DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 101, 105, and 130

[Docket Nos. 90N-0134 et al.]

RIN 0905-AD08 and 0905-AB68

Food Labeling: Establishment of Date of Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this final rule to establish May 8, 1994, as the date on which it will apply the mandatory nutrition labeling and nutrient content claims provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This action is in accordance with section 10(a)(3)(B) of the 1990 amendments which allows the Secretary (and, by delegation, FDA) to delay, for up to 1 year, the date on which FDA will apply those provisions to foods if the agency finds that compliance with the new provisions would cause "undue economic hardship."

DATES: The statutory effective date of sections 403(q) and 403(r)(2) of the Federal Food, Drug, and Cosmetic Act (the act) is May 8, 1993, except that section 403(q)(4) (raw agricultural commodities and raw fish) became effective November 8, 1991. However, FDA is delaying the date that it will apply sections 403(q) of the act (21 CFR 101.9) and 403(r)(2) of the act (21 CFR 101.13, all of the regulations in subpart D of 21 CFR part 101, and 21 CFR 130.10), except section 403(q)(4) of the act (21 CFR 101.42 through 101.45), until May 8, 1994. The effective date of the regulations published elsewhere in this issue of the **Federal Register** implementing sections 403(q) and 403(r)(2) of the act, except section 403(q)(4) of the act, is May 8, 1994.

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SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). This statute adds section 403(q) (21 U.S.C. 343(q)). which makes nutrition labeling mandatory for all food, and section 403(r)(2) (21 U.S.C. 343(r)(2)), which gives FDA authority to define nutrient content claims, among other sections, to the act.

In accordance with the 1990 amendments, FDA published proposed rules on November 27, 1991, to implement these sections of the act. Under section 2(b)(1) of the 1990 amendments (21 U.S.C. 343 note), FDA is to adopt final regulations by November 8, 1992. If the agency fails to do so, under section 2(b)(2) of the 1990 amendments, the proposed rules are to be considered final rules. Under section 10(a)(1)(A) and (B) of the 1990 amendments (21 U.S.C. 343 note), sections 403(q) and 403(r)(2) of the act are effective 6 months after the promulgation of the final regulations or after the proposed regulations are considered to be final regulations. Thus, by statute, sections 403(q) and 403(r)(2) of the act will become effective no later than May 8, 1993.

However, section 10(a) of the 1990 amendments provides that if the Secretary of Health and Human Services and, by delegation, FDA "* * * find that compliance with sections 403 (q) and 403(r)(2) of such Act would cause an undue economic hardship, the Secretary may delay the application of such sections for no more than one year." In its regulatory impact analysis (RIA) published in the **Federal Register** of November 27, 1991 (56 FR 60856), FDA tentatively found that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6-month and 1-year extensions of the compliance date would result in significant reductions in those costs. Therefore, given the extent of these costs, FDA felt that the possibility of "undue economic hardship" was raised. The agency consequently requested comments on the meaning of "undue economic hardship," and on whether a delay in the application of sections 403(q) and 403(r)(2) of the act was appropriate. The agency also requested comments on whether a determination of "undue economic hardship" should be based on aggregate costs to industry generally, on industry-by-industry costs, or on firm-by-firm costs.

Interested persons were given until February 25, 1992, to comment. FDA received comments from government organizations retailers, consumer groups, State groups, and private organizations. A discussion of the agency's decision, and a summary of the comments and the agency responses, follow.

II. Undue Economic Hardship

The 1990 amendments provide that the Secretary may delay the application of sections 403(q) and 403(r)(2),of the act for up to 1 year if he "* * * finds that compliance with [either section] would cause an undue economic hardship." There is no relevant legislative history on this provision. Clearly, however, Congress foresaw that there would be a significant cost to complying with these sections of the act. Its use of the phrase "undue economic hardship" implies that Congress recognized that some economic hardship may result from efforts to comply with the 1990 amendments. The question is whether that cost is so great as to constitute "undue" economic hardship.

"Undue" is defined as "exceeding what is appropriate or normal," "excessive," or "not just [or] proper." Synonyms include inequitable, inappropriate, extreme, and immoderate. As yet, no court has construed the meaning of the 1990 amendments; however, parallels may be drawn with cases discussing similar language. Cases involving an employer's accommodation of an employee's religious practices have looked for a simple increase in costs in assessing whether the accommodation created an "undue hardship" for the employer. See *Transworld Airlines v. Hardison*, 432 U.S. 63, 84 (1977) (more than a de minimis cost to employer is an undue hardship); State Division of Human Rights v. Carnation Co., 366 N.E.2d 869, 870 (N.Y. Ct. App. 1977) (a palpable or significant increase in costs is enough to establish undue hardship; threat to economic stability of enterprise is not required). In determining whether a punitive damage award was "excessive," a court looked at whether it was "out of all proportion to the defendant's financial position." *T.D.S., Inc. v. Shelby Mutual Insurance Co.*, 760 F.2d 1520 (11th Cir. 1985). Where a company was ordered to reopen a plant after closing it discriminatorily, the remedy was to be upheld unless the company could show an undue economic burden, which was interpreted as a "substantial outlay of new capital or [other] undue financial hardship." *Teamsters Local Union N. 171 v. NLRB*, 863 F.2d 946 (D.C. Cir. 1988), cert. denied, 490 U.S. 1065 (1989). In a case involving the Pension Benefit Guaranty Corporation's (PBGC's) authority to grant waivers under the Employee Retirement Income Security Act (ERISA) when an employer faced "unreasonable hardship," a court upheld the PBGC's denial of a waiver where the PBGC had considered only unusual, substantial economic hardship. *A-T-O, Inc. v. Pension Benefit Guaranty*

Corporation, 634 F.2d 1013 (6th Cir. 1980). According to the court, the waiver provision was Congress' way of dealing with unforeseeable, unexpected situations of serious employer hardship. Id., 1023.

