DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 136, 137, and 139

[Docket No. 91N–100S]

RIN 0910–AA19

Food Standards: Amendment of Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Clarification.

SUMMARY: The Food and Drug Administration (FDA) is clarifying how it intends to implement regulations that it issued in March 1996 that require that, by January 1, 1998, certain standardized enriched grain products be fortified with folic acid, with respect to foods to which this substance is to be added or that include ingredients to which this substance is to be added. Given that the U.S. Public Health Service (PHS) has recommended that women of childbearing age consume at least 0.4 milligrams (mg) (400 micrograms (mcg)) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects, FDA encourages firms to initiate the required fortification before the 1998 effective date of the regulations. To facilitate initiation of fortification for firms who elect to voluntarily fortify foods in a manner that is consistent with the new folic acid fortification requirements, the agency is unlikely to enforce the ingredient declaration and nutrition labeling requirements of the Federal Food, Drug, and Cosmetic Act (the act) with respect to this nutrient until after January 1, 1998.

FOR FURTHER INFORMATION CONTACT: Felicia B. Satchell, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

A. Folic Acid Requirements for Standardized Foods

In September 1992, PHS recommended that all women of childbearing age in the United States consume 0.4 mg (400 mcg) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects (Ref. 2). In response to the PHS recommendation, FDA issued regulations in the Federal Register of March 5, 1996 (61 FR 8781), that require that by January 1, 1998, certain standardized enriched grain products be fortified with folic acid (hereinafter referred to as the 1996 fortification final rule). Affected foods are enriched bread, rolls, and buns (21 CFR 136.115); enriched flour (21 CFR 137.165); enriched self-rising flour (21 CFR 137.185); enriched corn meals (21 CFR 137.260); enriched farina (21 CFR 137.305); enriched rice (21 CFR 137.350); enriched macaroni products (21 CFR 139.115); enriched nonfat milk macaroni (21 CFR 139.122); and enriched noodle products (21 CFR 139.155) and, by cross-reference, the standards of identity for enriched bromated flour (21 CFR 137.160), enriched vegetable macaroni products (21 CFR 139.135), and enriched vegetable noodle products (21 CFR 139.165).

B. Effective Date

In the Federal Register of October 14, 1993 (58 FR 53305), FDA published a proposed rule entitled ''Food Standards: Amendment of the Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid'' (hereinafter referred to as the 1993 fortification proposal). In the 1996 fortification final rule, FDA advised that many comments had expressed concern over the statement in the 1993 fortification proposal that the final rule would become effective 1 year after publication. The comments addressed both manufacturing and labeling issues. Comments explained that it would be difficult and impractical to synchronize the addition of a folic acid-fortified enriched cereal-grain product to a food with the availability of labels for that food that have been revised to declare folic acid in the ingredient statement and, where necessary, in the nutrition label. These comments pointed out that enrichment nutrients are generally not added to each product separately but are added, for example, to thousands of pounds of flour at the flour mill. The flour is sold to manufacturers as an ingredient, and this ingredient is used in many different products. Thus, the comments asserted that, as a matter of economic necessity, the enrichment of all products using the ingredient occurs at the same time, regardless of the availability of new labeling.

To resolve the problems of coordinating fortification with labeling, comments requested an effective date for the fortification requirement of 2 years or more from the date of publication of the final rule adopting that requirement. Further, comments pointed out that any less time to comply with the fortification requirement would create economic burdens on firms because large inventories of labels would have to be discarded. However, the comments did not provide data concerning the extent of the economic burdens from discarded label inventory. A few comments suggested that the agency permit folic acid to be added to the product without requiring declaration in the ingredient statement and the nutrition label.

In the preamble to the 1996 fortification final rule, FDA acknowledged the significance of the logistical concerns regarding label changes that must accompany the addition of folic acid to enriched cereal-grain products and the resultant addition of folic acid to the foods in which these products are used as ingredients. FDA stated that it was persuaded that it should provide 2 years for manufacturers to implement the label and formulation changes required by the 1996 fortification final rule. The agency concluded that a 2-year period should allow manufacturers time to exhaust current packaging inventory and to add folic acid to the statement of ingredients and nutrition label as other changes are made to update package labeling. Furthermore, the agency pointed out that a 2-year period is consistent with the amount of time given for implementation of the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). Thus, the effective date of this final rule was established as January 1, 1998.

The agency noted, however, that compliance with the requirements established in this final rule could begin immediately, provided that the label accurately reflects that folic acid has been added to the product. FDA explained that it would not permit folic acid fortification without label declaration because, traditionally, it has not permitted manufacturers who change their formulas by adding or deleting ingredients to use labels that do not reflect this fact. Furthermore, the agency believed that it was establishing an effective date that would provide manufacturers ample time to ensure that products enriched with folic acid are labeled in compliance with the regulations. The agency also reminded manufacturers that it considered stickers an acceptable means to correct labels.

