries in its annual menu contest, 89 percent of all printed menus include at least one nutrient content or health claim. Thus, nearly 362,000 individual menus and 233,000 establishments in the commercial sector are potentially affected by the regulations. Further, the association determined that at least 18 percent of printed menus would require revision of an entire section or symbol program. According to the association,

the cost of changing printed menus requiring changes in terminology or individual menu items would be \$500 per menu or \$144 million. The cost of changing printed menus requiring changes to alter or replace sections or symbols would be \$5,000 per menu, including the cost of analysis or data base use, or \$366 million. Therefore, the costs to food service establishments would be \$510 million. These cost estimates did not include costs associated with development of new menu items, costs of compliance for 178,355 commercial establishments likely to use menu boards, and costs of compliance for institutional establishments.

FDA has reviewed the calculations, data, and assumptions and is persuaded by the comments that certain costs to the food service industry as described in the 1991 RIA proposal were not accurately estimated. However, FDA notes that the association's estimates are overstated because of three issues: (1) The agency is requiring that food service establishments have only a reasonable basis to support nutrient content or health claims—no analyses or data bases are necessary; (2) the agency is deferring enforcement for small food service firms (10 or less individual establishments) for an additional year to facilitate compliance by this segment of the industry; and (3) the agency does not intend to include menus within its regulatory coverage.

The association estimated that analyses will cost between \$700 and \$950 for each of 4 recipes for 73, 149 menus, or a total of \$241 million. Total costs to food service establishments should be reduced by this amount. In the 1991 RIA proposal, FDA assumed that 30 percent of the establishments would normally change their food items during the proposed 6-month compliance period. FDA received no comments refuting this assumption. Extrapolating this assumption to account for the 9-month extension of the date of application of section 403(q) and (r)(2) of the act, indicates that 75 percent of all food offerings would normally be revised during the compliance period. For ease of calculation, the agency assumes that food service establishments make nutrient content claims only, not health claims for which the date of applicability has not been extended. In addition, the agency has determined that enforcement will be deferred on 75 percent of food service establishments. Therefore, the costs of compliance for food service establishments, adjusting for normal revisions and analytical testing, are \$17 million. This cost is assumed to be an

upper bound estimate as many claims made by restaurants may be consistent with the new definitions.

#### H. Other Costs

41. One comment stated that FDA overlooked the cost of advertising changes and related marketing expenditures that will be necessitated by these regulations. The comment stated that because most advertising in the visual media includes a picture of the product, the advertising will become obsolete because the label on the product will change. Also, marketing material such as recipe booklets, materials provided to the trade, and shelf tags will require revision or destruction.

FDA acknowledges that some firms may incur costs of changing advertising and marketing campaigns because of changes to the label required by these regulations. For example, in any instance in which a photograph of the product is shown in an advertisement, that advertisement will be made misleading if the label changes but the advertisement does not. Although advertising comes under the jurisdiction of the Federal Trade Commission, such changes will occur as an indirect result of FDA's regulatory actions, and the costs are attributable to these regulations. According to "Food Retailing Review" (The Food Institute, 1992 ed.) advertising budgets for food at home in 1991 were approximately \$12 billion, or 4 percent of the total cost. It is unclear how much, if at all, advertising expenditures will increase because of these regulations. Also, it is likely that, within the 15 months firms have to comply with the mandatory nutrition labeling and nutrient content claims regulations, many of those advertisements would have been changed for other reasons. Therefore, FDA believes that the marginal costs of changing advertising because of these labeling regulations will not add significantly to total costs. Therefore, FDA is not amending its final estimates based on this comment.

42. One comment stated that FDA should include the costs of consumer education campaigns.

FDA agrees with this comment. Although not a direct component of these regulations, consumer education campaigns are an essential element of the 1990 amendments. In 1991, FDA and USDA initiated a multiyear food labeling education campaign to increase consumers' knowledge and effective use of the new food label and to assist consumers in making accurate and sound dietary choices. FDA and USDA themselves do not have adequate

resources to inform and educate the public effectively about the new food label and how to use it to plan a healthy diet. The agencies are working with other public and private sector organizations. FDA interprets its role as one of providing leadership in developing, and encouraging others to develop, programs that enable diverse audiences to use food labels effectively. The agency estimates that its efforts in this role may cost as much as \$3 million in the next 5 years and in excess of 50 person-years. The agency, due to inadequate information, is not able to predict the costs to other Government agencies nor the multiplier effect on consumer groups, educators, mass media, the food industry, and other public and private sector organizations.

43. One comment concluded that much of the costs will be passed on to consumers, not borne by industry.

FDA does not have sufficient demand and supply information to estimate the amount of cost shifting that may occur as a result of the labeling costs. However, FDA has always considered costs to society without regard to who bears those costs. Therefore, FDA does not believe that it is important for the purposes of societal cost and benefit estimation to estimate the amount of cost shifting. However, for the purposes of estimating whether there is an "undue economic hardship" to industry, FDA does believe that this question is relevant, and this question has been addressed in the final rule published elsewhere in this issue of the **Federal Register** on the date of applicability of section 403(q) and (r)(2) of the act.

#### *I. Summary of Costs*

After examining the comments, FDA has recalculated the costs of the final rules. These final estimates are based on a 15-month compliance period ending in May 1994. Although some provisions of the 1990 amendments, i.e., health claims, will become effective on May 8, 1993, FDA received no comments regarding the separate costs of those provisions. Further, in the 1991 RIA proposal, FDA preliminarily determined that the costs of the labeling of ingredients in standardized foods and certified colors were \$16 million for administrative costs and \$112 million for printing. The costs of percent juice labeling have been estimated at \$40 million. Comments did not result in a recalculation of these costs.

