of Proposed Rulemaking is not required for this action.

Alaskan Low Altitude Reporting Points are listed in paragraph 7004 of FAA Order 7400.9R signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. Alaskan High Altitude Reporting Points are listed in paragraph 7005 of FAA Order 7400.9R signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Reporting Points listed in this document will be revised subsequently in the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by revising the Low Altitude Reporting Points; CRACK, GARRS, and MOCHA; and the High Altitude Reporting Points; GARRS, and MOCHA to match the published description with their actual locations. The high and low altitude reporting point FLUKE is being revoked.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Low and High Altitude Compulsory Reporting Points in Alaska.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, Environmental Impacts: Policies and Procedures. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9R, Airspace Designations and Reporting Points, signed August 15, 2007, and effective September 15, 2007, is amended as follows:

Paragraph 7004 Alaskan Low Altitude Reporting Points.

* * * * *

CRACK: [Amended]

Lat. 57°20′48″ N., long. 159°24′19″ W. (INT King Salmon, AK, LOM 226°, Port Heiden, AK, NDB 314° bearings).

GARRS: [Amended]

Lat. 58°19′06″ N., long. 161°20′32″ W. (INT King Salmon, AK, LOM 262°, Cape Newenham, AK, NDB 131° bearings).

MOCHA: [Amended]

Lat. 54°30′24″ N., long. 133°01′15″ W. (INT Nichols, AK, NDB 236°, Sandspit, BC, Canada, NDB 331° bearings).

FLUKE: [Revoked]

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Paragraph 7005 Alaskan High Altitude Reporting Points.

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GARRS: [Amended]

Lat. 58°19′06″ N., long. 161°20′32″ W. (INT King Salmon, AK, LOM 262°, Cape Newenham, AK, NDB 131° bearings).

MOCHA: [Amended]

Lat. 54°30′24″ N., long. 133°01′15″ W. (INT Annette Island, AK, 237°, Sandspit, BC, Canada, 331° radials).

FLUKE: [Revoked]

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Issued in Washington, DC, on September 12, 2008.

Edith V. Parish,

Manager, Airspace & Rules Group.

[FR Doc. E8–22648 Filed 9–26–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2004–P–0205] (formerly Docket No. 2004P–0464)

Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its labeling regulation authorizing a health claim on the relationship between calcium and a reduced risk of osteoporosis to include vitamin D so that, in addition to the claim for calcium and osteoporosis, an additional claim can be made for calcium and vitamin D and osteoporosis; eliminate the requirement that the claim list sex, race, and age as specific risk factors for the development of osteoporosis; eliminate the requirement that the claim does not state or imply that the risk of osteoporosis is equally applicable to the general U.S. population, and that the claim identify the populations at particular risk for the development of osteoporosis; eliminate the requirement that the claim identify the mechanism by which calcium reduces the risk of osteoporosis and instead make it optional; eliminate the requirement that the claim include a statement that a total dietary intake greater than 200 percent of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further benefit to bone health when the food contains 400 mg or more of calcium per reference amount customarily consumed or per total daily recommended supplement intake; and allow reference for the need of physical activity in either of the health claims to be optional rather then required. This final rule is, in part, in

response to a health claim petition submitted by The Beverage Institute for Health and Wellness, LLC.

DATES: This final rule is effective January 1, 2010.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 5, 2007 (72 FR 497), FDA published a proposed rule (the calcium and vitamin D proposed rule) to amend § 101.72 (21 CFR 101.72), which authorizes a health claim regarding the relationship between calcium and osteoporosis. The agency proposed the following five amendments: (1) Inclusion of vitamin D so that, in addition to the claim for calcium and osteoporosis, an additional claim can be made for calcium and vitamin D and osteoporosis; (2) elimination of the requirement in § 101.72(c)(2)(i)(A) that the claim list sex, race, and age as specific risk factors for the development of osteoporosis; (3) elimination of the requirement in § 101.72(c)(2)(i)(B) that the claim does not state or imply that the risk of osteoporosis is equally applicable to the general U.S. population, and that the claim identify the populations at particular risk for the development of osteoporosis; (4) elimination of the requirement in § 101.72(c)(2)(i)(C) that the claim identify the mechanism by which calcium reduces the risk of osteoporosis and instead make it optional; and (5) elimination of the requirement in § 101.72(c)(2)(i)(E) that the claim include a statement that reflects the limit of the benefits derived from dietary calcium intake, when the level of calcium in the food exceeds a set threshold level. FDA issued this proposed rule in response to a health claim petition submitted on July 12, 2004, by the Beverage Institute for Health and Wellness under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)) (Ref. 1). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (Secretary) (and, by delegation, FDA) shall issue a regulation authorizing a health claim only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (see also 21 CFR 101.14(c)). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a health claim petition. FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on October 20, 2004.

II. Summary of Comments and the Agency's Response

FDA solicited comments on the calcium and vitamin D proposed rule. The comment period closed on March 21, 2007. The agency received 27 responses, each containing one or more comments, to the calcium and vitamin D proposed rule. The comments were from trade associations, health-related organizations, academia, and consumers. Most of the comments supported the proposed amendments. A few comments expressed personal opinions on the use of health claims and labeling in general. These comments did not raise any issues about the calcium and vitamin D proposed rule, and therefore, we consider these to be outside the scope of this rulemaking and do not discuss them in this document. Another comment asserted that the standard of significant scientific agreement was not met and provided some citations and studies as support for its assertion. However, the studies that were submitted were not the type of studies that could resolve a question about the relationship between vitamin D and calcium, or calcium only, and osteoporosis that is the subject of the claim. The remaining comments and the agency's responses are discussed below.