C. Problems With Folate Labeling

After the March 1996 regulations requiring that standardized enriched

grain foods be fortified with folic acid were issued, the National Pasta Association (NPA) submitted a request (Ref. 1) that, at least until January 1, 2000, the agency permit folic acid addition to products without requiring declaration in the ingredient statement. NPA stated that such flexibility was urgently needed because, without it, manufacturers of all affected standardized enriched grain foods would suffer tremendous financial losses.

More specifically, NPA stated that pasta manufacturers would lose millions of dollars of label inventory. NPA advised that the logistical problems regarding label changes that must accompany folic acid fortification were not fully resolved by the agency's extension of the effective date until 1998 or by the agency's explicit permission for using stickering to correct ingredient lists on labels. NPA explained that the industry still faces high costs from labels that must be discarded, because coordinating folic acid fortification with labeling changes is a monumental task. NPA stated that once folic acid is added to a raw material that serves as an ingredient in food, all products using that material will include the substance, but it is not possible to change all labels for such products at the same time. Furthermore, because firms must regularly replenish label supplies, NPA stated that, without the requested labeling flexibility, firms would face losing the same level of label inventory, regardless of when the regulations take effect. NPA stated that its members had advised that about 5,000 pasta products would have label inventories costing more than $27 million that would have to be discarded when the regulations take effect.

In addition, NPA advised that using stickering to correct ingredient lists on labels would not resolve logistical problems regarding label changes because many companies would have to purchase special machines for stickering. A machine would have to be purchased for each packaging line, and pasta manufacturers typically have multiple packaging lines. NPA stated that each machine would cost about $10,000. In addition to these costs, NPA stated that production problems would be created by stickering. NPA explained that it is generally not practicable to cover the ingredient statement on pasta packaged in a folding carton because of the high speed of the cartoners and the manner in which the cartons are oriented as they move through the packaging line. Stickers would have to be applied to cartons before they enter the packaging line with significant loss of packaging efficiency. Production could be drastically reduced.

NPA explained that stickering would also not be practicable on pasta packaged in bags because stickers cannot be affixed to the package film without making the film significantly thicker. A thicker film could not be wound tightly on the packaging spool. Also, the stickers would not move smoothly through the forming tubes on the baggers. If manufacturers tried to sticker the bags after filling, they could not reliably cover existing ingredient information, given the speed of the packaging line and the fact that the bags are neither flat nor consistently oriented after they are filled.

Furthermore, NPA asked whether the effective date ultimately designated for fortification of standardized enriched grain products would apply to products labeled on or after that date or to products introduced into interstate commerce on or after that date. NPA suggested that the agency should adopt the former approach for consistency with the effective date established in the 1990 amendments, ease of enforcement, equity between small and large manufacturers, and maximization of cost savings derived from a delayed effective date.

II. The Agency's Position

Given the more specific information that was provided by NPA regarding folic acid label changes, the logistical problems with these changes, and the costs associated with label inventories that would have to be discarded, FDA has reviewed its position regarding the effective date of these regulations. FDA recognizes that its allowance, without label flexibility, of nearly 2 years for compliance with the fortification requirements did not resolve significant problems associated with formulation and label changes, and that there are significant reasons for flexibility in label declaration of folate content, at least pending the effective date of the regulations requiring fortification. These reasons are listed as follows:

(1) Among firms that add folic acid to their foods themselves (e.g., flour manufacturers), the raw material is commonly fortified in large batches, and the fortified material is then used in numerous products. Because each product requires at least one label (e.g., often a firm will pack one product for several companies, each of which uses a different label), numerous labels will have to be corrected once fortification begins. If all these labels have to be changed at once, existing label inventories would have to be discarded. Even if it were possible to change all (perhaps hundreds) labels at once, firms would logically postpone fortification as long as possible to allow for depletion of label inventory.

(2) For firms that do not themselves perform all folic acid fortification of the ingredients in the products they manufacture, the logistics of coordinating label changes with fortification are even more complicated. These firms have little or no control over when the fortification of ingredients with folic acid is to begin. Suppliers of ingredients that are to be fortified with folic acid are likely to initiate fortification at different times. In many, if not most, situations, firms may be advised of the fortification only through the ingredient list that comes from the supplier. Firms will thus have significant difficulty anticipating when label stocks that do not list folic acid as an ingredient will have to be depleted. Firms also will have difficulty anticipating how far in advance of the 1998 effective date new label stocks will be needed. Thus, many firms will likely incur costs associated with discarding label stocks. Also, where suppliers fortify early, some firms may not have new label stocks that appropriately reflect the composition of their food.