The comments mentioned many costs that FDA agrees could be included in the costs of food labeling regulations but cannot calculate because of a lack of information. These costs include the

cost of increased errors, the resources spent in reviewing and commenting on proposed regulations, the cost of lost products and packages destroyed to run analyses, the capital costs associated with label printing, the costs associated with smaller, less efficient print runs, and the costs of reformulation. FDA believes that, with the exception of reformulation, these costs represent a small portion of the total costs and that not including them in the final estimates does not significantly alter FDA's conclusions.

Based on the information provided by the comments and the contractor's cost study, FDA now finds that administrative costs are \$9,000 for small/medium firms and \$68,450 for large firms when the compliance period is 6 months. Because FDA is extending the compliance to 15 months, costs will be \$3,375 for small/medium firms and \$25,700 for large firms, or \$56 million for the 8,900 medium and large firms affected. Similarly, administrative costs to manufacturers of dietary supplements are \$850 per firm with a 6-month compliance period. Adjusted to a 15-month compliance period, administrative costs to dietary supplement manufacturers are \$320 per firm or \$52,000. However, these costs may be greatly reduced depending upon the outcome of the proposals to be issued at a later date, as discussed above, in response to the DS Act. Thus, the costs to dietary supplement manufacturers are not being included at this time.

FDA has agreed with the comments that the costs to the Federal Government for implementing the 1990 amendments should be considered in its final estimates. As previously described in comment 7 of this document, FDA estimates that implementing the 1990 amendments will cost the Federal Government approximately \$163 million in labor and capital over the next 20 years (5 percent discount rate). These costs will most likely not be incurred by increasing taxes on either consumers or industry as the food labeling information program will be funded by substituting efforts away from other Government programs. FDA did not attempt to estimate the costs to other governmental units or State governments.

FDA has determined that all products produced by medium and large firms will undergo some analytical testing. Approximately 40 percent of products will require full nutrient testing at a cost of \$1,785 per product. The remaining 60 percent of products will require only partial testing because they have already been tested for some nutrients. The cost

for testing these products is \$723 per product. FDA is assuming a range of retesting from once every year to every 5 years on average. Analytical costs for mandatory nutrition labeling are \$228 million in the first year. Total discounted analytical costs range from \$466 million assuming retesting every 5 years and \$1.1 billion assuming annual retesting (5 percent discount rate). The cost of collecting samples is between \$17.9 and 22.8 million over the next 20 years (discounted at 5 percent). In addition, FDA estimates the cost of protein quality testing will be \$540 per product or \$185 million over the next 20 years assuming retesting every 5 years or \$440 million assuming annual retesting.

The assumptions used to calculate printing costs for conventional foods remain unchanged by the comments. The cost of printing 257,000 food labels is estimated at \$518 million for a compliance period ending in February 1994.

Review of the comments did not lead to any changes in the assumptions used to calculate inventory disposal costs except that FDA no longer assumes dietary supplement manufacturers will have enough time to dispose of all labels. Total costs for inventory disposal of conventional food labels is \$6 million for a May 8, 1994, compliance date.

FDA has reviewed the calculations provided by food service establishments and has adjusted those calculations to account for a longer compliance period and normal menu revision. FDA is allowing food service firms the option of using a reasonable basis rather than analytical testing to support claims, further reducing costs. In addition, FDA is deferring enforcement for restaurants with 10 or less individual establishments. The cost to food service establishments, reflecting all adjustments, is \$17 million.

The total costs of food labeling regulations range from \$1.4 billion to \$2.3 billion (discounted at five percent), depending on the frequency of reanalyzing products, excluding the cost of labeling raw fruit, vegetables, and fish, and assuming a 15-month compliance period ending in May 1994. In addition, costs of Government activities are estimated at \$163 million.

#### **IV. Benefit Estimation**

As part of the 1991 RIA proposal, FDA published a labeling benefits model that examined the health benefits from consumer response to food labeling. In this model, FDA used economic theory to quantify the value of the reduction in coronary heart disease (CHD) and three types of cancer that

would result from modified diets in response to nutrition labeling. FDA received approximately 20 comments directly related to the benefits of nutrition labeling. Many comments addressed the benefits of specific rules. The agency is responding to these comments in the relevant individual final rules.

#### *A. Benefits—General*

44. Several comments questioned the credibility of the health benefit estimate, particularly as to whether risk reduction through change of dietary habits can be quantified.

FDA does not agree with tins comment although FDA stresses that it views the benefit estimation of the 1990 amendments as a preliminary investigation into quantification of mandatory information disclosure. In addition, FDA notes that the agency is required by Executive Order 12291 to quantify benefits where possible and to use such estimates to select regulatory policy options that generate the largest net benefits. Therefore, FDA is not changing its estimate of the benefits based on this comment, FDA will continue to refine the methodology employed here as well as to seek alternative methodologies to measure these effects.

45. One comment noted that there will be reductions in health care and insurance costs that will result in cost savings to all consumers, whether disease afflicted or not.

