the claim. FDA needs time to consider the supporting and opposing positions and to conduct any necessary rulemaking on the issues raised. Given these factors, the agency is persuaded that it is in the public interest to stay the provisions for the lower standards for sodium in the definition of ''healthy'' (§ 101.65).

Therefore, while the agency resolves these issues, FDA is staying until January 1, 2003, the provisions in § 101.65(d)(2)(ii)(C) for foods and in § 101.65(d)(4)(ii)(B) for meals and main dishes. The agency also is staying the provisions in § 101.65(d)(3)(ii)(C) for raw, single-ingredient seafood or game meat, a citation that was inadvertently omitted in the initial stay. This action is being taken to: (1) Allow FDA time to reevaluate the information that supports and opposes the petition, (2) conduct any necessary rulemaking on the sodium limits for the term ''healthy,'' and (3) provide time for companies to respond to any changes that may result from agency rulemaking.

Interested persons may submit comments regarding the appropriateness of the basis of this stay. In doing so, however, FDA encourages manufacturers who can meet the lower sodium levels for particular foods and still produce an acceptable product to do so even as the agency reevaluates the issues discussed.

Interested persons may, on or before April 15, 1999, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This document is issued under the authority of 15 U.S.C. 1453, 1454, 1455, and 21 U.S.C. 321, 331, 342, 343, 348, 371.

For the reasons set forth in the preamble, 21 CFR 101.65(d)(2)(ii)(C), (d)(3)(ii)(C), and (d)(4)(ii)(B) are stayed until January 1, 2003.

Dated: March 8, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6300 Filed 3–15–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P–0240]

Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''Baking powder, baking soda, pectin'' from 1 gram (g) to 0.6 g to more accurately reflect the amount of these products that is customarily consumed. The agency is also including 1/8 teaspoon (tsp) as an additional allowable household measure, because it is a common household measure available to consumers. This action is being taken in response to a petition submitted by Church Dwight Co., Inc., on behalf of Arm & Hammer.

DATES: Effective January 1, 2002. Full compliance is required for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 1, 2002. Voluntary compliance may begin April 15, 1999.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5662.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1997 (62 FR 61476), FDA published a proposed rule to amend the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''Baking powder, baking soda, pectin'' from 1 g to 0.6 g to more accurately reflect the amount of these products that is customarily consumed. The agency also proposed to include 1/8 tsp as an additional allowable household measure because it is a common household measure available to consumers. Interested persons were given until February 2, 1998, to comment on the proposal.

FDA had issued the proposal in response to a petition dated June 23, 1994, from Church Dwight Co., Inc., on behalf of Arm & Hammer (94P–0240). The petitioner requested that the agency amend Table 2 in § 101.12(b) (21 CFR 101.12(b)) under ''Miscellaneous Category: Baking powder, baking soda, pectin'' to create a separate subcategory for baking soda with a reference amount of ''500 milligrams (mg)'' and to permit a corresponding serving size of ''1/8 tsp (500 mg)'' (which would require amending § 101.9(b)(5)(i) (21 CFR 101.9(b)(5)(i)).

II. Final Action

The agency received no comments in response to the proposal. Therefore, FDA concludes that, for the reasons set out in the proposal, it is appropriate to amend §§ 101.9(b)(5)(i) and 101.12(b) as proposed to better reflect the amounts customarily consumed for these products. Thus, in the final rule set forth below, FDA is revising its food labeling regulations to: (1) Amend § 101.12(b) by changing the reference amount for ''Baking powder, baking soda, pectin'' from ''1 g'' to ''0.6 g'' (the weight of 1/8 tsp of baking powder and baking soda, and close to the weight of 1/8 tsp of pectin); (2) amend § 101.9(b)(5)(i) by including 1/8 tsp as an additional allowable household measure; and (3) reorganize § 101.9(b)(5)(i) to simplify the options for teaspoon and tablespoon measures and to improve clarity.

III. Effective and Compliance Dates

Voluntary compliance with this final regulation, including any required labeling changes, may begin April 15, 1999, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 1, 2002, shall fully comply.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (62 FR 61476 at 61479). 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.

V. Benefit—Cost Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety, and other advantages; (distributive impacts and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, or adversely affecting jobs or competition. A regulation is also considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues.

The Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires a cost-benefit analysis and other analyses when a rule is a significant rule. Under section 1532(a) of the UMRA, a significant rule is a rule containing ''any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.''

Finally, the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having resulted in or being likely to result in one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, investment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

FDA finds that this final rule is neither an economically significant rule nor a significant regulatory action as defined by Executive Order 12866. FDA has determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and, therefore, this rule does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act. Furthermore, this rule is not a major rule for the purpose of congressional review under the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121).

