

proportion of SKUs from small businesses as a whole equaled the proportion in the EED (73 percent). Across product categories the average low relabeling cost per SKU is about \$250 and the average high relabeling cost per SKU is \$585. The reported estimated costs of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 15 shows the total estimated costs of relabeling per product category and for all small businesses affected.

TABLE 15.—RANGE OF RELABELING COSTS FOR SMALL BUSINESSES BY PRODUCT CATEGORY

Product Categories	Low	Medium	High
Baked Goods	\$5,760,000	\$8,988,000	\$15,822,000
Baking Ingredients	\$807,000	\$1,274,000	\$2,167,000
Baby Foods	\$51,000	\$78,000	\$128,000
Selected Beverages	\$15,828,000	\$20,459,000	\$27,941,000
Breakfast Foods	\$422,000	\$696,000	\$1,194,000
Selected Candy	\$1,215,000	\$1,915,000	\$3,161,000
Selected Condiments, Dips and Spreads	\$3,438,000	\$4,898,000	\$7,180,000
Dairy Foods	\$6,102,000	\$9,456,000	\$15,041,000
Desserts	\$1,604,000	\$2,597,000	\$4,409,000
Dietary Supplements	\$9,303,000	\$13,882,000	\$23,150,000
Selected Dressings and Sauces	\$1,848,000	\$2,800,000	\$4,238,000
Eggs	\$1,286,000	\$1,923,000	\$3,447,000
Entrees	\$1,205,000	\$1,892,000	\$3,065,000
Fats and Oils	\$647,000	\$1,020,000	\$1,561,000
Fruits and Vegetables	\$7,839,000	\$11,062,000	\$16,797,000
Seafood	\$1,167,000	\$1,682,000	\$2,446,000
Side Dishes and Starches	\$1,796,000	\$2,897,000	\$4,904,000
Snack Foods	\$1,967,000	\$2,987,000	\$4,821,000
Soups	\$783,000	\$1,105,000	\$1,621,000
Weight Control Foods	\$109,000	\$164,000	\$279,000
Total	\$63,177,000	\$91,775,000	\$143,372,000

Table 16 of this document shows the total costs to small businesses of the final rule. The adjusted total costs of the final rule equal the unadjusted total minus 1.8 percent of the total cost of the rule to all businesses (see 58 FR 2927 at 2928, January 6, 1993). The average cost per small business is about \$10,000.

TABLE 16.—TOTAL COSTS FOR SMALL BUSINESSES

Cost Category	Low	Medium	High
Testing	\$13,311,000	\$14,841,000	\$18,921,000
Relabeling	\$63,177,000	\$91,775,000	\$143,372,000
Total	\$76,488,000	\$106,616,000	\$162,293,000
Adjustment for Exemption	-\$2,120,000	-\$ 3,260,000	-\$5,100,000
Adjusted Total	\$74,000,000	\$103,000,000	\$157,000,000

### *C. Regulatory Options*

The Regulatory Flexibility Act requires that FDA consider options for regulatory relief for small entities.

#### 1. Exemption for Small Businesses

The exemption of small businesses from the provisions of the final rule would provide regulatory relief. Table 16 of this document shows that small businesses are expected to bear total costs of about \$103 million as a result of the final rule, an average of \$10,000 per small business. As a first approximation, then, exempting small businesses would reduce the burden by an average of \$10,000 per small business.

FDA believes that this option would not be desirable. On the one hand, because so many of the businesses in the food processing industry are classified as small by the Small Business Administration, if small businesses are exempted, most of the potential benefits from the final rule would not be realized. On the other hand, exempt businesses may be forced by market pressures to adopt the final label in any case. In addition, under section 403(q)(5)(E) of the act and implementing regulations, very small producers (those with fewer than 100 full-time employees) that: (1) File a notice with the Office of Nutritional Products, Labeling, and Dietary Supplements; (2) make very low volume products (fewer than 100,000 units annually); and (3)

place no claims or other nutrition information on product labels, labeling, or advertising would already be exempt from this final rule.