FDA notes that health care estimates were included in the 1991 RIA proposal. FDA agrees that as demand for health care resources decreases, there will be price decreases that will affect all consumers and consequent reductions in insurance costs. However, benefit estimates are societal benefits which are real resource savings to all members of society, without regard to incidence. For example, estimates of the willingness-to-pay to reduce risk of illness and death reflect total societal values. Therefore, the benefits estimated in the 1991 RIA proposal reflect savings to all of society, whether disease afflicted or not, but this fact does not alter the quantitative total societal benefits and does not affect the final estimate of the benefits.

46. Another comment noted that there may be significant benefits from reduction in allergic responses to food.

The agency believes that the most significant additional ingredient information resulting from the 1990 amendments is the listing of ingredients in standardized foods. The agency believes, however, that the labeling of almost all standardized foods already

contained this information before the passage of the 1990 amendments. Although the agency agrees that the required labeling of allergens such as hydrolyzed corn protein will have some benefits for preventing allergic responses, these benefits are expected to be small relative to the nutritional benefits of the final rules.

47. One comment suggested that because the agency accounted for the costs of product reformulations, it should estimate the benefits of reformulation.

Although FDA agrees that product reformulation will occur as a result of the 1990 amendments, FDA did not estimate either costs or benefits of product reformulation (see comment 38 of this document). The assumption underlying the benefit estimate is that firms did not reformulate foods just to participate in the shelf flag study (the FDA/Giant Special Dietary Alert (SDA) study cited in the 1991 RIA proposal) because the relative size of the market used in the study is small, and the time span was relatively short (1 year). The agency noted in the 1991 RIA proposal how difficult it would be to estimate the amount of reformulation that would take place.

48. Some comments addressed the purpose of the food label with respect to the projected benefits of the new labeling. One comment stated that the purpose of the food label is to inform consumers (presumably about nutritional values), while another stated that the purpose of the food label is to sell a product.

Compliance with the final regulations that respond to the 1990 amendments as well as with other regulations governing food labels will make the label, both the PDP and the information panel, more informative for consumers. Thus, estimated benefits derived from compliance with the 1990 amendments are not benefits to manufacturers from selling food but rather are benefits to consumers because manufacturers must comply with the law.

49. Another comment expressed concern that diet deficiencies might be a possible response to the new labeling information. This comment noted that some consumers may have negative benefits because they use food labels to modify their diet in a detrimental way. According to the comment, this result would occur because food nutrients are grouped in foods such that, for example, a product substitution may decrease fat intake slightly but result in a large increase in sodium intake.

As mentioned in the 1991 RIA proposal, FDA was aware of the possibility that these effects may occur

and represent a potential bias towards overestimating benefits. However, FDA believes that it is unlikely that the provision of more information on food labels will lead to such effects. It is difficult to construe the labeling changes that respond to the 1990 amendments as being the cause of many ill-considered food choices. The disqualifying disclosure levels are intended to prevent such effects from occurring. Further, FDA believes that the consumer information campaigns now underway in response to the 1990 amendments will serve to further mitigate the chances of any such effect.

50. One comment stated that the only benefits that would arise from requiring restaurants to carry nutritional information would be for the chemical laboratories that do the testing.

The agency advises that it is not requiring full nutrition labeling for restaurants in these final rules. However, restaurants will be required to ensure that their judgments that a food has an appropriate level of a nutrient to qualify for a health claim or a nutrient content claim have a reasonable basis. There is no requirement for laboratory testing of such foods. Moreover, FDA does not agree that no other parties will benefit from these rules with respect to restaurants. Consumers will now have consistent, reasonably based signals from restaurant menus with regard to health claims and nutrient content claims that they can use to control their diets.

#### *B. Consumer Response to Labeling*

51. One comment contended that FDA's estimate of the consumer response to labeling was low. The comment argued that FDA's estimate of the percentage of consumers that read and understand labels, 45 percent, should be used as a measure of consumer behavior change in response to new labeling.

The agency rejects this view. The agency's estimate was based on actual consumer behavior measured in response to new labeling information (the FDA/Giant SDA study). As for the estimate of consumers who read and understand labeling, the agency notes that the cost of changing dietary behavior is greater than the cost of simply reading and understanding labels. The cost of changing dietary behavior includes search costs, costs of giving up some elements of taste, and possibly paying higher prices for the more nutritious foods. For this reason, it is likely that only a small percentage of consumers actually change their purchases in any meaningful way. In addition, FDA acknowledged factors

that would cause the benefit projections to be overestimated. For example, as noted in the 1991 RIA proposal, FDA does not have evidence that changes made in the FDA/Giant SDA program were lasting. Although FDA expects that consumers' diet/health link awareness will increase over time, it is not clear how much of an effect this increased awareness will have.

52. Other comments questioned whether consumers will use labels to actually change purchase behavior.

FDA believes that the SDA study supports its view that some consumers, although a small percent, will use labels to change their purchase behavior. In this study, shelf flags were used to alert consumers to the presence of desirable nutrient attributes. Netting out price changes, there were measurable shifts to more nutritious foods. Moreover, the SDA categories covered less than one-fourth of all of the food categories, and FDA believes it is likely that there will be responses in other categories of food because of the addition of other nutrients of concern as part of the 1990 amendments.

53. One comment to the RIA stated that the shelf flag highlighting in the SDA study overestimates benefits of the 1991 initiative because they do not apply to information required on the food label. The comment noted that, since shelf flag highlighting may have been used in addition to highlighting the product characteristics on the label, similar results will not be obtained unless retailers use shelf flags. The comment went on to say that it is unlikely that retailers will use shelf flags given disclosure requirements, type-size-and placement requirements, and density-based requirements.