(Comment 1) FDA received two comments opposing the elimination of the requirement in § 101.72(c)(2)(i)(A) that the claim list sex, race, and age as specific risk factors for the development of osteoporosis. One of these comments did not give a reason for its opposition to the elimination of this requirement. The comment also asserted that high levels of calcium will inhibit the intake of manganese, and that the primary cause of osteoporosis in the United States is manganese deficiency. The other comment stated that the ''published docket'' did not provide adequate support to eliminate references to age, sex, race, and the need for an adequate level of exercise. The comment noted that studies have linked calcium and vitamin D to bone health only in specific demographic categories.

(Response) The comment opposing the elimination of listing sex, race, and age as specific risk factors in the claim language failed to provide any explanation, data, or evidence to support its opposition to eliminating the listing of these risk factors in the claim. Without such explanation, data, or evidence, FDA has no basis upon which to revise its analysis. As such, FDA will continue to rely on the analysis as set forth in the calcium and vitamin D proposed rule (72 FR 497 at 506–507). As to the comment's concern about manganese, the agency is not aware of, nor did the comment provide, any data or evidence to substantiate the statement that high levels of calcium intake will inhibit the intake of manganese or that the primary cause of osteoporosis in the United States is manganese deficiency.

FDA disagrees with the comment that information in the docket does not provide adequate evidence to eliminate the requirement that the claim reference age, sex, and race. The information in the record of this proceeding demonstrates that benefits of adequate calcium and vitamin D in reducing the risk of osteoporosis is not confined to any particular subpopulation in the United States. The scientific evidence from both the 2004 Surgeon General's Report on Bone Health and Osteoporosis and the 2000 National Institutes of Health (NIH) Consensus Statement concludes that osteoporosis occurs in all populations and at all ages (72 FR 497 at 506). Moreover, both the 2000 NIH Consensus Statement and the 2004 Surgeon General's Report on Bone Health and Osteoporosis conclude that achieving and maintaining optimal bone health is a process that is important in both men and women throughout the lifespan and is not a specific need to any particular subpopulation in the United States (72 FR 497 at 506–507). Given that the risk of osteoporosis applies to the general U.S. population, the benefits of adequate calcium and vitamin D in terms of reducing risk of disease apply to both sexes at all ages and race categories. Accordingly, because these benefits do not apply only to specific demographic groups, the language of the health claim in question should not state or suggest otherwise. For this reason, FDA is eliminating the requirement that the calcium and osteoporosis health claim or the calcium, vitamin D, and osteoporosis health claim list sex, race, and age as specific risk factors for the development of osteoporosis.

In any discussion about osteoporosis and bone health, it is important to recognize the difference between risk of bone disease, including osteoporosis, and the prevalence of the disease in various subpopulations in the United

States. Risk measures the probability that a disease will occur whereas prevalence measures the number of cases of a disease that are documented in a given population or subpopulation. Both the 2000 NIH Consensus Statement and the 2004 Surgeon General's Report on Bone Health and Osteoporosis state that all populations in the United States are at risk of osteoporosis, although the prevalence of the disease is not equally distributed among all subpopulations. Specifically, osteoporosis is most prevalent in White postmenopausal women. However, as noted, the disease often goes unrecognized in other age and ethnic groups as well as in men (72 FR 497 at 508).

In sum, while the prevalence of osteoporosis varies in different subpopulations in the United States, all populations are at risk of osteoporosis and, in fact, the disease does occur in all populations. Thus, the benefits of calcium or calcium and vitamin D on reducing the risk of bone diseases, including osteoporosis, apply to both sexes at all ages and in all race categories (72 FR 497 at 507). For this reason, FDA is eliminating the requirement that the calcium and osteoporosis health claim or the calcium, vitamin D, and osteoporosis health claim list sex, race, and age as specific risk factors for the development of osteoporosis.

Importantly, however, although this final rule eliminates the requirement that the claim reference age, sex, and race for the development of osteoporosis, § 101.72(d)(4) allows the claim to include optional information related to the prevalence of osteoporosis. In particular, the claim could include information about the number of people in the United States, including the number of people in certain subpopulations in the United States, who have osteoporosis or low bone density. For example, under § 101.72(d)(4), a claim could include a statement that, according to the National Osteoporosis Foundation, 20 percent of non-Hispanic Caucasian and Asian women aged 50 and older are estimated to have osteoporosis.

(Comment 2) FDA received two comments opposing the elimination of the requirement in § 101.72(c)(2)(i)(C) that the calcium and osteoporosis health claim identify the mechanism by which calcium reduces the risk of osteoporosis. One comment did not give a reason for its opposition to the elimination of this requirement. The other comment noted that building a strong bone matrix relies on proper mineral balance and that science is continually evolving to elucidate the specific mechanisms involved. This comment further stated that although calcium is required to develop and sustain proper bone health and to prevent osteoporosis, the scientific community recognizes that calcium alone is not adequate, and a balance of normal minerals and hormones are also critical for bone health. Thus, this comment suggested that there is not enough scientific evidence either to eliminate or make optional the requirement in § 101.72(c)(2)(i)(C) because incomplete information is not accurate information.

(Response) The comment opposing elimination of the requirement in § 101.72(c)(2)(i)(C) failed to provide any explanation, data, or evidence to support its position. Without any explanation, data, or evidence provided in the comment, we have no basis upon which to revise our analysis or to alter our conclusion to eliminate the requirement that the health claim identify the mechanism by which calcium reduces the risk of osteoporosis; thus we will continue to use the analysis as set forth in the calcium and vitamin D proposed rule (72 FR 497 at 508–509).