It appears from these cases that an undue economic hardship must entail at least an increase in costs and at most an unusual and substantial economic burden. Given Congress' implicit assumption that compliance with the 1990 amendments would involve an economic burden, the agency believes that the best interpretation of Congress' intent would require that an undue economic hardship be a substantial economic burden, in excess of what Congress would have envisioned, although not necessarily threatening the viability of a company attributable to the 6-month compliance date established by the 1990 amendments.

1. The comments that the agency received were generally consistent with this view of what constitutes undue economic hardship. A comment from a trade group stated that "undue economic hardship" should be defined by the lost product lines and businesses that will occur as a result of a short compliance time. Another comment defined "undue economic hardship" as any increase in costs of goods to consumers in the current economic climate. A large company stated that undue economic hardship was shown where there were large costs "without appreciable benefit."

The agency agrees with the comments that a large increase in industry's costs attributable to the application of sections 403(q) and 403(r)(2) of the act 6 months from November 8, 1992, would provide evidence of undue economic hardship if that increase is more than what was likely to have been envisioned by Congress. However, a simple increase in costs alone is insufficient to demonstrate such hardship because Congress envisioned that there would be some economic burden to industry when it passed the 1990 amendments.

2. One comment from a consumer group argued that industry will not experience undue economic hardship. The comment stated that: (1) There is no undue burden on industry because consumers would bear the costs, not industry; and (2) since the public at large would be the recipients of the benefits of labeling, and the benefits outweigh the costs, the public should be willing to bear the costs.

The agency disagrees with the first point. It is likely that much of the costs of nutrition labeling will not be passed on to consumers, although the agency is not in a position to estimate exactly how much of the amount will be passed on to consumers. Because the costs per product are primarily fixed costs, it is likely that manufacturers with low volume products, which constitute 80 percent of all products, with higher per product costs will not be able to pass these costs on if they are in competition with high volume products.

The agency agrees that the public at large will be the recipient of the benefits of nutrition labeling. However, because it is likely that many manufacturers will not be able to pass the costs on, and because the agency received no information with which to estimate the amount that can be passed on, the agency is not persuaded by this argument.

3. Several comments suggested that "undue economic hardship" should be based on a cost-benefit analysis. Both industry and consumer groups provided their views that benefits should be balanced against the costs of implementing the labeling provisions. Industry groups generally found the costs to be disproportionate to the benefits, while consumer groups commented that the potential health benefits far exceeded the cost to industry.

The agency finds that there is no basis in the statute, the legislative history, or the case law to find that the assessment of undue economic hardship entails a balancing of the costs and benefits of a delayed application date. In fact, it can reasonably be inferred from the 1990 amendments that Congress balanced the competing interests in framing the statute and provided in section 10(a)(3)(B) of the 1990 amendments that should the economic burden imposed by meeting the statutory compliance date be greater than reasonable, FDA is authorized to grant relief to affected industry. The court held in *A-T-O, Inc. v. PBGC*, that Congress, before enacting the ERISA statute, engaged in just such a "finely tuned balance between protecting pension benefits for employees while limiting the cost to employers." *A-T-O*, 634 F.2d at 1021. In enacting ERISA, as in the passage of the 1990 amendments, Congress could not foresee all possible situations of undue economic hardship, so it granted discretion to the administrative agencies to determine the circumstances in which undue economic hardship exists. Id., 1023.

III. How to Assess Whether There is Undue Economic Hardship

In its November 1991 RIA, the agency requested comments on whether it should assess undue economic hardship on a firm-by-firm, industry-by-industry or on an aggregate basis.

4. Several comments argued that because FDA can expect requests for extension from most of the industry regulated by FDA as well as from many foreign firms, it would be difficult, if not impossible, for FDA to grant extensions on a firm-by-firm basis. Some comments stated that company-specific extensions would give some firms an unfair competitive advantage based solely on production and inventory schedules and would create consumer confusion. One comment stated that a firm-by-firm approach would not adequately judge economic hardship since many firms manufacture products that overlap different industries and, therefore, have different costs. Another comment appeared to advocate use of the firm-by-firm basis because it was seeking relief for itself.

In addition, one consumer advocate organization preferred that FDA assess undue economic hardship on a case-by-case basis. However, if this would be too burdensome, the comment suggested that FDA consider granting extensions by categories of firms, based on size or labeling capacity. Several other comments voiced similar requests by suggesting that if FDA does not determine the aggregate economic impact to be undue, then it should consider whether the impact is particularly burdensome to specific industries. Several comments, including two from governmental units, suggested that if FDA does not delay the application of sections 403(q) and 403(r)(2) of the act for all manufacturers subject to the 1990 amendments, FDA should consider applying a later date for small business. Other comments suggested that the industry-by-industry approach would create competitiveness problems and would be extremely difficult to apply fairly. The majority of comments expressed the opinion that undue economic hardship should be determined on an aggregate basis because it would be the only equitable and practical approach. The one consumer group that argued against an extension agreed that FDA should consider undue economic hardship on an aggregate basis.