The agency notes that these final rules do not prohibit shelf flags from being used by manufacturers exactly as they were used by Giant Foods during the SDA study. The agency is announcing in the final rule on nutrient content claims, published elsewhere in this issue of the **Federal Register**, that it is encouraging retailers to use such devices consistent with the nutrient content claim definitions provided in that final rule. Thus, the agency believes that similar results will occur as a result of the 1990 amendments and is not changing its estimate based on this comment.

54. One comment expressed the view that the shelf flags in the SDA study are best related to regulations allowing health claims and nutrient content claims on labels, and that benefit estimates should be related to those provisions of the 1990 amendments.

FDA believes that all implementing regulations of the 1990 amendments will have benefits, although the bulk of such benefits may come with changes to the PDP where nutrient content claims and some health claims will be displayed. However, FDA is unable to separate the effects of the various aspects of the 1999 amendments on the basis of this comment or any other of the comments received. Therefore, FDA is not changing the benefits estimate based on this comment.

55. Another comment on the SDA study noted that FDA did not separate the effects of the shelf flags from other marketplace events such as price changes, advertising campaigns, price reductions, or couponing.

The agency notes that price changes were accounted for in the SDA study, although the other events mentioned represent a possible bias in the study. To the extent that such effects caused consumer purchase changes independent of the shelf flags, the agency agrees that such changes would result in the benefit estimate being an overestimate. However, no information was presented that would allow the agency to calculate the extent of this bias. The agency points out that this is one of several biases in the analysis that were noted in the 1991 RIA proposal.

56. One comment suggested that FDA examine microdata from SDA to determine whether Giant stores had a disproportionate number of people at risk for developing chronic diet-related diseases. They pointed out that if so, it would bias the outcome when the study is extrapolated to the entire U.S. population. Other comments noted that the Washington D.C. metropolitan area may not be representative based on demographic data.

The agency acknowledges these limitations of the data presented in the SDA study and recognizes that the benefit estimates provided in both the preliminary and the final RIA are soft because of the many assumptions made and the tenuous support for many of these assumptions. The agency believes, however, that it has made a novel first attempt at estimating the effects of this type of mandatory label information. A number of comments addressed the viability of the agency's assumptions in estimating these benefits but offered no data upon which to fashion better assumptions. The agency agrees that the Washington D.C. area may not be representative of the U.S. population as a whole but does not have any way to make the study representative. Thus, FDA is very aware of the imprecision of these benefit estimates. From these comments FDA has received no

information that would alter its assessment of the expected change in dietary behavior from that reported in the 1991 RIA proposal.

#### *C. Health Response to Improved Diet*

57. One comment noted that FDA's estimate of the maximum preventable cases of cancer and CHD prevention from dietary changes was low relative to what was predicted by "significant scientific agreement." The comment used Table 13 in FDA's 1991 RIA proposal (56 FR 60856 at 60871, November 27, 1991), and estimated that, of the total cases estimated to be avoided, cancer cases represent 89.7 percent, and CHD the remaining 10.3 percent. Eliminating the years where 0 cases are expected to be prevented, the first 10 years for cancer and 2 years for CHD, the above percentages were applied to the total cases, 503,448 (Table 16, 56 FR 60856 at 60872). From these calculations, the comment noted that FDA's figures appear to show only 45,310 cancer cases and 2,797 heart disease cases are preventable through dietary intervention per year. These numbers were compared by the comment with other published numbers. For total preventable cancers, the comment updated a 1991 published estimate of 1, 100, 000 cases (per year in the United States) with an annual growth rate of 0.9 percent to obtain an average over the 10th to 20th years from the 1990 amendments of 1,258,230. The comment noted that FDA's estimate of preventable cancers (45,310) was only 3.6 percent of this figure, less than the 5 percent to 35 percent of cases preventable through diet. Another comment noted that the 2,797 estimated cases of CHD that would be prevented represent only 0.9 percent of the total cases, which it said was extremely low.

The agency disagrees that its figures are low. First, the agency's estimates were based on the difference between current dietary intakes and DRV's. DRV's are the U.S. Government recommendations for an achievable diet, not a maximal diet. A maximal diet would be much lower in fat content, for example, as well as containing other nutrient values much "stricter" than the RDI diet. The RDI diet might be construed to be "perfect," however, in the sense that it does not involve giving up all desirable foods to meet a reasonable health goal.

In addition, FDA notes that although there is significant scientific agreement that reductions in fat intake will reduce the risk of some cancers, the precise quantitative relationship has not been firmly established. It is unlikely, however, that the relationship between

fat intake and cancer will prove to be false.

Finally, it should be noted that FDA's figures from Table 16 in the 1991 RIA proposal (56 FR 60856 at 60872) are from reducing fat intake for FDA foods only, which does not include meat and poultry (regulated by USDA).

Reductions of fat from consuming those foods will save additional lives and cases. Thus, FDA disagrees that its estimates are low and has not changed the benefit estimate of the 1990 amendments based on this comment.

58. One comment requested that FDA explain an apparent discrepancy. The comment took the number of total cases of illness estimated to be avoided for each scenario and divided them by the total number of deaths estimated to be avoided. The comment stated that the discrepancy arose because the total number of cases (cancer and CHD) avoided in the maximal FDA diet, approximately 42 percent resulted in lives saved, whereas in the scenario that applies to the benefit estimate, only 32 percent of cases avoided will result in lives saved.