FDA agrees with the comment that stated: Building a strong bone matrix relies on proper mineral balance and that science is continually evolving to elucidate specific mechanism(s) involved. Calcium is an important nutrient for achieving and maintaining good skeletal health. FDA discussed the findings that many nutrients are involved in bone health, and tentatively concluded in the proposed rule that a well-balanced diet is important for bone health throughout life (72 FR 497 at 507). Thus, the agency proposed that the claim make clear the importance of calcium intake or calcium and vitamin D intake in a healthful well-balanced diet over a lifetime. Conveying the information about calcium intake in the context of a healthful, well-balanced diet recognizes that calcium alone is not sufficient for bone health. Furthermore, results from a 1995 health claims report showed that consumers had learned elsewhere that calcium intake is related to bone health and that they thought the food label was not the right means for conveying this information (72 FR 497 at 509). This consumer awareness of calcium's ability to ''build and maintain good bone health,'' as well as the observation that the food label is not necessarily the most appropriate means to convey this information, prompted the agency to request comment in the calcium and vitamin D proposed rule on whether to make information of the mechanism by which calcium reduces the risk of osteoporosis optional in the health claim. Therefore, for the reasons set forth previously in this document, FDA is eliminating the requirement that the claims identify the mechanism by which calcium reduces the risk of osteoporosis, and instead is making such information optional. FDA is also revising the language from the proposed rule for use of the optional statement about slowing the rate of bone loss, by removing the following phrase: ''When reference is made to persons with a family history of the disease, post-menopausal women, and elderly men and women * * *'' so the language now reads: ''The claim may also state that adequate intake of calcium, or when appropriate, adequate intake of calcium and vitamin D, is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss for persons with a family history of the disease, post-menopausal women, and elderly men and women.'' This change makes the use of the optional language related to the mechanism of slowing the rate of bone loss consistent with the final rule to remove reference to specific targeted populations as to risk of osteoporosis, but allows reference to family history of the disease, post-menopausal women, and elderly men and women in the context of the mechanism of slowing the rate of bone loss.

(Comment 3) Several comments opposed the elimination of the conditional requirement in § 101.72(c)(2)(i)(E) that the calcium and osteoporosis health claim include a statement that a total dietary intake greater than 200 percent of the recommended daily intake (2,000 mg of calcium) has no further known benefit to bone health. Some of the comments were concerned that eliminating this requirement could potentially mislead consumers because there will be nothing on the label to remind them that ''more is not always better when it comes to nutrients, especially in the form of supplements or fortification.'' One comment stated that withholding this information could encourage consumers to over consume calcium products while other comments were concerned that withholding this information could be potentially harmful for those individuals who may be taking high doses of supplemental calcium, along with high amounts of vitamin D. One comment highlighted its concern regarding the elimination of this conditional requirement by pointing out that the Institute of Medicine (IOM) of the National Academy of Sciences (NAS) has found that the toxic effects of excess calcium

increased the risk of kidney stone formation and that this condition affected 12 percent of individuals in the United States, as well as renal insufficiency and decreased absorption of other essential minerals (iron, zinc, magnesium and phosphorus) (72 FR 497 at 502). Another comment questioned how FDA could be assured that cumulative vitamin D intake from all dietary sources would remain 'at non-toxic levels' (e.g., less than the Tolerable Upper Intake Level (UL) for vitamin D) when supplementation is encouraged in a variety of foods, including staples such as milk, cereal, and bread.

(Response) FDA's decision to eliminate the conditional requirement was made, in part, in response to the IOM's 1997 report on ''Dietary Reference Intakes (DRIs) for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride,'' which was not available at the time the calcium and osteoporosis health claim was authorized in 1993 (72 FR 497 at 510). IOM conducted a major review of bone-related nutrients to determine the level of nutrient intake for normal, healthy individuals that would prevent the development of a chronic condition (e.g., osteoporosis) associated with calcium (Ref. 2). IOM set the UL for calcium at 2,500 mg per day for all individuals ages 1 and above. The UL, as defined by IOM, is the highest level of nutrient intake that is likely to pose no risks of adverse effects to all individuals in the general population. When IOM set the UL for calcium it divided the lowest- observed-adverse-effect level (LOAEL) of calcium by an uncertainty factor of two to take into account the relatively high prevalence of kidney (renal) stones in the U. S. population, which is 12 percent, and the potential increased risk of hypercalciuria and depletion of other minerals among susceptible individuals (72 FR 497 at 502). An increased risk of kidney stone formation from toxic effects of excess calcium, as noted in one of the comments, was addressed when IOM established the UL for calcium.

Furthermore, inclusion of the conditional requirement was based, in part, on a concept that calcium was a threshold nutrient, which means that there is a level of calcium intake below which bone health is jeopardized and above which no further benefit to bone health occurs (72 FR 497 at 510). Neither IOM in its 1997 report, the 2000 NIH Consensus Statement, nor the 2004 Surgeon General's Report on Bone Health and Osteoporosis discusses a threshold level of calcium beyond which no further bone benefit occurs; instead these reports discuss scientific evidence that is useful for establishing a desirable level of intake for calcium as well as intake levels of calcium that pose no risk of adverse health effects (72 FR 497 at 510).

Moreover, contrary to concerns expressed by some of the comments, the lack of calcium in the American diet is more of a concern than the potential over consumption of the nutrient. For example, the 2005 Dietary Guidelines for Americans identified calcium as a ''nutrient of concern'' due to low calcium consumption in the U.S. population (Ref. 3).