(3) Where firms purchase an enriched ingredient from multiple suppliers, planning for depletion of old label stock and for acquiring new label stock will present particular problems. Some ingredient shipments may be fortified with folic acid, others may not. Consequently, such firms will be faced with having to switch back and forth between old and new label stocks. Where enriched ingredient shipments are pooled into an automatic bulk handling system, folic acid-enriched and non-folic acid-enriched ingredients will be commingled. The commingled ingredient may not conform to fortification requirements, and both old and new label stocks may be inappropriate as a result.

(4) NPA has presented logical reasons why stickering will not provide a practicable way to correct lists of ingredients and nutrient declarations on old labels because of adverse impact on manufacturing productivity.

(5) NPA has provided data concerning the extent of the economic burden from discarded label inventory in the pasta industry. For that industry, the costs appear to be substantial. Pasta manufacturers are not likely to be the only firms affected by the problems associated with the folic acid label changes and the logistical problems and costs associated with these changes. Thus, costs from discarded label inventory may be much higher than the

$27 million that NPA estimated. Such costs will surely be passed on to consumers.

Although NPA has demonstrated that significant problems will be presented by the transition to fortification of enriched grains with folic acid, it has not explained why the effective date should be changed from January 1, 1998, to January 1, 2000. If firms have flexibility to use existing label stocks that do not have folic acid ingredient labeling until January 1, 1998, most of the cost burdens on these firms should be eliminated. The only continuing concern would be if label suppliers could not meet the demand for new labels by January 1, 1998. However, neither NPA nor the comments on the 1993 fortification proposal indicated that large numbers of firms would be faced with such a situation. To the contrary, the agency knows of no reason why most firms cannot acquire new label stocks by that date.

On May 23, 1996, the March of Dimes wrote to FDA that the desire to begin to fortify early was widespread in the industry, but that many firms were not doing so because fortifying their foods would mean that they could not use up existing label stocks (Ref. 3). The March of Dimes suggested that if the agency provided flexibility in the use of label supplies, it would make it more likely that firms would proceed with folic acid fortification at an earlier date, thereby helping to reduce a woman's risk of having a pregnancy affected with spina bifida or other neural tube defects.

Given this significant benefit from folic acid fortification and the significant difficulties in label modification as folic acid is being phased into enriched grain products, FDA advises that, until the amendments to the standards of identity for enriched grain products are effective on January 1, 1998, it is unlikely to take regulatory action against enriched grain products, or products that contain enriched grain products, because the ingredient list in the labeling of such foods fails to include folic acid, or because the nutrition label fails to accurately declare the level of folate, unless folate claims are made for the product. If folate claims are made FDA will expect the food to comply fully with all applicable labeling requirements.

With respect to NPA's request for clarification of the applicability of the effective date, FDA advises that the January 1, 1998, effective date for fortification of standardized enriched grain products applies to the date such products are initially introduced into interstate commerce. FDA does not agree with the NPA suggestion that the effective date should be tied to the date that products are labeled. The agency has for many years used the date of initial introduction into interstate commerce as the effective date for compliance with regulations. Using the date of initial introduction into interstate commerce is a more efficient enforcement approach because this date is easier to determine (e.g., from shipping documents) than the date the food was labeled (from manufacturers' records). Even though the effective date established by the 1990 amendments was the date on which the label was applied to the food, there is no indication in that law or its legislative history that Congress intended that provision to change FDA's approach to effective dates for other labeling requirements from the one the agency has traditionally used.

III. References

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

1. Centers for Disease Control and Prevention, ''Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects,'' in *Morbidity and Mortality Weekly Reports*, 41, 1–7, 1992.

2. Kinnaird, Jula J., letter to F. Edward Scarbrough, April 18, 1996.

3. Howse, Jennifer L., letter to Secretary Donna Shalala, May 23, 1996.

Dated: August 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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21 CFR Part 177

[Docket No. 84F–0330]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a copolymer of ethyl acrylate, methyl methacrylate, and methacrylamide in combination with melamine-formaldehyde resin as a coating for polyethylene phthalate films intended for use in contact with food. This action is in response to a petition filed by ICI Americas, Inc.

DATES: Effective September 5, 1996; written objections and requests for a hearing by October 7, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of October 26, 1984 (49 FR 43111), FDA announced that a food additive petition (FAP 4B3786) had been filed by ICI Americas, Inc., Wilmington, DE 19897. The petition proposed that the food additive regulations be amended to provide for the safe use of a copolymer of ethyl acrylate, methyl methacrylate, and methacrylamide in combination with melamine-formaldehyde resin for use in contact with food in coatings for polyethylene phthalate films as defined by § 177.1630(a) (21 CFR 177.1630(a)).

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted ethyl acrylate, 1,4-dioxane, and ethylene oxide, all of which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as ethyl acrylate, 1,4-dioxane, and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

II. Determination of Safety

Under the so-called ''general safety clause'' of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''