FDA believes that it should determine whether there is undue economic hardship for the food industry as a whole. Because there are approximately 17,000U.S. food companies in the portion of the food industry regulated by FDA, as well as a large number of foreign food manufacturers, it would be administratively infeasible for FDA to grant extensions on a firm-by-firm basis because the agency does not have the

resources to process and act on petitions. Similarly, the agency also is persuaded by the evidence provided by the comments that granting extensions on an industry-by-industry basis would be perceived as arbitrary because it would be extremely difficult to distinguish among industries on the basis of the costs that would have to be borne if there is early application of sections 403(q) and 403(r)(2) of the act. The overwhelming majority of comments provided evidence that such costs will have to be borne by most companies.

Moreover, from a compliance standpoint, FDA's job would be made more difficult if a delay was granted on other than an industry-wide basis. In such a situation, compliance checks would require not merely looking at the label but at whether the labeling requirement applied to the particular firm or segment of the industry. Therefore, FDA has decided to define "undue economic hardship" on an aggregate basis.

IV. Evidence of Hardship

A. General

In conformity with the case law cited above, the agency has interpreted the undue economic hardship standard to require a determination as to whether the costs of complying with sections 403(q) and 403(r)(2) of the act by May 8, 1993, impose an unexpected and excessive burden on industry. It is the costs that exceed the costs of implementing sections 403(q) and 403(r)(2) of the act that can reasonably be said to have been foreseeable that FDA has looked to in deciding whether there is undue economic hardship.

FDA has sought to determine the amount of those foreseeable costs even though the legislative history does not provide any explicit estimates of what Congress expected the costs of implementing sections 403(q) and 403(r)(2) of the act to be. However, the agency notes that Congress acted after FDA proposed to require nutrition labeling on food products to the **Federal Register** of July 19, 1990 (55 FR 29487). FDA's proposal contained a preliminary cost assessment of $315 million for implementation of the nutrition labeling proposals. Although this estimate was very rough and based on preliminary figures, and although there are differences between the agency's July 19, 1990, proposal and the 1990 amendments, Congress apparently was aware of, and may well have considered, FDA's estimate in considering the 1990 amendments (see H. Rept 101-538, 101st Cong., 2d sess. 9 (1990)).

The agency now estimates the cost of implementation of all label changes required by the 1990 amendments to be $1.5 billion if the date of application of the nutrition labeling and nutrient content claims provisions is not delayed beyond May 8, 1993. Therefore, if $315 million is used as a baseline, the current estimated cost to industry of implementing sections 403(q) and 403(r)(2) of the act approximately quadruples it. In the RIA in which the 1990 estimate was calculated, for those costs that FDA did not have information to calculate, FDA stated that it was plausible that they would be considerable, but the agency was not specific as to exactly how large they could be. Therefore, the 1991 estimate, published in the **Federal Register** of November 27, 1991, as part of the RIA (56 FR 60856), can be considered unexpected and greatly increased because the available public data in July 1990, 4 months before the passage of the 1990 amendments, did not predict costs in that range. The 1991 estimate was based in large measure on data developed by FDA in interviews with food manufacturers and in a mailed survey that were conducted after July 1990.

Consequently, the agency concludes that the food industry will have significantly higher costs than could have been anticipated from the estimates and data at the time of passage of the 1990 amendments. The majority of comments that the agency received in response to its November 1991 RIA support the agency's cost estimates and demonstrate that there are substantial additional costs that result from a 6-month (November 1992 to May 1993), rather than a 1-year, 15-month, or 18-month, compliance date. These comments and the agency's responses are discussed in the section that follows.

B. Costs of Compliance With Section 403(q) of the Act

Having defined the term "undue economic hardship," the agency has considered whether compliance with section 403(q) of the act would cause an undue economic hardship for the affected industry. The comments received from industry overwhelmingly expressed concern regarding, and provided evidence of, such hardship.

5. Many comments stated that the cost of analytical testing for nutritional composition of products will be burdensome to meet within the proposed timeframe of May 8, 1993, especially for small companies that cannot afford the testing and that do not have their own laboratories to perform the nutritional analysis. Many of these comments stated that the increased demand for testing services would lead to increased costs for testing, which would burden all firms but especially smaller firms. The comments stated that as firms compete for laboratory services, preferred treatment will be given to the larger firms that can better afford these additional costs, thus exacerbating the competitive advantage of larger firms. One trade association estimated the average cost per product for nutrition testing to be $1,433 for small firms and between $627 and $864 for larger companies. Other comments provided estimates for the costs that ranged from $400 to $2,600 per product

Based on the data developed by the agency in producing its November 1991 RIA, the agency believes that the estimates provided by these comments are accurate and thus finds that a short compliance period will increase the cost to firms of analytical testing. Food manufacturers will have to compete for position in the queue and to pay queuing costs to improve their position in line. In that RIA, FDA determined that 40 percent of the packaged food products covered by the labeling amendments are currently labeled and have undergone some analytical testing. The agency estimated the average cost per product to bring the product into compliance for products already nutritionally labeled to be $750, and for those not already so labeled, the agency estimated a cost of $1,785 per product (56 FR 50856 at 50864). Because less than half of all products have been tested, and because once the regulations become final, all firms will require at least some testing, the demand for laboratory services will more than double as a result of labeling regulations. The prices of these services will consequently increase substantially in the shortrun. However, because laboratory capacity is expected to increase based on an increase in long-term demand, FDA cannot predict the final price for these services. It is clear, however, that the increase in costs will be greatly mitigated by a delay in the date of compliance. Such a delay will reduce the pressure on the supply of these services because not all firms will test products at the same time, and therefore, a delay will mitigate the increase in prices for laboratory services.