FDA also notes that a ''high'' level of calcium and vitamin D is at least 20 percent of the Reference Daily Intake (RDI) of calcium and vitamin D per reference amount customarily consumed (RACC). Since the RDI for calcium is 1,000 mg per day and the RDI for vitamin D is 400 IU (10 micrograms per day (µg per day)), 20 percent of the RDI for calcium (200 mg per day) is well below the UL of 2,500 mg per day intake level of calcium that poses no risk of adverse health effects and 20 percent of the RDI for vitamin D (80 IU (2 µg per day) is well below the 2,000 IU (50 µg per day) intake level of vitamin D that poses no risk of adverse health effects.

To evaluate potential maximum intake levels of calcium and vitamin D in the United States, FDA examined the most recent nationally representative data available from the National Health and Nutrition Examination Survey on median intake values for calcium and vitamin D and common dietary supplement products that contain calcium, or calcium and vitamin D in the calcium and vitamin D proposed rule (72 FR 497 at 500 to 502). Results from this evaluation suggested that consumers who choose foods that bear the calcium, or the calcium and vitamin D, and osteoporosis health claim would be able to incorporate such foods into the diet in a manner that would likely keep their total intake of calcium well below the UL of 2,500 mg per day and their total intake of vitamin D below the UL of 2,000 IU per day (72 FR 497 at 502). Further, FDA determined that consumers who choose conventional foods that bear the calcium or the additional calcium and vitamin D claim and that consume up to 1,500 mg of calcium per day from supplements (the maximum daily intake of calcium suggested in commonly found supplements) and that consume up to 400 IU of vitamin D per day from supplements (the most common daily intake of vitamin D suggested in supplements) would also likely keep their total intake of calcium and vitamin D below the ULs of calcium and vitamin D (id.). None of the comments questioned these findings. Finally, the agency is not aware of any basis for why the elimination of the conditional requirement would be misleading or encourage over-consumption of calcium products.

For these reasons, FDA is eliminating the conditional requirement in § 101.72(c)(2)(i)(E), as proposed.

(Comment 4) One comment noted that retaining in § 101.72(e) and (f) physical activity as part of the calcium and osteoporosis health claim as well as the calcium, vitamin D and osteoporosis health claim, might have the unintended consequence of leading consumers to believe that the benefits to bone health (or reduced risk of osteoporosis) of consuming adequate amounts of calcium or calcium and vitamin D can only be achieved by regularly engaging in physical activity.

(Response) FDA agrees with this comment. The agency's tentative decision to retain physical activity as part of the calcium and osteoporosis claim as well as the calcium, vitamin D and osteoporosis health claim was based primarily on the 2000 NIH Consensus Statement and the 2004 Surgeon's General Report (72 FR 497 at 507), which indicate that physical activity is beneficial to bone health and can have an additive effect on increasing bone mineral density (BMD) in conjunction with adequate intake of calcium and vitamin D. On the other hand, several studies show that consuming adequate levels of calcium and vitamin D supports bone health and reduces the risk of osteoporosis in the absence of physical activity (Refs. 4 to 12). Since consumption of adequate amounts of calcium and vitamin D reduces the risk of osteoporosis without physical activity, FDA will not require physical activity to remain as part of the claim language for the calcium and osteoporosis or the calcium, vitamin D and osteoporosis health claim. However, since the importance of physical activity to bone health is well established, FDA will allow optional reference to physical activity in the health claim.

Given the information discussed in the preamble to the calcium and vitamin D proposed rule and the absence of contrary information in the comments, FDA is adopting the following amendments to § 101.72: (1) Inclusion of vitamin D so that, in addition to the claim for calcium and osteoporosis, a claim can be made for calcium and vitamin D and osteoporosis; (2) elimination of the requirement in § 101.72(c)(2)(i)(A) that the claim list sex, race, and age as specific risk factors for the development of osteoporosis; (3)

elimination of the requirement in § 101.72(c)(2)(i)(B) that the claim does not state or imply that the risk of osteoporosis is equally applicable to the general U.S. population, and that the claim identify the populations at particular risk for the development of osteoporosis; (4) elimination of the requirement in § 101.72(c)(2)(i)(C) that the claim identify the mechanism by which calcium reduces the risk of osteoporosis, and instead make it optional; (5) elimination of the conditional requirement in § 101.72(c)(2)(i)(E) that the claim include a statement that a total dietary intake greater than 200 percent of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further benefit to bone health, when the level of calcium in the food exceeds a set threshold level; and (6) elimination of the provision in § 101.72(c)(2)(i)(A) about physical activity, and instead make it optional. Therefore, FDA is not including the term ''physical activity'' in some of the model health claims as proposed. Moreover, FDA is revising § 101.72(e) and (f) by removing the term ''regular exercise'' in the model health claims.

III. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. The final rule amends the current calcium and osteoporosis health claim language and will require changes to the claim language on products currently bearing the health claim. Thus, the only mandatory costs of this final rule will be the costs to update the current wording of the calcium and osteoporosis health claim on those products that currently bear the claim. Based on FDA's 2001 Food Label and Package Survey (FLAPS) (see discussion in section III.A.2 ''Background'' of this document), very few products bear the calcium and osteoporosis health claim. Therefore, because of the limited use of the current calcium and osteoporosis health claim, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes 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 one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount and has determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

1. Need for This Regulation

Current regulations do not permit food producers to claim health benefits for products by linking the intake of vitamin D, when combined with the intake of calcium, with a reduced risk of osteoporosis. However, current regulations do permit food producers to claim health benefits for products by linking calcium intake with a reduced risk of osteoporosis only if they also list the specific risk factors and at-risk subpopulations for osteoporosis, the mechanism by which calcium reduces the risk of osteoporosis, and the limit of the benefits of dietary calcium at certain levels.