## 2. Longer Compliance Period for Small Businesses

Longer compliance periods provide regulatory relief for small businesses. Some comments requested that the compliance period be extended several years (e.g., 4 to 7 years) for small businesses. These comments stated that it was important for small businesses to be able to phase in the cost associated with the new label requirements so that they have extra time to absorb the costs of these changes. Some small manufacturers reported that they have significant inventories of labels. Also, smaller manufacturers indicated that they would incur costs, including, loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates. These small businesses believe that a longer compliance period would allow them to more easily manage their inventories and phase in the *trans* fat labeling requirements along with other scheduled labeling revisions. This will help minimize unnecessary labeling costs and costs passed on to consumers.

To minimize the need for multiple labeling changes and to provide additional time for compliance by small businesses to allow them to use current label inventories and phase in label changes, the agency is setting the effective date at January 1, 2006, the next uniform effective date following publication of this rule. This allows firms more than 2 years to implement this final rule providing some regulatory relief and economic savings for small businesses. This should be long enough for most small businesses to coordinate the label change for this rule with other label changes and reprinting. However, in this final rule, FDA has decided not to extend the compliance period for small businesses beyond what is given for all businesses. Because this final

rule does not affect nutrient content or health claims, no small businesses will have to change the principal display panels or marketing of their products, which could be very costly.

With small businesses producing 85 percent of the products and 73 percent of the SKUs, extending the compliance period for small businesses to the uniform effective date after January 1, 2006, would leave most labels not listing *trans* fat for almost 5 years after publication. This could result in significant confusion for consumers looking for *trans* fat content on labels and would make the Nutrition Facts panel inconsistent across product categories. This inconsistency would be contrary to the intent of the 1990 amendments. It also would undermine the policy goal of providing consistent nutrition information to consumers. Also, extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

### 3. Exemptions for Particular Products Produced by Small Entities

In the category of breakfast foods, the average intake of *trans* fat for both men and women is less than one-tenth of a gram per day. Because the entire category contributes so little to the overall dietary intake of *trans* fats, exempting small businesses in this category from the rule would have small effects on health. The exemption, however, would provide regulatory relief for approximately 60 small businesses (including cereal and frozen breakfast foods). The total burden on small businesses would fall by \$871,000 (the sum of \$696,000 relabeling costs and \$175,000 testing costs for 600 products). The relief offered by this option, then, would be small.

An objection to this option for regulatory relief is that by exempting an entire class of products, FDA could create incentives for small firms to create products in that category. These new products would have no effective limits

on *trans* fat. The exemption would therefore allow small firms to develop products with high *trans* fat content but no indication of that content on the label. The contribution of breakfast cereals to total dietary intake of *trans* fats could increase because of the exemption. The most telling objection to this option is that exempting some products from the final labeling rule would make the Nutrition Facts panel inconsistent across product categories. This inconsistency would contradict the intent of the 1990 amendments. It would undermine the policy goal of providing consistent nutrition information to consumers.

#### *D. Recordkeeping and Reporting Requirements*

The Regulatory Flexibility Act requires FDA to include a description of the recordkeeping and reporting required for compliance with this final rule. This final rule does not require the preparation of a report or a record.

#### *E. Summary*

FDA finds that under the Regulatory Flexibility Act (5 U.S.C. 605(b)) this final rule will have a significant economic impact on a substantial number of small entities. Approximately 10,300 small businesses could be affected by the rule. The total burden on small entities is estimated to be between \$74 and \$157 million, or about \$7,200 to \$15,200 per entity.

### **XI. Unfunded Mandates**

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses for rules that would cost more than \$100 million in 1 single year. The final rule qualifies as a significant rule under the statute. FDA has carried out the cost-benefit analysis in sections IX.C and

IX.D of this document. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on the following:

1. Future costs;
2. Particular regions, communities, or industrial sectors;
3. National productivity and economic growth;
4. Full employment and job creation; and,
5. Exports.

#### *A. Future Costs*

Most of the costs of this rule will be incurred during the compliance period. Future costs beyond that period would likely be small, because the food industry would have adjusted to the new requirements by that time.

#### *B. Particular Regions, Communities, or Industrial Sectors*

The final rule applies to the food industry and would, therefore, affect that industry disproportionately. Any long run increase in the costs of food production would largely be passed on to the entire population of consumers.