6. Comments from small companies stated that the cost of laboratory testing could be reduced greatly by the use of nutrition data bases instead of requiring laboratory analyses of their products. One comment from a data base supplier

stated that a small data base product that could cover several products would sell for $1,000 to $2,000 and would last for several years--significantly cheaper than analytical tests, estimated in the November 1991 RIA at $723 to $1,785 per product.

The agency agrees with the comments. Nutrition data bases are currently under development throughout the food industry, particularly by large companies. There is no discussion of use of analytical data bases in the legislative history of the 1990 amendments, however, so Congress must have been unaware of the significant cost savings that these data bases would guarantee. The lack of data bases contributes to the costs of compliance, and a short compliance period limits the possibility of using data bases to mitigate costs. The agency has been informed that these data bases will not be operational in time to meet the May 8, 1993, deadline. To date, FDA has not approved any nutritional data bases for use in nutrition labeling. Many of those commenting, particularly small companies, requested at least a year beyond May 8, 1993, to develop and use these data bases. Assuming FDA will approve nutritional data bases, an extension will thus help in getting more data bases developed, approved by FDA, and in use by the food industry.

7. Some firms expressed concern that the capacity of analytical laboratories will be insufficient to provide all of the food testing needed by the 17, 000 U.S. companies in the food industry by the 6-month effective date.

FDA does not have any data, nor was any submitted, on the number of laboratories equipped to perform nutrition analyses. FDA also does not know how many companies have inhouse facilities. However, a comment from an independent laboratory stated that it is increasing its capacity to meet "the huge surge of work brought about by the FDA mandatory labeling." Firms will continue to need to have their products tested as they reformulate their products or develop new ones. Also, firms will periodically retest their products to verify the information. The agency, therefore, anticipates that laboratory capacity will expand to meet this sustained demand. Thus, FDA does not believe that there will be undue economic costs associated with laboratory capacity.

8. Many firms expressed concern that labels could not be redesigned and printed on time to meet the statutory deadline of May 8, 1993, across the food industry because label designers and suppliers have stated that they do not have the capacity to handle the volume of business that will be generated as a result of the regulations. The comments stated that there is little incentive for printing and packaging firms to make capital improvements to meet the excess demand. The cost of capital improvements is high, and unlike the demand for analytic testing which will continue in the future, the demand for label printing is essentially a one-time label change for the entire industry. One firm estimated the cost to label printers for relabeling equipment to be $11,000 if compliance is required by May 8, 1993, with that cost dropping to $8,000 if compliance is delayed for 1 year. The comments suggested that the same scenario applies to printing capacity, whether inhouse printing or by contract. In some cases, if demand is high enough for a short compliance period, new equipment could be used which would result in excess printing capacity in the future. The comments pointed out that an additional problem with the earlier compliance date is the inability of some label suppliers to purchase and install new equipment and to find new personnel to operate such equipment within the established timeframe.

Packaging suppliers and label printers estimated that it would take between 2 to 5 months per label for redesign and printing. The comment said that time needed for other tasks, such as analytical testing, label approval, and distribution, would add considerable time to this estimate. Several comments stated that between one-third and one-half of all relabeling could be completed by May 1993, and that approximately two-thirds could be completed by November 1993. The agency also received a comment from a label printer who services 14, 000 labels that stated that the company anticipates that the time that it will take it to do a job will double. Based on its present resources, the comment stated that even with a doubling of its capacity achieved by hiring new personnel, they will be almost 54 percent short of the estimated label changes needed by its customers.

FDA believes that redesign and printing of the food label to accommodate the new requirements of the 1990 amendments are compliance costs. FDA agrees that many firms may have difficulty relabeling their products in the 6-month compliance period in the statute. Because there is little incentive to increase printing capacity given the one-time nature of much of what needs to be done to print new labels, the agency does not anticipate additional printers entering the market to relieve the shortage. Because Congress did not have available to it printing cost differentials associated with different compliance periods, these costs may be construed as unexpected and undue.

9. Some firms commented that the costs of label inventory disposal would be great. According to the comments, small companies in particular carry large inventories of labels and will have a disproportionately large cost if forced to dispose of those inventories. One small firm stated that it would have to destroy 2 years worth of label inventory. In addition, specialty firms (e.g., manufacturers of gourmet products) noted that they have a large number of individual labels and a low volume of individual unit sales, which results in a large inventory of labels. Firms reported a cost of inventory disposal ranging from $79,000 to $3,803,000 for a May 1993 effective date and $0 to $227,000 for an extension to May 1994. Only one large food manufacturer provided an estimate of the cost of inventory disposal (i.e., approximately $800,000) for a compliance period ending in November 1993. One industry association representing supplement manufacturers estimated the cost of disposal for a November 1993 compliance date at $15 million. Another industry association, after conducting a survey of its members, stated that 37 member companies reported a total inventory disposal cost of $26 million and 1.5 billion labels for a compliance date of May 8, 1993. According to the comment, the cost to these 37 firms would decline to $2 million and 150 million labels with a 1-year extension.

In addition, several comments stated that another label disposal problem involves production of private labels for retail grocery and other companies. Typically, the manufacturer provides the art work and printing plates for private label customers. When orders for products are below normal, the manufacturer stores the packaging material at his cost. The comments stated that the new labeling changes will necessitate modification of all customer labels at the manufacturer's expense, and the manufacturer may have to write off as a loss considerable quantities of label and packaging material.

These figures do not conflict with those estimated by FDA in its November 1991 RIA. Based on a contractor's study of the food processing industry, FDA estimated the cost of disposal of remaining inventory to be $306 million. Although conducted before passage of the 1990 amendments, the information generated from this study was not available to Congress or to the public.