Health claims can inform consumers about diet-disease relationships and encourage producers to produce more healthful foods. This final rule will allow producers to make more nutrition information related to osteoporosis available to consumers (linking the intake of calcium and vitamin D to the risk of osteoporosis), while eliminating other information currently required to be given to consumers when claiming health benefits relating to the relationship between calcium intake and the risk of osteoporosis.

2. Background

Osteoporosis represents a major public health problem in the United States. This disease affects more than 10 million individuals and causes approximately 1.5 million fractures annually. Every year, these lead to more than 2.6 million physician office visits, over 800,000 emergency room visits, and more than 500,000 hospitalizations, and the placement of nearly 180,000 people into nursing homes. The direct care expenditures for osteoporotic fractures alone range from 12 to 18 billion dollars each year (measured in 2002 dollars) (Ref. 13). The indirect health costs of osteoporosis, such as pain, suffering, and lost mobility, are also large. Average calcium and vitamin D intakes are below recommended levels for many consumers (Refs. 13, 14 and 15). Even though many consumers are not achieving recommended intakes of calcium, producers have rarely placed the calcium and osteoporosis health claim on products that qualify for the claim. FDA's 2001 FLAPS (the most recently available data) showed only 1 out of the 87 shelf-stable juice products surveyed, a fortified orange juice, bearing the calcium and osteoporosis health claim. None of the 10 milk products surveyed bore the claim (Ref. 16).

3. Regulatory Options

FDA identified four regulatory options for this final rule: (1) Take no new regulatory action; (2) reduce the required language in the existing calcium and osteoporosis health claim; (3) expand the existing calcium and osteoporosis health claim to include vitamin D; or (4) reduce the required language in the existing calcium and osteoporosis health claim and include vitamin D as an option to the claim, as described in this final rule.

4. Changes in Market Behavior in Response to Options

This final rule will require that any food manufacturers wishing their products' labels to make the calcium, or calcium and vitamin D, and osteoporosis health claim be redesigned. Labels must be redesigned in order for a food to carry the health claim since information on populations at particular risk for osteoporosis would no longer be required or allowed for the claim (see § 101.72(c)(2)(A) and (c)(2)(B)).

Manufacturers that wish to continue making a calcium and osteoporosis health claim on their products will not need to reformulate their products under the final rule. The nature of the food eligible to make a calcium and osteoporosis health claim remains food that meets or exceeds a ''high'' level of calcium (as defined in 21 CFR 101.54(b)). Manufacturers wishing to take advantage of the expanded calcium, vitamin D, and osteoporosis health

claim may voluntarily choose to reformulate their products. If some producers choose to reformulate their products to take advantage of the calcium, vitamin D, and osteoporosis health claim, they reveal that they expect the private benefit that the claims give them to exceed the expense of making the claims. If this is not the case, no producer will voluntarily choose to use the claims. Likewise, consumers who choose to purchase the products with the amended health claims reveal that they value the products more highly than other alternatives, including not purchasing the products.

We considered five potential effects in estimating the relative public health benefits of the options: (1) The extent to which the option encourages producers to use the health claims on their food labels; (2) the extent to which the option encourages producers to reformulate their products to make the health claims; (3) the extent to which the option provides information to consumers; (4) potential risk-risk tradeoffs (where the action taken to reduce the risk posed by one hazard causes an increase in the risk posed by another hazard) with each option; and (5) the availability of information on the relationship between osteoporosis and calcium and vitamin D to consumers who do not consume dairy products.

a. *Producer responses.* There are four likely responses to this final rule from producers: (1) Make no changes (i.e., continue not making the calcium or calcium and vitamin D health claim; (2) create new product labels to continue making the calcium and osteoporosis health claim (for products already making the existing claim); (3) add the health claims to their products that qualify for the health claims (increase usage of the claim due to the new wording requirements); and (4) reformulate their products (by fortifying with calcium or vitamin D, for example) to qualify for the health claims.

Several factors affect whether producers choose to use health claims, including the flexibility of the health claims and how appealing the health claims are to consumers. Revising the existing calcium and osteoporosis health claim language to make it shorter will make it more appealing to put the health claims on labels. Package space is limited, so more flexible and shorter claims are easier to use. Also, Wansink, et al. (2004) found that shorter health claims on the front of the package led to more favorable beliefs about the product and a more positive image of the product among consumers (Ref. 17).

Approving a calcium, vitamin D, and osteoporosis health claim should encourage the manufacturers of foods that are eligible for fortification with vitamin D to do so because they will be able to publicize the relationship between calcium, vitamin D, and osteoporosis on their labels. If producers fortify more products with vitamin D, consumers can get more vitamin D in their diet without making changes in their dietary choices.

b. *Consumer responses.* Providing information about the relationship between calcium, vitamin D, and osteoporosis on food packages provides a number of benefits to consumers, including: (1) Informing them about the nutrient-disease relationship; (2) helping them identify products that are high in calcium and vitamin D; and (3) helping them make dietary choices that reduce their risk of osteoporosis. The extent to which consumers realize these benefits will depend on the consumer's knowledge of the relationship between calcium, vitamin D, and bone health; how many products bear the calcium or calcium and vitamin D health claims; how many consumers read the health claims; and how much they change their behavior to include such products in their diets. There is evidence that consumers who read nutrition information on packages eat healthier diets (Refs. 18 and 19). However, there is a great deal of uncertainty about how much consumers change their behavior in response to label information.

c. *Risk-risk tradeoffs.* A potential concern is that allowing these osteoporosis health claims on juice drinks will result in consumers switching away from milk to juice drinks, which are higher in calories, for dietary sources of calcium and vitamin D. Table 1 of this document presents the caloric and nutrient profile of non-fat and low-fat milk products and an orange juice drink product as reported in the U.S. Department of Agriculture (USDA) National Nutrient Database for Standard Reference. Orange juice drinks are higher in calories and contain less of some important nutrients than either non-fat or low-fat milk (table 1 of this document).