The agency does not believe that this difference is a discrepancy. The explanation is that both total cases avoided and total lives saved are based on cancer and CHD. In the Browner model, which was used as a component of the FDA labeling benefits model, reducing fat intake changes the ratio of saturated fat to cholesterol intake. In the maximum health benefits scenario, this ratio is 2. As the amount of fat intake is reduced in response to labeling, this ratio declines to 1.3. The ratio of saturated fat to cholesterol changes are based on actual intake changes measured in the SDA study. In turn, as the ratio of saturated fat to dietary cholesterol decreases, the rate of CHD cases avoided (based on saturated fat) will decline relative to that of cancer cases avoided (based on total fat).

In the Browner model, it is assumed that all CHD cases result in death, but that only 45 percent of the cancer cases result in death. Thus, as there is no discrepancy, FDA concludes that no changes in the agency's benefit estimate are necessary in response to this comment.

59. One comment argued that it makes no sense to postulate that a perfect diet would only prevent 3.6 percent of cancer cases, but 42 percent of cancer deaths. Similarly, the comment stated that it is unlikely that there would be only a 0.9 percent reduction in incidence of head disease but 4.5 percent reduction in deaths.

The agency disagrees with this Comment. The comment is referring to

the agency's estimate of the number of preventable cases of cancer and cases of death that would result from adoption of a perfect diet by all consumers (Table 15, 56 FR 60872). The comment appears to have incorrectly calculated the percentage of cancer deaths that will be avoided as a result of a perfect diet relative to the total number of cancer deaths in the United States. Rather than 42 percent as calculated by the comment, the agency calculates that 3.5 percent of all cancer deaths in the United States would be avoided if consumers adopt a perfect diet. This number, 3.5 percent, is calculated as follows: On average, it is expected, based on FDA calculations (56 FR 60872), that there would be approximately 18,985 cancer deaths avoided per year (following the 10-year lag from the beginning of a perfect diet). This number is obtained by multiplying the total number of deaths avoided (212,596) by 89.3 percent (the proportion of cancer deaths avoided) and dividing by 10, the number of years for which the model estimates cancer deaths being avoided. Therefore, if there are 545,718 total cancer deaths per year, then 18,985 deaths per year (3.5 percent) can be avoided as a result of adoption of a perfect diet. A similar calculation determines that CHD deaths avoided as a percent of CHD deaths per year (500,000) is about 0.3 percent.

60. Another comment states that the "total impact of the approved health claim on lipids and cancer will be a reduction of 0.28 percent of all cancer cases and an estimated prevention of 1,188 cancer deaths per annum, a total decline of 0.23 percent."

The agency's estimate of the benefits of the 1990 amendments apply to the whole of the 1990 amendments. Changes in dietary behavior, such as lipid reduction, are likely to be made by consumers in response to changes in the information panel including new nutrient and ingredient information, as well as to PDP changes such as new definitions for nutrient, content claims and health claims. The agency is unable to separate out, based on this or any other comment received, the marginal change in consumer behavior solely in response to health claims, and the resulting health effect. Thus, no change to the agency's benefit analysis has been made in response to this comment.

61. One comment noted that FDA has estimated a reduction in the consumption of fats by men and women to be 1.4 and 1.1 percent, which translates to 1.49 and 0.67 grams, respectively. The comment went on to say that given that a "less" fat item will have a minimum of 3 grams less fat than

a comparable choice, FDA's estimate would amount to only one improved serving choice every other day for an average male and every 4.5 days for an average female. The comment contended that this appears to underestimate the potential impact. The comment also noted that:

The apparent use of a typical consumer, rather than of a bell distribution, would dramatically skew the impacts of the reduction on health \*\*\* as minor reductions (1.1 to 1.4 percent) \*\*\* cannot be expected to have a significant impact on risk reduction. Because actual reduction would be distributed across a curve, those whose reduction in cholesterol would be significant would experience a significant reduction in risk unrevealed by the FDA single typical consumer model.

The agency did not use a typical consumer to estimate the benefits of the proposed regulations. In the Browner model, all age groups were used in 5-year increments (e.g., 40-to 45-year-olds) which would approximate the full distribution of age groups, not collapse all age groups into a typical consumer. This data (the actual distribution of intakes) came from the Continuing Survey of Food Intakes by Individuals. Furthermore, the agency is not persuaded by the argument concerning food choices. FDA agrees with the comment that rather than all consumers making small changes, what is more likely is that a small subset of consumers will make dietary changes, or that some consumers will only change a small portion of their diets. This pattern of response would explain the relatively modest changes that occurred in the SDA study. FDA notes that consumer response to new information has been shown to be modest in other studies, such as response to radon information provided by the Environmental Protection Agency. However, the agency believes that reformulation of foods, which were not estimated in this benefit analysis, will increase the size of the total benefits. FDA acknowledges that this bias exists in the estimate but, as noted elsewhere in this document, FDA does not have sufficient information to estimate these effects and FDA is not altering its estimate based on this comment.

Although the estimate of the number of deaths avoided will not be adjusted based on the comments received, FDA acknowledges that a letter to the Department of Labor from the Office of Management and Budget (OMB) returning a rule which would lower permissible exposure limits for 375 substances in the construction and maritime industries has implications for

its estimate of the number of lives saved (Ref. 2). In that letter OMB took note of a series of papers and books that estimated the effect of wealth on health. They noted that, "Richer workers on average buy more leisure time, more nutritious food, more preventive health care, and smoke and drink less than poorer workers." Thus, money spent by society to improve nutrition labeling will not be spent in other areas such as smoke detectors and airbags which will reduce risk. OMB cited a U.S. Court of Appeals decision which in turn cited research showing that each \$7.5 million in additional regulatory expenditures may result in one additional death from lowered income.