#### *C. National Productivity and Economic Growth*

The final rule is not expected to substantially affect productivity or economic growth. It is possible that productivity and growth in certain sectors of the food industry could be slightly lower than otherwise because of the need to divert research and development resources to compliance activities. The diversion of resources to compliance activities would be temporary. Moreover, FDA anticipates that, because the health benefits are estimated to be significant, both productivity and economic growth would be higher than in the absence of the rule. In section IX.C.3 of this document, FDA estimated benefits from the reduction in functional disability associated with a reduction

in nonfatal CHD. A reduction of functional disability would result in an increase in productivity. The increased health of the population and the reduction in direct and indirect health costs could increase both productivity and economic growth.

#### *D. Full Employment and Job Creation*

The human resources devoted to producing certain foods would be redirected by the final rule. The final rule could lead to some short-run unemployment as a result of the structural changes within the food industry, the rise of some product lines and decline of others. The growth of employment (job creation) could also be temporarily slower.

#### *E. Exports*

Because the final rule does not mandate any changes in products, current export products will not be required to change in any way. Food processors, however, do not necessarily distinguish between production for export and production for the domestic market. The effect of the final rule on U.S. food exports depends on how foreign consumers react to information about *trans* fats and to product formulations that contain lower amounts of partially hydrogenated oils. The new label and possible new formulations could either increase or decrease exports. Products in Germany and certain other European countries, for example, currently use partially hydrogenated oils to a lesser degree than in the United States, so the final rule could make U.S. exports of margarine more attractive to consumers in those countries than they have been. However, it could also make U.S. exports of unreformulated products that reveal the presence of *trans* fat less attractive to consumers in those countries than they have been.

## **XII. Environmental Impact**

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (64 FR 62746, November 17, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

## **XIII. Paperwork Reduction Act**

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title:* Food Labeling; *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims.

*Description:* Section 403(q)(1)(A) and (q)(1)(B) of the act requires that the label or labeling of a food bear nutrition information on the amount of nutrients present in the product. Under these provisions of the act and section 2(b) of the 1990 amendments, FDA has issued regulations in § 101.9(c)(2) that require that the Nutrition Facts panel disclose information on the amounts of fat and certain fatty acids in the food product. This final rule establishes § 101.9(c)(2)(ii) to require that the Nutrition Facts panel disclose information on the amount of *trans* fat in the food product. Similarly, under the provisions

of section 403(q)(5)(F) of the act, FDA has issued regulations in § 101.36(b)(2) that specify the nutrition information that must be on the label or labeling of dietary supplements. This final rule establishes § 101.36(b)(2) (21 CFR 101.36(b)(2)) to specify that when nutrition information is declared on the label and in labeling, it must include the amount of *trans* fat.

The regulations set forth in this final rule require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fat.

*Description of Respondents:* Persons and businesses, including small businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 17.—ESTIMATED REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Responses per Respondent	Total No. of Responses	Hours per Response	Total Hours	Operating Costs (in thousands)
101.9(c)(2)(ii)	10,490	26	270,200	2	540,400	\$130,300
101.36(b)(2)	910	32	29,500	2	59,000	\$12,900
Totals					599,400	\$143,200

<sup>1</sup> There are no capital costs and or maintenance costs associated with this collection of information.

The impact of these requirements concerning *trans* fatty acids would be largely a one-time burden created by the need for firms to revise food and dietary supplement labels. FDA used data from the 1999 County Business Patterns to estimate the number of respondents. The total number of responses is equal to the total number of SKUs being changed (table 3 of this document). Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 2 hours per SKU (hours per response) to comply with the nutrition labeling requirements in this final rule. Multiplying the total number of responses by the hours per response gives the total hours. FDA has estimated operating costs by combining the medium testing and relabeling costs from table 7 of this document (\$17.5 million +

\$125.7 million) to get the total operating cost. This total was then apportioned between §§ 101.9 and 101.36 according to the proportion of responses for each section. FDA expects that, with a compliance period of over 2 years, firms will coordinate labeling revisions required by this final rule with other planned labeling for its products.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### **XIV. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to “construe \* \* \* a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Section 403(A) of the act (21 U.S.C. 343–1) is an express preemption provision. That section prohibits a “State or political subdivision of a State to directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce” certain food labeling requirements, unless an exemption is provided by the Secretary (and by delegation, FDA). One such prohibition, that is relevant to this final rule,

is any requirement for nutrition labeling of food that is “not identical to the requirement of section 403(q) \* \* \*” Although this rule has preemptive effect in that it would preclude States from issuing regulations that are not identical to the *trans* fat labeling required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403(A) of the act.