Because FDA received no comments on the proposal, the benefit-cost analysis included in the proposed rule will not be changed.

This final rule will cause the labels of baking powder, baking soda, and pectin to be revised. FDA estimates that there are 29 firms producing baking powder, baking soda, or pectin. There are 23 baking powder labels, 18 baking soda labels, and 25 fruit pectin labels for a total of 66 labels affected by this rule. On average, the administrative, redesign, and inventory disposal costs for a labeling change of this type, with a 1-year compliance period, are $600 per product, or a total of $39,600.

The benefit of this proposed regulation is that because manufacturers will provide information on a serving size that is more appropriate for baking soda, baking powder, and pectin, product labels will provide more accurate information to consumers.

VI. Small Entity Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. Under the Regulatory Flexibility Act, FDA concludes that this final rule will have a significant economic impact on a substantial number of small entities.

FDA is amending the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for baking powder, baking soda, and pectin to more accurately reflect the amount of these products customarily consumed. The agency is also adding 1/8 tsp as a household measure because it is a common household measure available to consumers.

A. Estimate and Description of the Small Entities

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For baking powder, baking soda, and pectin, a business is considered small if it has fewer than 500 employees.

FDA estimates that four of the firms producing baking powder, baking soda, or pectin are small. FDA also estimates that each small firm produces two products that might be relabeled as a result of this rule.

B. Description of the Impacts

FDA received no comments on the preliminary regulatory flexibility analysis and will, therefore, not alter that analysis. As estimated in the analysis in the proposed rule, the cost of this rule per small firm will be $1,200 ($600 x 2 products). The 95th percentile firm has annual sales of $275,000 and 1 employee. The cost of the rule as a percentage of annual sales is 0.4 percent. Return on sales for this industry is 8.3 percent for the upper quartile, 2.9 percent for the median, and 0.9 percent for the lower quartile. FDA is uncertain which quartile this firm belongs to because the number of employees and annual sales do not imply anything about the profitability of a firm. The costs of this rule will be 4.8 percent of profits if this firm falls into the upper quartile for the industry, 13.8 percent of profits if this is a median firm, and 44.4 percent of profits if this firm falls into the lower quartile. Therefore, the smallest 5 percent of affected firms will be adversely affected by this rule. Under the Regulatory Flexibility Act (5 U.S.C. 605), the agency concludes that this final rule will have a significant impact on a substantial number of small entities.

C. Compliance Requirements and Necessary Skills

The Regulatory Flexibility Act also requires agencies to describe the projected reporting, recordkeeping, and other compliance requirements of the rule and the type of professional skills necessary for preparation of the report or record. Manufacturers of baking soda, baking powder, and pectin who are not exempt from compliance as described in section VI.D.1 of this document will be required to amend their labels to reflect the new serving sizes and to recalculate the reported levels of nutrients in the foods based on the new serving sizes. No further analyses are required, only that the reported amounts are based on the correct serving size.

D. Alternatives

In the proposed rule, FDA examined alternatives to the rule that may minimize the significant economic impact on small entities consistent with stated objectives. Both alternatives are described as follows.

1. Exempt Small Entities

In § 101.9(j)(18), the agency exempts from mandatory nutrition labeling low volume food products of certain small businesses (see 61 FR 40963, August 7, 1996). Section 101.9(j)(18) applies to manufacturers, packers, distributors, or retailers of low volume products, defined as fewer than 100,000 units, produced by firms with fewer than 100 employees. To the extent that baking powder, baking soda, or pectin products are eligible for this exemption and manufacturers have chosen to take advantage of the exemption, then

products might not require relabeling as a result of this rule. However, if the products are currently nutritionally labeled either because the label contains nutrient content claims or because the manufacturer has voluntarily labeled the product, then the Nutrition Facts panel must be correct and the label must be changed. FDA is uncertain how many products, if any, can or will take advantage of this option. FDA discussed this exemption in the proposed rule but no comments were submitted.

2. Lengthen the Compliance Period

FDA also considered the option of providing small entities with a longer compliance period. Longer compliance periods typically result in lower costs because firms can combine mandated label changes with planned changes and because firms have more opportunity to use up existing labels. A compliance period longer than 1 year would reduce costs to less than $1,200 per small firm. Because the mandatory compliance date for this rule is January 1, 2002, firms will have almost 3 years to come into compliance with this rule.

E. Description of Outreach to Small Entities

The Regulatory Flexibility Act requires a description of the outreach activities undertaken by the agency to inform small entities about the rule and to encourage comments from small businesses. In addition to publishing the proposed rule in the **Federal Register**, the agency also notified by phone all small businesses known to produce products affected by the rule.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements 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: Serving Sizes; Reference Amount for Baking Powder, Baking Soda, Pectin.