TABLE 1—PROFILES OF SELECTED NUTRIENTS IN NON-FAT AND LOW-FAT MILK AND ORANGE JUICE DRINK (PER 8-OUNCE SERVING)

Nutrient	(1) Orange Juice Drink	(2) Non-fat Milk (Skim), With Added Vitamin A	(3) Low-fat Milk (1%), With Added Vitamin A
Energy, kilocalorie (kcal)	134	83	102
Protein, gram (g)	0.5	8.25	8.22
Total Fat, g	0	0.2	2.37
Saturated Fat, g	0	0.286	1.545
Carbohydrate, g	33.36	12.14	12.18
Total Dietary Fiber, g	0.5	0	0
Total Sugars, g	23.29	12.46	12.69
Calcium, mg	5	306	290
Iron, mg	0.27	0.07	0.07
Magnesium, mg	7	27	27
Phosphorus, mg	10	247	232

TABLE 1—PROFILES OF SELECTED NUTRIENTS IN NON-FAT AND LOW-FAT MILK AND ORANGE JUICE DRINK (PER 8-OUNCE SERVING)—Continued

Nutrient	(1) Orange Juice Drink	(2) Non-fat Milk (Skim), With Added Vitamin A	(3) Low-fat Milk (1%), With Added Vitamin A
Potassium, mg	104	382	366
Sodium, mg	5	103	107
Zinc, mg	0.05	1.03	1.02
Copper, mg	0.045	0.032	0.024
Manganese, mg	0.017	0.007	0.007
Selenium, µg	0	7.6	8.1
Vitamin C, mg	37.3	0	0
Thiamin, mg	0.945	0.11	0.049
Riboflavin, mg	1.07	0.446	0.451
Niacin, mg	12.44	0.23	0.227
Pantothenic acid, mg	0.149	0.874	0.881
Vitamin B–6, mg	1.244	0.091	0.09
Folate, µg	10	12	12
Vitamin B–12, µg	0	1.3	1.07
Vitamin A, IU	109	499	478
Vitamin D, IU	0	101.46	126.77
Cholesterol, mg	0	5	12

The likelihood of consumers switching from non-fat or low-fat milk or to higher caloric juice drinks because of this rule is expected to be small because non-fat and low-fat milk and juice drinks that are eligible can already make the existing calcium and osteoporosis health claim. Permitting the same set of products to make the final, simpler calcium and osteoporosis health claim should not change the relative appeal of the claim to producers of one type of beverage over another. The allowance of the new calcium, vitamin D, and osteoporosis health claim could expand the set of products making an osteoporosis health claim; however, the relative appeal of the new claim (calcium and vitamin D) to producers of non-fat and low-fat milk and juice drinks should be similar to the appeal of the existing calcium and osteoporosis health claim.

There is little evidence to support that consumers would switch from non-fat or low-fat milk to juice drinks as a result of this final rule. As stated in the Surgeon General's Report on Bone Health and Osteoporosis, consuming adequate levels of calcium and vitamin D throughout life are critically important to an individual's bone health. However, the report's review of national surveys suggests that the average calcium intake of individuals is far below the levels recommended for optimal bone health. One reason cited by the report for these low levels of calcium intake relates to current lifestyle and food preferences, which have resulted in reduced intake of dairy products and other naturally occurring calcium-rich foods. The report also posits that for some individuals lactose intolerance[1] may also play a role in not consuming adequate levels of calcium. Given this information on the current preference and tolerance for dairy products, expanding the calcium and osteoporosis health claim to include vitamin D as a result of this final rule should only lead to an increase in the overall consumption of these essential, under consumed nutrients.

[1]Lactose intolerance is a condition in which individuals cannot metabolize lactose, the main sugar found in milk and other calcium-rich dairy products. Information in the Surgeon General's 2004 Report on Bone Health and Osteoporosis indicates that an estimated 30 to 50 million Americans are affected by lactose intolerance, although to varying degrees.

In addition, according to the American Beverage Association, U.S. sales of calcium-fortified orange juice have grown dramatically over recent years, reaching nearly $1 billion in 2003 (Ref. 20), while overall sales of juice have not grown. Therefore, FDA expects that the nutritional profile of diets would most likely improve as a consequence of changes in consumption resulting from this final rule. Switching from unfortified to fortified juices would increase needed consumption of calcium and vitamin D.

5. Benefits and Costs of Regulatory Options

The simplification of the current health claim for calcium and osteoporosis, along with the additional health claim for calcium, vitamin D, and osteoporosis should increase and expand the current usage of the health claim and therefore improve the U.S. population's intake of these two important nutrients. Therefore, all the options considered below would improve public health relative to the baseline of taking no new regulatory action. In our analysis of the benefits and costs of the options, we compare

the benefits and costs of each option with each other option based on their relative effects on consumer and producer behavior.

Option 1: Take no new regulatory action.

This option would result in no change to the current situation. This is the baseline for comparison of options and entails no costs or benefits.

Option 2: Reduce the required language in the existing calcium and osteoporosis health claim.

Compared with Option 1, this option would increase the appeal of the claim for producers, increase the use of the claim on products, and thereby provide consumers with more information on the calcium and osteoporosis diet-disease relationship. It could encourage more reformulation of products to fortify with calcium than has occurred with the existing claim. Like Option 1, this option provides consumers with no information about the relationship of vitamin D to osteoporosis.