In the 1900 estimate, FDA assumed that 1 year was sufficient to dispose of all labels and thus did not estimate cost

of label disposal. Because the 1990 estimate was apparently the only information Congress had available to it, it may be presumed that these costs were unforeseen and, hence, are in excess of those anticipated by Congress.

10. Some small firms stated that the implementation of the nutrition labeling provisions would drive them out of business because the cost of compliance would eliminate their already low profit margins. These small firms claim that they cannot absorb costs, and relabeling will prevent their prices from being competitive.

FDA is aware that firms with low profit margins may be significantly affected by their effort to come into compliance with section 403 (q) of the act. Although section 403 (q) of the act includes a small business exemption, many small firms do not meet the requisite levels. Extending the date of application will help alleviate the impact on small businesses by mitigating increases in the cost of analytical, redesign, and printing services, and by reducing the amount of label inventory destroyed. Also, an extension will assist those firms forced to scale back or halt operations because they are unable to produce complying labels in a timely manner.

11. Comments from specialty food distributors noted that the cost of relabeling to be in compliance with section 403(q) of the act could result in the elimination of profitable product lines when the manufacturer decides that the unit cost of the labeling does not justify compliance or may trigger a price increase.

FDA agrees that some profitable product lines have such small profit margins that it is not unreasonable to expect that the cost associated with a short compliance period might increase the cost of manufacturing such that the product line is no longer profitable. The agency is currently exploring the possibility of legislation to relieve this undue hardship on small firms.

12. A European Community (EC) Commission expressed concern that overseas suppliers will be unable to meet the 6-month, May 8, 1993, deadline because of differences in definitions and analytical procedures between EC and the United States. The comment noted that the 6-month effective date would be impossible for EC producers to meet because there is a delay of several months between the labeling of products in Europe and their arrival in the United States because of travel time and customs formalities, giving overseas suppliers effectively only 3 months to analyze and relabel their products. Additionally, a trade association for herbal products confirmed that printing and analysis of the product for overseas suppliers would have to be accomplished in 3 months.

FDA agrees that foreign food manufacturers might need a longer compliance period than domestic manufacturers because of the differences in language, analytical methodology, and length of time it takes to transport the product. FDA believes the longer compliance period specified in this final rule will alleviate the concerns expressed by the comment. The agency notes that all products introduced into interstate commerce on or after May 8, 1994, must comply with sections 403 (q) (except section 403(q)(4)) and 403(r)(2) and any final regulations promulgated to implement those sections.

13. A comment from a trade group for the sugar manufacturers pointed out that because in their industry the label is the package, the product cannot be packaged until it can be labeled. These manufacturers expressed concern that a substantial amount of sugar inventory will be misbranded and unmarketable, thus causing sugar to be destroyed or returned, opened, poured out, and reprocessed to be finally placed in packages conforming to label requirements. One sugar company estimated its cost of process and inherent losses to be $3.6 million.

As previously stated, FDA believes the longer compliance period specified in this final rule will alleviate the concerns expressed by the comment. Again, the agency notes that these manufacturers will have until May 8, 1994, to use up their inventory. They will also have ample time to develop their new packaging.

14. One trade association commented that their business was, in large part, seasonally based because of the holiday trade, such as Halloween, and that other businesses had special holiday or seasonal considerations. The comments noted that seasonal products need unusually long advance planning. Graphics and packaging must be finalized and ordered 9 months to 1 year in advance. The comment argued that label changes would occur in the middle of the packaging and shipping season for products that represent 20 percent of some of their members' product lines.

The agency agrees that the 6-month effective date might be impossible for some seasonal products and could result in some product lines being dropped. The agency believes that the loss of product lines would be an undue economic cost. The agency notes that a delay of applicability of section 403(q) of the act of approximately 15 total months will, according to the comments, be sufficient lead time for these products.

15. Some comments requested an extension of the date of application of the labeling provisions because initial analytical results might induce companies to reformulate their products in order to improve the nutritional composition of those products to appeal to the public. An industry association stated that the costs of reformulating products would be substantial--$20,000 per product. Another firm estimated the cost of reformulation to be $60,000 per item plus $400,000 to convert processing time to include controls.

The agency notes that one of the purposes of the 1990 amendments was precisely to encourage manufacturers to produce healthier products as a result of mandatory disclosure of food content. Reformulation, however, does not constitute undue economic hardship in itself because the industry is not required by statute to reformulate its products.

16. Several comments stated that the reduction in total costs that would result from a delay in the application of section 403(q) of the act would justify an extension. One comment from a major industry association stated that the total cost of food labeling would be reduced from $3.36 billion for the May 8, 1993, compliance date to $1.69 billion for a November 8, 1993, compliance date, and ultimately to $974 million for a May 8, 1994, compliance date. Another industry association stated that the total costs to its members would be reduced from $4.3 million to $900,000 if the compliance period were extended an additional year to May 1994. One large firm stated that total costs would be $251,146,000 for a May 1993, compliance date. Additionally, an industry association estimated that an extension from May 1993 to May 1994 would reduce total costs for its members from $160 million to one-tenth of that amount. Other firms stated their total costs would be reduced by 30 to 90 percent with a 1-year extension.

FDA finds that these comments are generally consistent with its own estimates. The agency estimates that the benefits of nutrition labeling and nutrient content revision will remain nearly the same ($3.6 to $3.4 billion) over the 1-year period from May 8, 1993 to May 8, 1994, while costs will decrease dramatically. In the No v timber 1991 RIA, the agency estimated that a 6-month delay of the date of applicability would result in a savings of $600 million, a 9-month delay, $700 million

savings, and a 1-year delay, $835 million. As discussed in the final RIA published elsewhere in this issue of the **Federal Register**, FDA has found it appropriate to adjust these cost estimates upward somewhat.