The relationship between income and death is still somewhat controversial. In a recent article, researchers found that the effect is likely if the income reduction is permanent, as opposed to transitory (Ref. 3). Keeney has examined the extent to which the mortality effects on income changes are greater for poorer people than for richer people (Ref. 7). As the expenditure on nutrition labeling is a one-time expenditure affecting all consumers very slightly, it is likely that it is a transitory expenditure. On the other hand, because food expenditures account for a significantly larger share of the family budget for poorer families, the cost of these regulations are likely to have larger impacts on those families. Thus, it is unclear whether or not these expenditures will, in fact, increase some deaths while saving others. Nevertheless, FDA has estimated the possible effects this potential bias could have on the benefit estimate.

FDA's final estimate of additional regulatory costs resulting from the 1990 amendments is \$1.6 to \$2.7 billion. This would result in between 216 and 360 additional deaths which should be subtracted from FDA's estimate. Based on the Keeney estimate of one death for each \$7.5 million of cost, the final estimates for the total deaths avoided as a result of the 1990 amendments are between 12,542 and 12,689 (from 12,902 estimated in the 1991 RIA proposal, Table 13, 56 FR 60856 at 60871). Life-years gained are reduced to between 78,672 and 79,577 (from 80,930, also in Table 13). The results of these changes affect the total benefits very slightly with the new range being \$4.5 to \$21 billion.

#### *D. Quantification of Health Response*

62. One comment argued that the average medical care costs estimated in Table 14 (56 FR 60856 at 60871) should not be discounted at a 5 percent inflation rate because the rising costs of

medical care have been increasing 10.5 percent in recent years.

The agency agrees that the costs of medical care have been rising at approximately 10.5 percent. If this trend were to continue, however, a net of 5.5 percent increase (10.5 percent medical care cost inflation minus 5 percent general inflation) should be added to these costs, although future cost increases are difficult to predict, and the agency does not wish to infer that great precision accompanies these estimates. The agency notes that medical care costs estimated in the 1991 RIA proposal may be over or underestimates of actual medical care costs. That is, because some people who will not get cancer or CHD will get other illnesses that will result in medical care costs, using the total cost savings from reduced cancer and CHD cases is an overestimate. Because the agency was unable to net out increases in medical care from other diseases, it overestimated medical care cost savings. Thus, the agency acknowledges that there is a bias in both directions for the medical care cost estimate. Because it is not possible to estimate the net direction of these biases, however, the agency will not make further adjustments in these numbers. Finally, the agency's estimates of the benefits of nutrition labeling derive primarily from the willingness-to-pay for increased longevity, not from non fatal medical care costs.

63. One comment expressed the view that the willingness-to-pay generated benefits of the 1990 amendments of \$3.6 to \$21 billion are for nonmedical outlays only.

FDA disagrees with this comment. In fact, the willingness-to-pay estimates of health benefits in the 1991 RIA proposal are individual dollar amounts that market studies demonstrate consumers (and workers) will pay to reduce the probability of death from these illnesses. Many people are willing to pay to reduce the probability of death and illness, and these payments include expected expenditures on medical care as well as other types of disability, such as pain and sickness. As noted earlier in this document, however, the total benefit estimates do not cover the cost savings from illnesses that do not result in death, which are estimated in the section on medical care cost savings. Thus, no change in the benefit estimate will be made as a result of this comment.

64. One comment pointed out that a willingness-to-pay model is not anchored in any real occurrence in the marketplace and reflects only a subjective valuation of good health. This

comment added that risk is not traded in the marketplace.

The agency disagrees with this comment. The agency believes that willingness-to-pay estimates represent the individual's valuation of loss of productivity, medical care costs, pain and suffering, and other utility losses as demonstrated in economic literature. In this case, the decisions reflect payments to reduce the risk of death rather than using those resources for other goods.

FDA also believes that risk, including health risk, is ubiquitously traded in the marketplace. For example, expenditures on seatbelts, airbags, airline safety, safety caps on medicine, preventive check-ups, suntan lotion, and a multitude of other factors represent market expenditures on risk reduction. Many of the studies conducted to estimate willingness-to-pay to avoid death were based on the workplace transactions by estimating wage differentials for jobs with varying levels of risk and wages. Therefore, the willingness-to-pay figures for reductions in the probability of death are strongly grounded in economic theory such that the agency will not change the benefit estimate based on this comment.

65. One comment suggested that "hard figures" such as lost productivity should be used instead of willingness-to-pay estimates.

FDA disagrees with this comment because the use of such "hard figures" alone (productivity) will ultimately undervalue the total utility of reducing risk to the individual as it does not include the utility derived from reduced medical care costs and pain and sickness. The agency believes that the willingness-to-pay methodology is strongly grounded in economic theory and is the conceptually correct method to estimate these health benefits. Therefore, no change will be made to the benefit estimates based on this comment.

66. One comment contended that the quantitative estimate provided in the 1991 RIA proposal for the amount and value of reduced risk were too low because: (1) The estimate chosen for the value of risk reduction (value of life) from secondary studies was low because the mean of these type of studies was not chosen; (2) the estimate for value of risk reduction did not include the impact of recent inflation; (3) the estimate for the value of risk reduction did not include growth in real income before 1990; and (4) the estimate for value of risk reduction did not include future real growth of income.