With this option, manufacturers of some products making the current calcium and osteoporosis health claim may have to re-label their products to reflect the updated wording provided by the claim. The potential costs associated with a required label change will vary depending on when the new effective compliance date is established. Table 2 of this document shows the possible range of costs by product type of having to re-label to be in compliance with the revised calcium and osteoporosis health claim. The product re-labeling costs were estimated using the FDA Labeling Cost Model (Ref. 21). The costs of re-labeling included are administrative, graphic, prepress, engraving, and inventory costs. Re-labeling costs are shown for both a 12-month and 24-month compliance period.

TABLE 2.—COST OF LABEL CHANGES FOR OPTION 2

NAICS Codes	Product	12 Months to Comply, Cost Per Label SKU			24 Months to Comply, Cost Per Label SKU		
		Low Cost	Med Cost	High Cost	Low Cost	Med Cost	High Cost
311421 311411	Fruit Juices	$7,478	$10,186	$15,282	$5,455	$7,595	$11,897
311514 311511	Non-fat and Low-fat Milk, fluid, dry, powered, condensed, flavored	$11,216	$14,086	$20,437	$7,127	$9,236	$14,327
311513	Low-fat Cheese, multiple types	$6,611	$8,759	$13,758	$5,106	$6,999	$11,489
311511	Yogurt-like products	$4,554	$6,490	$10,857	$4,140	$5,900	$9,880
325412	Dietary Supplements	$9,728	$13,345	$22,834	$8,540	$11,739	$20,266
Average cost of label change regardless of product type		$7,917	$10,573	$16,633	$6,074	$8,294	$13,572

Option 3: Expand the existing calcium and osteoporosis health claim to include vitamin D.

Failing to shorten the existing calcium and osteoporosis health claim will not make the health claim as appealing to producers and consumers as Option 2, leading to less claim use and reformulation and less information provided to consumers than Option 2. This option would provide consumers with more information on vitamin D than Option 2, should producers decide to voluntarily re-label and/or reformulate their products to make use of the added vitamin D language.

Option 4: Reduce the required language in the existing calcium and osteoporosis health claim and include vitamin D as an option to the claim, as described in this final rule.

Like Option 2, this option would increase the appeal of the calcium and osteoporosis health claim for producers and thereby provide consumers with more information on the calcium and osteoporosis diet-disease relationship. Also like Option 2, producers of products with existing calcium and osteoporosis health claim labeling will have to revise their labeling in order to comply with the revised claim language. Like Option 3, this option would provide consumers with more information on vitamin D than Option 2 because the new, simplified calcium and osteoporosis health claim can now contain information about vitamin D as well. It could also encourage more reformulation of products to fortify with vitamin D than would Option 2 and as many products to fortify with calcium as Option 2.

Summary

FDA is unable to quantify the benefits of this final rule due to uncertainty about the degrees of changes in consumer and producer behavior. However according to information compiled in the Surgeon General's 2004 Report on Bone Health and Osteoporosis, there are about 1.5 million osteoporotic fractures in the United States each year that carry annual direct care expenditures of 12 to 18 billion dollars per year (2002 dollars). These fractures cause more than half a million hospitalizations, over 800,000 emergency room encounters, more than 2.6 million physician office visits, and the placement of nearly 180,000 individuals into nursing homes annually (Ref. 13). The direct costs of other complications from osteoporosis, and the indirect costs of these fractures and other osteoporotic ailments (e.g., the value of functional disability to the patient, the value of the pain and suffering to the patient, the costs experienced by the care giver) if calculated, would add substantially to the annual costs of this disease. Any increase in calcium and vitamin D intake by consumers insufficient in these nutrients as a result of this final rule could possibly lower the incidence of osteoporosis and therefore the annual costs associated with the disease.

Table 3 of this document provides a summary of the effects of the rule, and which options create the smallest and largest behavior changes for consumers and producers. All options should produce positive net benefits, with the largest net benefit arising from Option 4, the final rule. With Option 4, the largest number of products and labels would

change, leading to the largest reduction in the risk of osteoporosis.

TABLE 3.—SUMMARY OF EFFECTS OF OPTIONS

Effect	Largest Effect	Smallest Effect
Encouraging producer use of the claims	Option 4	Option 1
Encouraging fortification	Option 4	Option 1
Informing consumers	Option 4	Option 1
Informing consumers who do not buy dairy products about alternative food sources for vitamin D	Option 4	Option 1

B. Small Entity Analysis (or Initial Regulatory Flexibility 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 economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. FDA does not believe that this final rule will have a significant economic impact on a substantial number of small entities because the only mandatory costs of this rule are the costs to update the current wording of the calcium and osteoporosis health claim for manufacturers of products that currently make the claim and wish to continue doing so. Also previously mentioned, FDA's 2001 Food Label and Package Survey showed only 1 out of 87 shelf-stable juice products surveyed bore the current calcium and osteoporosis health claim while none of the 10 milk products surveyed bore the claim. This implies that not many products eligible to bear the current claim would need to be re-labeled as a result of this final rule.

In addition, FDA establishes uniform compliance dates for final food labeling regulations in 2-year intervals. Therefore, companies whose products currently make the calcium and osteoporosis health claim and wish to continue doing so will have between 1 and 2 years to use existing label inventory and expense the costs of designing revised labeling. FDA estimates that on average, the cost to re-label a product according to the revised health claim language will be $7,900 to $16,600 per product if the compliance period is 12 months; and $6,100 to $13,600 per product if the compliance period is 24 months. In the calcium and vitamin D proposed rule, FDA requested comments on whether the rule would have a significant impact on a substantial number of small entities. FDA received no comments on the issue of significant impacts on any size business. Manufacturers that wish to begin using the revised calcium and osteoporosis health claim or the new calcium, vitamin D, and osteoporosis health claim will only do so if the benefits of labeling their products to inform consumers of the claim outweigh the costs of doing so.