C. Whether a Delay in Application of 403(q) of the Act is Appropriate

17. One comment from a consumer group favored no delay in applying section 403(q) of the act primarily because it wanted consumers to obtain health benefits as soon as possible from the mandatory disclosure of nutrients on food labels. A few comments tentatively favored an extension, but only if the food industry makes a strong case for undue economic hardship and provides substantial evidence of such hardship.

FDA has reviewed these comments and rejects the position that no extension of the May 8, 1993, deadline should be granted. FDA realizes that providing for early compliance with the 1990 amendments is desirable and follows the intent of Congress to implement promptly the provisions of section 403(q) of the act. However, the agency cannot ignore the evidence of undue economic hardship presented by industry comments and supported by FDA's own cost estimate. This hardship is particularly acute for small and medium-sized firms which will not be able to afford the analytical testing, printing, and inventory disposal costs if section 403(q) of the act is applied on May 8, 1993. Congress specifically provided that the Secretary may grant a delay of section 403(q) of the act of up to 1 year if such undue economic hardship is found.

Given the fact that a delay of the date of applicability for section 403(q) of the act will result in substantial cost reductions, and the evidence presented above that the costs of analytical testing, label printing, and inventory disposal far exceed the apparent expectations of Congress, a May 8, 1993, compliance date will generate a substantial economic burden. Therefore the agency has decided that undue economic hardship will result from implementation of section 403 (q) of the act on May 8, 1993, and has decided to delay the date of application of section 403(q), except for section 403(q)(4) (raw agricultural commodities and raw fish) which became effective November 8, 1991, as provided in section 403(q)(4)(B)(i).

D. Undue Economic Hardship from Application of Section 403(r)(2) of the Act

The agency also is authorized by the 1990 amendments to consider whether compliance with section 403(r)(2) of the act on May 8, 1993, will cause an undue economic hardship. Very few comments directly addressed the issue of undue economic hardship resulting from compliance with this section. Most comments did not distinguish between the two sections.

18. One comment from a consumer advocacy group stated that, because FDA's original estimates of the costs to restaurants represent roughly one percent of that industry's output, the economic burden to the food service industry cannot be deemed undue.

The agency disagrees with the comment. In its original assessment of the costs of food labeling (July 1990), FDA did not consider the costs to restaurants. Therefore, Congress had no information regarding the expense that would be incurred by restaurants as a result of the 1990 amendments. While no restaurant associations requested a delay of application of section 403(r)(2) of the act, according to a study conducted by the National Restaurant Association in a special analysis of their 1991 menu collection submitted in response to the November 1991 RIA, 89 percent of all menus would need to be changed to comply with the requirements of section 403(r)(2). While FDA is not including menus in the regulatory purview of this action, it is including restaurant signs and placards. Because this material is clearly reflective of the menu, much of it will have to be modified in response to the new law at significant cost. Thus, by any reasonable estimate, this figure is more than Congress could have envisioned and provides evidence of undue economic hardship.

The agency has decided not to undercut the relief that it is granting in delaying the application of section 403(q) of the act by forcing industry to comply with section 403(r)(2) of the act on May 8, 1993. The agency has considered that if a delay were granted in the application of section 403(q) of the act, but not in the application of section 403(r)(2) of the act, a substantial number of firms would still have to relabel their products to at least remove claims that are not in compliance with, or are not defined in, the regulations that FDA is issuing under section 403(r)(2).

The agency also notes that in section 10(a)(1)(B)(ii)ofthel990 amendments, Congress provided that persons who use a brand name that includes a term that is defined in section 403(r)(2)(A)(i) of the act have an additional 6 months, until November 8, 1993, to comply. FDA believes that the terms defined under section 403(r)(2)(A)(i) of the act will be most useful to consumers if they come onto the market at the same time. Therefore, FDA believes that an across the board delay in the application of section 403(r)(2) of the act for at least 6 months is appropriate.

E. Agency Finding of Undue Economic Hardship

The agency has considered the comments, relevant case law, and its November 1991 RIA, to determine whether undue economic hardship exists in implementing sections 403 (q) and 403(r)(2) of the act by May 8, 1993. Having defined "undue economic Hardship" above as a substantial economic burden in excess of what Congress would have envisioned attributable to the 6-month compliance date established by the 1990 amendments, the agency has examined the evidence presented and concludes the following:

The evidence from the comments demonstrates that undue economic hardship will occur in the aggregate because of increased analytical testing costs and pressures on printer capacity, Congress presumably was not aware that printing costs varied with different compliance periods. Therefore, a significant percentage of printing costs are unexpected costs. An estimate of label inventory disposal costs of $306 million was also not available to Congress. These costs have the greatest effect on small firms, which have low profit margins and which normally retain higher inventories of labels.

Consistent with agency figures, the comments demonstrate that the magnitude of the nutrition labeling costs are 4 times that which was reasonably expected by Congress. Additionally, these costs decrease dramatically with a 6-month, 9-month, or 12-month delay of the nutrition labeling and nutrient content provisions. Thus, the costs of applying sections 403(q) and 403(r)(2) of the act on May 8, 1993, are unnecessary and unexpected and constitute undue economic hardship for affected industry. Therefore, the agency concludes that there is an appropriate basis to delay the application of these sections.

V. How Long Should Application of Sections 403(q) and, 403(r)(2) of the Act be Delayed?

Having concluded that there will be undue economic hardship to the food

industry if it is forced to comply with sections 403(q) and 403(r)(2) of the act on May 8, 1993 and that some delay is appropriate the agency has considered how long to delay the application of these sections. Section 10(b)(3)(A) of the 1990 amendments permits the agency to delay the application of these sections for up to 1 year.