FDA does not agree that the estimates chosen for the value of risk reduction, \$1.5 to \$3 million, from secondary

studies is necessarily low. Market studies of willingness-to-pay to avoid death have produced a range of values—some higher and some lower than the values used in this study. In order to capture this diversity, FDA used a wide range of benefits. Thus, FDA is unconvinced that sufficient data are either available in the literature or were in the comments to warrant changing these estimates.

As to the second point, FDA agrees that some inflation has occurred since the publication of the study that the agency used to estimate the value of risk reductions. The study's results were calculated in 1986 dollars (Ref. 4) and inflation from 1986 to 1991 was 16.5 percent (not 15.5 percent as mentioned in the comment). In addition, the comment noted that there have been increases in real personal disposable income since 1986. Real personal disposable income has increased from 1986 to 1990 by 8.5 percent, not 10 percent as cited in the comment (Table B-25 in the Economic Report to the President (Ref. 6)). To the extent that individuals can now purchase 8.5 percent more goods than they could in 1986, it is likely that they would be willing to pay more for risk reduction as well. Updating the range of estimates noted above of \$3.5 to \$21 billion to account for inflation and real personal disposable income yields the new range of \$4.4 to \$26.5 billion.

The comment also noted that FDA should include in the benefits estimates future real growth of income because if income continues to grow, people in the future will purchase more risk reduction. FDA disagrees with using long-term real growth of income to increase benefits. The benefits estimate derives from the choice that is made by individuals today. That choice reflects the amount of money people are willing to give up today to reduce risk in the future. Those estimates reflect individuals subjective evaluation of both their future health states as well as their assessment of their future income changes that will occur as a result of the regulation. If FDA were to forecast future growth in personal income and estimate the income/risk trade-offs (income elasticity of demand for risk reduction) that would be made for each future period, it would result in double counting. Again, this would be true as people implicitly account for future income growth in decisions made today. Furthermore, as income rises, people may choose to add even more labeling information at some time in the future but that would represent a separate choice with separate marginal costs and benefits.

FDA concedes, however, that choices that are made in most, if not all, willingness-to-pay studies associated with risk reduction are reflective of individuals valuation of their own change in probability of risk of death. They do not include the individual's altruistic expenditures to reduce risk for future generations. This effect is expected to be small for this regulation, however, as benefits and costs are estimated for over 20 years.

#### *E. Health Claims*

67. One comment expressed concern that FDA had ignored some fundamental findings from consumer behavior studies and the economics of information. It also stated that approval of health claims should be done on a cost-benefit basis rather than by consensus. The comment noted that allowing partial information produces a more efficient marginal adjustment process in the market than requiring full information. The comment noted that it did not believe there was such a thing as "Gresham's Law" (which essentially says that "bad" money drives out "good" money) of health claims in advertising.

The agency does not necessarily disagree with this assessment of the state of the economics of information. However, section 403(r)(3) of the act requires "substantial scientific agreement" for approval of a health claim for conventional food. The standard for substances in dietary supplements under section 403(r)(5)(D) of the act will be determined in accordance with the DS Act. The agency believes that the final rules for health claims are as flexible as is possible. Also, the agency notes that there is a set period of time for Government review of petitions for authorization to make additional health claims.

On the issue of whether or not there is a "Gresham's Law" with respect to advertising, the agency notes the widespread persistent use of the misleading "percent fat free" advertising. Thus, it is not clear whether or not "good" advertising in terms of being truthful and not misleading will ultimately drive "bad" advertising from the marketplace without regulation. Thus, FDA does not believe that this comment affects the ultimate benefits from the 1990 amendments and will not change its assessment based on the comment.

There is an opportunity cost of the choices made with respect to health claims and nutrient content claims. Opportunity costs of the regulation of these claims include the benefits foregone by not choosing an alternative

option. Some of these costs arise from the statute itself, and some arise from the interpretations made in these regulations. If firms are either prohibited from making certain kinds of claims, or if the incentives are such that firms make fewer valid health claims or nutrient content claims, there is a cost imposed on society in that some valuable information may not be conveyed to consumers. For instance, if firms find that the required disclosures surrounding health claims are too cumbersome, they may find that this adversely affects the marketing of their product and fail to make a valid health claim.

In fact, FDA has no data to evaluate the potential market outcomes that would arise with alternative regulatory choices with respect to health and nutrient content claims. Although FDA has benefited from numerous comments on the subject, including a lengthy comment from the Federal Trade Commission, no comments have been able to show the quantitative outcomes of allowing more health claims in a different format or allowing more flexible use of nutrient content claims. However, although these rules are final, FDA will continue to evaluate information that will help refine these rules and encourages interested parties to submit such information.

#### **V. Summary**

FDA has evaluated comments on the costs and benefits of the impact of the changes in the food label occurring as a result of the 1990 amendments. The benefits of the 1990 amendments and the implementing regulations include decreased rates of cancer, CHD, osteoporosis, obesity, hypertension, and allergic reactions to food. As consumers are given more informative labeling in an improved format, uncertainty and ignorance concerning the ingredient and nutrient content of the foods they eat will decrease, and some consumers will select more nutritious, healthier foods. Also, the creation of consistent metrics and definitions, such as standardized serving sizes and nutrient content claim definitions, that consumers can use to judge the nutritional aspects of foods will encourage manufacturers through competition to reformulate their products into healthier foods. Thus, even those consumers who may be unaware of the effects of diet on health will inadvertently eat a better diet.