Description: Section 403(q)(1)(A) and (q)(1)(B) of the Federal Food, Drug, and Cosmetic Act requires that the label or labeling of a food bear information that provides the serving size that is appropriate to the food and the number of servings per container. FDA has issued regulations in § 101.9(d)(3) that require the Nutrition Facts panel on the label of a food product to disclose information on serving size and on servings per container. FDA has also issued regulations in § 101.9(b) that provide that the serving size declared on a product label shall be determined from the ''Reference Amounts Customarily Consumed Per Eating Occasion'' that appear in § 101.12(b).

The regulations set forth in this final rule revise the reference amount that is used for determining the serving sizes for baking powder, baking soda, and pectin. As a result, manufacturers and other producers of these products are required to change the serving sizes and the number of servings per container that they disclose in the nutrition facts panel for their products. The regulations also provide for the use of 1/8 tsp as an additional household measure for the disclosure of serving sizes for food products.

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

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours	Operating Costs
101.12(b)	29	66	1	66	$39,600

[1]There are no capital or maintenance costs associated with this collection of information.

FDA believes that the burden associated with the disclosures required by this final rule will be a one-time burden created by the need for firms to change the statement of serving size and the number of servings on the labels for their products. As noted above, FDA estimates that there are 29 firms producing baking powder (23 labels), baking soda (18 labels), and pectin (25 labels). FDA estimates that these firms will require an average of 1 hour per product to comply with the requirements of this final rule. Further, as noted above, FDA estimates that the final rule will result in a one-time operating cost of $39,600.

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

The information collection provisions in this final rule have been approved under OMB control number 0910–0357. This approval expires on January 31, 2001. 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.

List of Subjects in 21 CFR Part 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 revising paragraph (b)(5)(i) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(b) * * *

(5) * * *

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. For beverages, a manufacturer may use fluid ounces. Cups shall be expressed in 1/4- or 1/3-cup increments. Tablespoons shall be expressed as 1, 1 1/3, 1 1/2, 1 2/3, 2, or 3 tablespoons. Teaspoons shall

be expressed as 1/8, 1/4, 1/2, 3/4, 1, or 2 teaspoons.

* * * * *

3. Section 101.12 is amended in paragraph (b), in Table 2, under the ''Product category'' column, under ''Miscellaneous category'' by revising the entry for ''Baking powder, baking soda, pectin'' to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
* * * * *	*	*
Miscellaneous Category:		
Baking powder, baking soda, pectin	0.6g	__tsp (__g)
* * * * *	*	*

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term ''piece'' is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

* * * * *

Dated: March 9, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6299 Filed 3–15–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SPATS No. IN–144–FOR]

Indiana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving, with certain exceptions, an amendment to the Indiana regulatory program (hereinafter referred to as the ''Indiana program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Indiana proposed revisions to and additions of statutes pertaining to other State and Federal laws and permit revisions. Indiana intends to revise its program to incorporate the additional flexibility afforded by SMCRA and to provide the guidelines for permit revisions, including incidental boundary revisions.

EFFECTIVE DATE: March 16, 1999.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204–1521. Telephone (317) 226–6700. Internet: INFOMAIL@indgw.osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Secretary of the Interior conditionally approved the Indiana program. You can find background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the July 26, 1982, **Federal Register** (47 FR 32107). You can find later actions concerning the conditions of approval and program amendments at 30 CFR 914.10, 914.15, 914.16, and 914.17.

II. Submission of the Proposed Amendment

By letter dated May 14, 1998 (Administrative Record No. IND–1606), Indiana sent us an amendment to its program under SMCRA. The amendment concerns revisions to IC 14–8 and several sections of IC 14–34 made by the Indiana House Enrolled Act No. 1074. Indiana sent the amendment at its own initiative.

We announced receipt of the amendment in the May 29, 1998, **Federal Register** (63 FR 29365). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. The public comment period closed on June 29, 1998. Because no one requested a public hearing or meeting, we did not hold one.

During our review of the amendment, we identified concerns relating to IC 14–34–4–18, Permit Conditions; IC 14–34–5–7, Definition of Permit Revision; IC 14–34–5–8.2, Nonsignificant Permit Revisions; and IC 14–34–5–8.4, Minor Field Revisions. We notified Indiana of these concerns by letter dated September 15, 1998 (Administrative Record No. IND–1621).

Indiana responded to our concerns by letter dated December 21, 1998. Included with Indiana's response letter was a letter sent by Indiana to the Indiana Coal Council, Inc. (ICC) and a