Section 4(c) of the Executive order further requires that “any regulatory preemption of State law shall be restricted to the minimum level necessary” to achieve the regulatory objective. The agency is exercising its discretion under section 403(q)(2)(A) of the act, in a manner that is consistent with such section, to require that the amount of *trans* fat be listed in the label or labeling of food. This action is the minimum level necessary to achieve the agency’s regulatory objective. Further, section 4(e) provides that “when an agency proposed to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” FDA sought input from all stakeholders through publication of the proposed rule in the **Federal Register**. There were eight comments from State and local governmental entities received and all supported the proposal. In addition, one supportive comment was received from a municipal health agency in response to the reopening of the comment period relating to the proposed footnote option.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with Executive Order 13132.

**XV. References**

The following references have been placed in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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### **List of Subjects in 21 CFR 101**

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

### **PART 101—FOOD LABELING**

1. The authority citation for 21 CFR part 101 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.9 is amended by: (a) Redesignating paragraphs (c)(2)(ii) and (c)(2)(iii) as (c)(2)(iii) and (c)(2)(iv), (b) Adding new paragraph (c)(2)(ii), and

(c) Revising paragraphs (c)(2)(i), (d)(1)(ii)(A), the first sentence of paragraph (f), the first sentence of paragraph (g)(5), (g)(6), and the sample labels in paragraphs (d)(11)(iii), (d)(12), (d)(13)(ii), (e)(5), (j)(13)(ii)(A)(1), and (j)(13)(ii)(A)(2).

The revisions and additions are to read as follows:

**§ 101.9 Nutrition labeling of food.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(i) “Saturated fat,” or “Saturated”: A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid, or cholesterol content, and if “calories from saturated fat” is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement “Not a significant source of saturated fat” shall be placed at the bottom of the table of nutrient values. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 gram (1/2) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) “*Trans* fat” or “*Trans*”: A statement of the number of grams of *trans* fat in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration, except that label declaration of *trans* fat content information is not required for products that contain less than 0.5 gram of total fat in a serving

if no claims are made about fat, fatty acid or cholesterol content. The word “*trans*” may be italicized to indicate its Latin origin. *Trans* fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero. Except as provided for in paragraph (f) of this section, if a statement of the *trans* fat content is not required and, as a result, not declared, the statement “Not a significant source of *trans* fat” shall be placed at the bottom of the table of nutrient values.

\* \* \* \* \*

(d)(1) \* \* \*

(ii) \* \* \*

(A) Except as provided for in paragraph (c)(2)(ii) of this section, a single easy-to-read type style,

\* \* \* \* \*

(11) \* \* \*

(iii) \* \* \* [insert revised label]

(12) \* \* \* [insert revised label]

(13) \* \* \*

(ii) \* \* \* [insert revised label]

\* \* \* \* \*

(e) \* \* \*

(5) \* \* \* [insert revised label]

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans*

fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron; \* \* \*

\* \* \* \* \*

(g) \* \* \*

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. \* \* \*

(6) Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

\* \* \* \* \*

(j) \* \* \*

(13) \* \* \*

(ii) \* \* \*

(A) \* \* \*

(1) \* \* \* [insert revised label]

(2) \* \* \* [insert revised label]

\* \* \* \* \*

3. Section 101.36 is amended by revising paragraph (b)(2)(i) to read as follows:

**§ 101.36 Nutrition labeling of dietary supplements.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(i) The (b)(2)- dietary ingredients to be declared, that is total calories, calories from fat, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c) of this part.