The model chosen to estimate these benefits focused on the two largest health problems, cancer and CHD (Ref. 5). This model involved the following three-step estimation process:

(1) Estimate changes in consumer purchase behavior and resulting changes in nutrient intakes as a result of receiving new nutrient information about foods. Some comments stated that consumers will not use labels at all, and some comments asserted that many more changes will come about than those that FDA estimated. A number of comments noted particular bias in the FDA/Giant SDA study. Although FDA agrees that there is bias both in the SDA study and in applying the results of the SDA study to the benefits of the 1990 amendments, no comments provided a sufficient basis either to replace or amend the study's result in this RIA.

(2) Estimate the changes in health states that would result from consumers changes in nutrient intakes, particularly for reduced incidence of cancer and CHD. Again, FDA was presented with a number of comments on the changes that will result from changed diets, but none were convincing. Many comments were directed at the Browner model which was incorporated into FDA's benefit estimate in this section of FDA's analysis. The comments focused on the fact that nutrition labeling and other components of the 1990 amendments are estimated in FDA's model to make only a relatively small decrease in the number of cases of CHD and cancer and the deaths associated with them. However, FDA is unpersuaded by these arguments. The Browner model is well documented and contains realistic health assumptions. However, FDA did account for studies cited by OMB that demonstrated that regulatory expenditures may cause increased death. This resulted in FDA's estimate of lives saved and life-years saved decreasing by very small amounts, to between 12,542 and 12,689 (from 12,902 estimated in the 1991 RIA proposal, Table 13, 56 FR 60856 at 60871) and to between 78,672 and 79,577 (from 80,930, also in Table 13) for the number of life-years saved.

(3) Estimate the value of changes in health states in terms of life-years gained, number of cases and deaths avoided, and the dollar value of such benefits. FDA has been persuaded by some of the arguments that the benefits are underestimated in this component of the analysis. Specifically, the agency has adjusted for inflation and for the growth of real personal disposable income that occurred in the 4 years

between when the estimates were cited in the economic literature and the time the 1991 RIA proposal was concluded. Coupled with changes made to the number of life-years and lives saved mentioned above, these adjustments change the benefits to \$4.4 to \$26.5 billion (discounted at 5 percent over a 20-year period).

FDA also evaluated comments on costs of the 1990 amendments and has amended its cost estimates based on these comments. The total costs of food labeling regulations range from \$1.4 billion to \$2.3 billion (discounted at 5 percent), depending on the frequency of reanalyzing products, excluding the cost of labeling raw fruit, vegetables, and fish, and assuming a 15-month compliance period for nutrition labeling and nutrient content claims ending in May 1994. If a discount rate of ten percent is used, total costs are estimated between \$1.3 and \$1.8 million. These costs include costs to food manufacturers and food service establishments. Costs to Government entities are estimated to be \$163 million. Costs to dietary supplement manufacturers were not included in this estimate because of the moratorium imposed by the DS Act.

FDA believes that the study of the costs and benefits of food labeling is as accurate as possible for a forward looking study of the costs and benefits of regulatory action. FDA published the initial study in the **Federal Register** and received over 300 comments on it. As a result of the comments and new information, FDA revised its figures upward for both costs and benefits. In addition, FDA acknowledges that many deficiencies remain in these estimates because there are elements of both costs and benefits that remain unqualified. Nonetheless, the purpose of the RIA is to estimate the general magnitude of these effects in accordance with Executive Order 12291 and to determine whether the benefits of this action exceed the costs, and FDA has met that burden. With the exception of reformulation, FDA has examined the unqualified costs and benefits and believes that they are likely to be small relative to those that have been quantified and are not likely to change the estimates significantly.

Furthermore, the analysis contains assumptions that are subject to challenge, and many of the comments

did so. However, where neither data nor convincing evidence were submitted to contradict the assumptions, FDA has not changed them. Finally, FDA advises that the dollar amounts estimated in the final RIA are not exact amounts but rather reasonable estimates of the impacts of nutrition labeling on U.S. society. The final RIA demonstrates that although this action is expensive, the likely benefits to U.S. consumers substantially exceed the costs that shareholders, taxpayers, and consumers will ultimately bear.

## VI. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Peto, Richard, "Cancer Around the World: Evidence for Avoidability," in *Diet and Prevention of Coronary Heart Disease and Cancer*, B. Hallgren et al., editors, Raven Press, New York, 1986.

2. MacRae, James, B. Jr., Acting Administrator and Deputy Administrator of the Office of Information and Regulatory Affairs, OMB, letter to the Honorable Nancy Risque-Rohrbach, Assistant Secretary for Policy, Department of Labor, March 10, 1992.

3. Graham, John D., Bei-Hung Chang, and John S. Evans, "Poorer is Riskier," *Risk Analysis*, vol. 12, No. 3, 1992.

4. Fisher, A., L. Chestnut, and D. Violette, "The Value of Reducing Risk of Death: A Note on New Evidence," *Journal of Policy Analysis and Management*, vol. 8, No. 1, 1989.

5. RTI, "Estimating Health Benefits of Nutrition Label Changes," April 1991.

6. Economic Report of the President, transmitted to Congress February 19, 1992, p. 327, U.S. Government Printing Office, Washington DC.

7. Keeney, R.L., "Mortality Risks Induced by Economic Expenditures," *Risk Analysis*, vol. 10, No. 1, 1990.

Dated: December 17, 1992.

**David A. Kessler,**  
*Commissioner of Food and Drugs.*

**Louis W. Sullivan,**  
*Secretary of Health and Human Services.*  
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