In deciding on the length of the delay, the agency notes that several factors are relevant. First, Congress has passed a second law that will require a change in food labels. The American Technology Preeminence Act of 1991 (Pub. L. 102-245) (amended in Pub. L, 102-329 (hereinafter referred to as "the metric amendments") which amended the Fair Packaging and Labeling Act (the FPLA), requires that manufacturers revise their labels and labeling by February 14, 1994 to declare net weight declarations in both the customary unit/pound system of measure and the International System of Units metric system on food labels. Second, as a result of circumstances beyond FDA's control, the issuance of the final regulations with which industry will have to comply was delayed by slightly more than a month. Both of these factors must be considered in deciding on an appropriate applicability date.

19. The agency received several comments related to the metric amendments, requesting that the agency apply sections 403(q) and 403(r)(2) of the act on the same date as the metric amendments in order to avoid a costly relabeling. One comment argued that the date of application of the nutrition labeling and nutrient content revisions and the effective date of the metric amendments should be May 8, 1994, while another comment, requested simultaneous implementation on November 8, 1994, or May 8, 1995.

FDA agrees with the comments that it would be desirable if the date of application of sections 403(q) and 403(r)(2) of the act and the effective date of the metric amendments were the same. Section 107(b) of the metric amendments requires that the metric provisions take effect 2 years after the date of enactment of the act which will occur on February 14, 1994. While section 10(a)(3)(B) of the 1990 amendments provides for a delay of the date of application of sections 403(q) and 403(r)(2) of the act, the metric amendments contain no such provision.

Initially, FDA intended to make the regulations issued under section 403(q) and (r)(2) of the act effective on February 14, 1994, providing a 9-month extension and enabling manufacturers to coordinate their compliance with both laws. However, as stated above, events beyond the agency's control have led to a delay in the publication of these final regulations. Therefore, requiring compliance with the regulations implementing section 403 (q) and (r)(2) of the act by February 14, 1994, would not provide industry with sufficient relief from undue economic hardship. The agency has thus decided that it is appropriate for those regulations to go into effect May 8, 1994. The resulting period provided to industry to comply with the regulations is in the range of the 15-month compliance period that the agency had earlier contemplated providing.

FDA recognizes that the metric amendments will take effect February 14, 1994. FDA encourages those firms that are able to consolidate their relabeling efforts and comply with both the metric amendments and the 1990 amendments by February 14, 1994, to do so. Moreover, FDA notes that under the metric amendments, firms are free to use up their existing label stocks before they are required to comply with the new provision. Thus, FDA is unlikely to bring an action against a product because it fails to comply with the metric amendments until after May 8, 1994.

20. Several comments favored the 6-month delay option because most of the cost burden will be alleviated by a delay of that length. The comments argued that a 6-month delay will have the effect of reducing the demand for printers, thereby causing a substantial decrease in printing costs. They also pointed out that inventory disposal costs will be significantly reduced because firms would be given additional time to use up old labels.

While the 6-month option relieves much of the economic hardship on industry by reducing the cost of labeling from $1.5 billion dollars to $800 million, the agency has rejected this option because it would leave firms in the position of having to make a second relabeling within 3 months to comply with the metric amendments. The agency has always sought to minimize the cost of relabeling. Furthermore, both seasonal products and products from other countries would have particular problems with only a 1-year compliance period which includes a 6-month delay in application, of sections 403(q) and 403(r)(2) of the act.

21. Some comments suggested a phasein date of applicability over a longer period such as 18 to 24 months. One comment requested a period of trial application of the proposed regulations followed by a 90-day period for comment.

The agency rejects these comments because the 1990 amendments make no provision for such a trial period or for a longer than 1-year delay in application. Additionally, such a phasein period would be extremely difficult for FDA to administer because it does not have the personnel to ensure compliance with an application date that, as it is phased in, affects only some firms or products. Thus, the agency finds no basis to adopt the approach suggested by this comment.

22. One comment from a consumer favored a 2-year delay because the consumer believed that the costs of compliance by the May 8, 1993, deadline would be excessive ($10 billion), and that most of this added cost would be passed on to consumers. Several industry comments also requested a 2-year delay because of the cost of making label changes to meet the May 8, 1994, date.

The agency estimated in the November 1991 RIA that the cost of compliance with the 1990 amendments would be $1.5 billion. While some industry comments assert that the cost would be as high as $3 to $4 billion, there simply is no basis to find, as the comment suggests, that the cost of relabeling would be $10 billion. More importantly, a 2-year delay in the application of sections 403 (q) and 403(r)(2) of the act cannot be granted because section 10(a)(3)(b) of the 1990 amendments authorizes a delay of no more than 1 year.

23. An ice cream manufacturer requested that FDA defer the date of applicability of the 1990 amendments to ice cream products until 12 months after the agency takes final action on the International Ice Cream Association's petition to establish specific standards for modified ice cream.

The agency disagrees with this comment. First, the agency does not have legal authority to grant the relief requested. As discussed above, the act grants the agency authority to delay application of sections 403(q) and 403(r)(2) of the act for 1 year from their effective date, not for a 1-year period from any particular date in the future. Secondly, the agency cannot presume that it will grant the petition in question. Even if it does, however, the modified ice cream products in question will be new foods. Thus, the costs involved in labeling these products will be the costs attributable to starting a new product line, and not costs attributable to the changes imposed by the act. Therefore, FDA finds no basis to grant the requested delay.