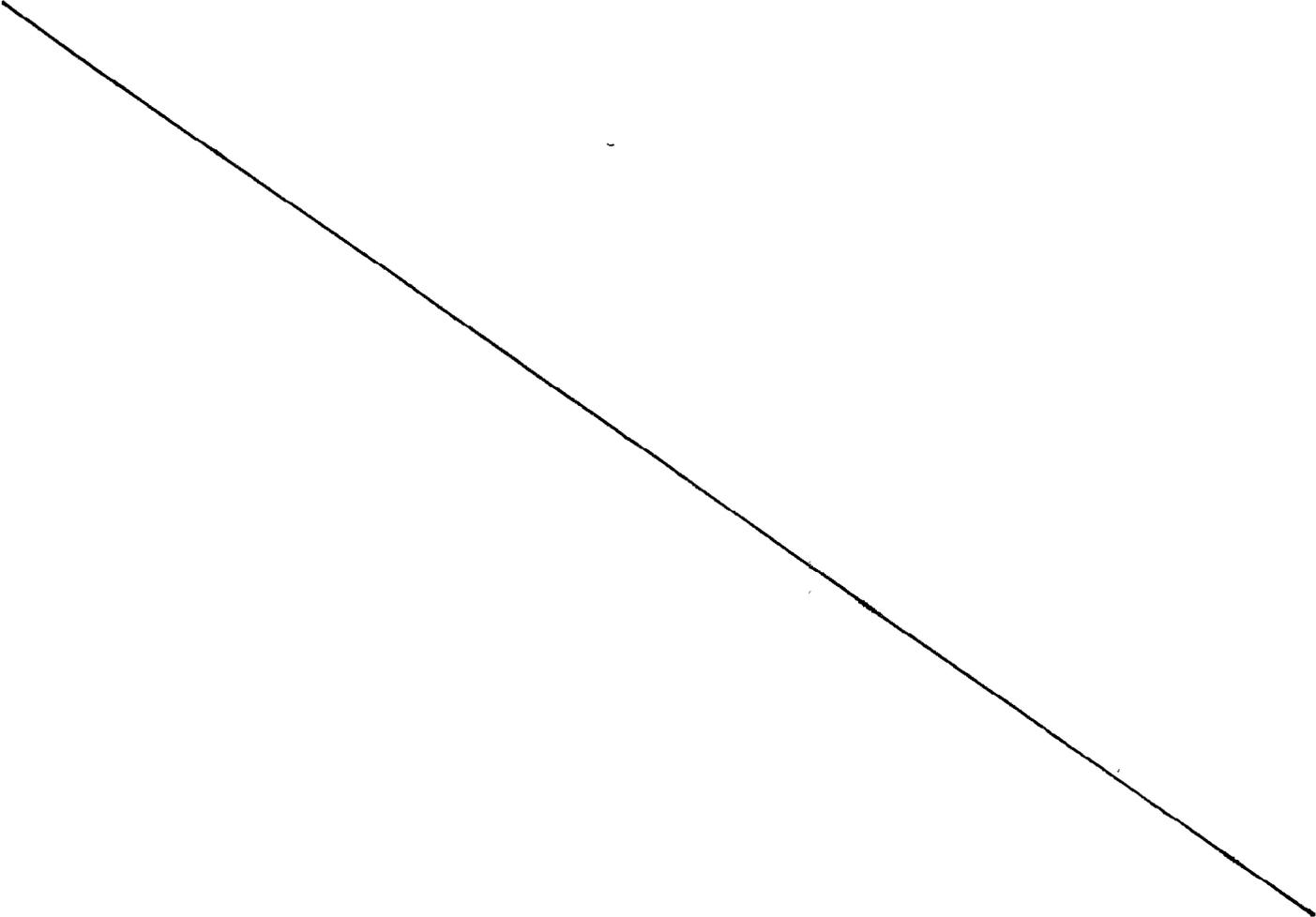
\* \* \*

\* \* \* \* \*

4. Appendix B to Part 101 is amended by revising the sample label showing graphic enhancements used by FDA as follows:

**Appendix B to Part 101—Graphic Enhancements Used by the FDA**

[insert revised label and graphics]



Dated: May 7, 2003

  
\_\_\_\_\_

Dated: \_\_\_\_\_

\_\_\_\_\_

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**