24. Two comments from food manufacturers stated that if the date of

applicability is delayed, two relabelings will occur because the ingredient labeling rules are statutorily mandated to take effect on May 8, 1993.

FDA finds no merit to these comments. By delaying the application of sections 403(q) and 403(r)(2) of the act until February 1994, FDA is not requiring firms to delay relabeling until that date. Quite the contrary, FDA urges firms to relabel their products as quickly as possible. However, FDA has no authority to delay the effect of the ingredient labeling provisions. Thus, whether a firm that must make labeling changes to comply with the ingredient labeling provisions makes all its changes at that time, or decides to take advantage in the delay of applicability and thus has two relabelings is up to the firm.

25. The overwhelming majority of comments supported a delay of the date of applicability for the full 1 year for sections 403(q) and 403(r)(2) of the act. The primary reasons for these requests were that a 1-year delay is necessary to give printers time to meet the excess demand for labels imposed by the nutrition labeling provisions, and that printing and analytical testing costs, prohibitive in a short compliance period, would be reduced to more reasonable levels.

The agency agrees with these comments that a delay of the date of application of sections 403(q) and 403(r)(2) of the act will alleviate the undue economic hardship for the industry. As discussed above, FDA had intended to provide a 9-month extension to February 14, 1994, but considers that an extension to May 8, 1994, is now appropriate because of the delay in publication of these rules.

The agency is thus providing the most time for compliance permissible under the 1990 amendments, as requested by these comments, although the total compliance time provided will be closer to 15 than 18 months.

The agency fully expects that many firms will begin to comply well in advance of the May 8, 1994, date of application of the nutrition labeling and nutrient content claim provisions. For firms that have their own in house analytical testing or printing capability, the transition will be easier than for those who do not. Some firms are already conducting nutritional analysis of their products and may be able to comply before the required date. Some firms may receive favorable positions in the queue of label printers and may complete labeling well in advance of the May 8, 1994, date. As these firms complete nutritional analysis and labeling, they will begin to use the revised labels. Therefore, consumers will receive some of the expected health benefits of the label changes during the period between May 8, 1993, and May 8, 1994.

VI. Effective Date of Regulations Implementing Sections 403(q) and 403(r)(2) of the Act

The agency is announcing that the regulations implementing sections 403(q) and 403(r)(2) of the act will be effective May 8, 1994, the date that the agency will begin to apply these provisions. Under section 10(b)(1)(D) and (E) of the 1990 amendments, the effective date of the regulations implementing sections 403(q) and 403(r)(2) of the act need not be the same as the effective date of those provisions. There is nothing in the 1990 amendments nor in the legislative history that states when FDA's regulations are to be effective. FDA is, therefore, free to make them effective on whatever date it considers appropriate.

The agency has chosen May 8, 1994. As a result, the current regulations on nutrition labeling and nutrient content claims will remain in effect until the agency begins to enforce the new statutory provisions on these matters. The agency finds that it would be most appropriate to have the new regulations that implement those provisions take effect at that time. Thus, on the effective date of the final rule on nutrition labeling, current § 101.9 (21 CFR 101.9) will disappear and be replaced by the new provision.

Therefore, under the act and under authority delegated to the Commissioner of Food and Drugs, FDA is establishing May 8, 1994, as the effective date of the regulations implementing sections 403(q) and 403(r)(2)of the act (except section 403(q)(4)), with a date of applicability of May 8, 1994.

Accordingly, compliance with the implementing final regulations on mandatory nutrition labeling and nutrient content claims published elsewhere in this issue of the **Federal Register** in response to the following November 27, 1991, proposals: (1) Food Labeling: Reference Daily Intakes and Daily Reference Values and Nutrition Labeling, Mandatory Status and Content Revision (Docket Nos. 90N-0134 and 90N-0135) (56 FR 60366); (2) Serving Sizes (Docket No. 90N-0165) (56 FR 60394); (3) Nutrient Content Claims, General Principles, Petitions, and Definition of Terms (Docket No. 91N-0384) (56 FR 60421); (4) Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content (Docket No. 84N-0153) (56 FR 60478); (5) Use of Nutrient Content Claims for Butter (Docket No. 91N-0344) (56 FR 60523); (6) Food Standards: Requirements for Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term (Docket No. 91N-0317 et al.) (56 FR 60512); and (7) Format for Nutrition Label (Docket No. 91N-0162) (57 FR 32058, July 20, 1992) may begin immediately. All products initially introduced into interstate commerce on or after May 8, 1994, shall comply.

VII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive RIA that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA, published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

Comments to the November 1991 RIA indicated that costs of complying with the proposed May 8, 1993, effective date would exceed FDA' estimate in the RIA. These costs would include queuing costs to food manufacturers trying to comply with the short deadline to relabel food products. The final RIA contains revised cost estimates for the societal costs involved, which, for the most part, do not include queuing costs. Such costs, which have been analyzed in this document, are largely transfers between food manufacturers and labeling firms.

FDA concludes, based on its review of available data and comments, that the costs of the overall food labeling reform initiative will be reduced by nearly one-

half (a cost savings of approximately $700 million) by extending the date for compliance with the food labeling requirements to May 8, 1994. Further the agency concludes that this action will significantly alleviate the economic hardship that would otherwise result if sections 403(q) and 403(r)(2) of the act were made applicable, as proposed, on May 8, 1993.

VIII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27, 1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in those comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA' final rules on several food labeling actions, including this action, However these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to not make these rules effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services

[FR Doc. 92-31500 Filed 12-28-92; 8:45 am]

BILLING CODE 4160-01-F.