IV. Environmental Impact

FDA has determined under 21 CFR 25.32(p) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act

FDA concludes that the labeling provisions of this final rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the food labeling health claims on the association between calcium and osteoporosis or calcium, vitamin D, and osteoporosis is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public.'' (5 CFR 1320.3(c)(2)).

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule will have 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 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(5) of the act (21 U.S.C. 343–1(a)(5)) provides that: ''* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—* * * (5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r) * * *.''

This final rule amends the existing food labeling regulations on health claims for calcium and osteoporosis. Although this rule has a preemptive effect in that it precludes States from issuing any health claim labeling requirements for calcium and osteoporosis or calcium, vitamin D, and osteoporosis that are not identical to those required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both State legislative requirements and State common law duties. *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008).

FDA believes that the preemptive effect of the final rule is consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes 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.''' On February 17, 2006, FDA's Division of Federal and State Relations provided notice by fax and e-mail transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors as well as FDA field personnel, of FDA's intended amendments to the calcium and osteoporosis health claim (21 CFR 101.72). FDA received no comments in response to this notice.

In addition, the agency sought input from all stakeholders through publication of the proposed rule in the **Federal Register** on January 5, 2007 (72 FR 497). FDA received no comments from any States on the proposed rulemaking.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive order and has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

VII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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20. American Beverage Association, Press Release, September 17, 2004 (*http://www.ameribev.org/news-detail/index.aspx?nid=32*).

21. ''Food and Drug Administration Labeling Cost Model,'' Health, Social, and Economics Research, Research Triangle Park, NC, January 2003 (*http://www.cfsan.fda.gov/~dms/lab-flap.html*).

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 to read 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; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.72 is revised to read as follows:

§ 101.72 Health claims: calcium, vitamin D, and osteoporosis.

(a) *Relationship between calcium, vitamin D, and osteoporosis.* An inadequate intake of calcium or calcium and vitamin D contributes to low peak bone mass, which has been identified as one of many risk factors in the development of osteoporosis. Peak bone mass is the total quantity of bone present at maturity, and experts believe that it has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life. Another factor that influences total bone mass and susceptibility to osteoporosis is the rate of bone loss after skeletal maturity. Vitamin D is required for normal absorption of calcium and to prevent the occurrence of high serum parathyroid hormone (PTH) concentration, which stimulates mobilization of calcium from the skeleton and can lower bone mass. Calcium, along with vitamin D and several other nutrients, is required for normal bone mineralization. While vitamin D is required for optimal bone mineralization, it is more effective when calcium intake is adequate. An adequate intake of calcium and vitamin D is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone that is laid down. However, the upper limit of peak bone mass is genetically determined. The mechanism through which adequate intakes of calcium and vitamin D and optimal peak bone mass reduce the risk of osteoporosis is thought to be as follows. All persons lose bone with age. Hence, those with higher bone mass at maturity take longer to reach the critically reduced mass at which bones can fracture easily. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of adequate intakes of calcium and vitamin D later in life is thought to be important in reducing the rate of bone loss particularly in the elderly and in women during the first decade following menopause, but a significant protective effect is also seen among men and younger women.

(b) *Significance of calcium or calcium and vitamin D.* Adequate calcium intake, or adequate calcium and vitamin D intake, is not the only recognized risk factor in the development of osteoporosis, which is a multifactorial bone disease. Maintenance of adequate calcium and vitamin D intakes throughout life is necessary to achieve optimal peak bone mass and to reduce the risk of osteoporosis in later life. However, vitamin D is most effective in this regard when calcium intake is adequate. Increasing intake of calcium has been shown to have beneficial effects on bone health independent of dietary vitamin D.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating calcium or, when appropriate, calcium and vitamin D with a reduced risk of osteoporosis may be made on the label or labeling of a food described in paragraphs (c)(2)(ii) and (d)(1) of this section, provided that:

(A) The claim makes clear the importance of adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, throughout life, in a healthful diet, are essential to reduce osteoporosis risk. The claim does not imply that adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, is the only recognized risk factor for the development of osteoporosis;

(B) The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake, or when appropriate, an adequate dietary calcium and vitamin D intake, throughout life.

(ii) *Nature of the food.* (A) The food shall meet or exceed the requirements for a ''high'' level of calcium as defined in § 101.54(b);

(B) The calcium content of the product shall be assimilable;

(C) Dietary supplements shall meet the United States Pharmacopeia (USP) standards for disintegration and dissolution applicable to their component calcium salts, except that dietary supplements for which no USP standards exist shall exhibit appropriate assimilability under the conditions of use stated on the product label;

(D) A food or total daily recommended supplement intake shall not contain more phosphorus than calcium on a weight per weight basis.

(d) *Optional information.* (1) The claim may include the term ''vitamin D'' if the food meets or exceeds the requirements for a ''high'' level of vitamin D as defined in § 101.54(b);

(2) The claim may include information from paragraphs (a) and (b) of this section.

(3) The claim may make reference to physical activity.

(4) The claim may include information on the number of people in the United States, including the number of people in certain subpopulations in the United States, who have osteoporosis or low bone density. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or the National Osteoporosis Foundation.

(5) The claim may state that the role of adequate calcium intake, or when appropriate, the role of adequate calcium and vitamin D intake, throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase ''build and maintain good bone health'' may be used to convey the concept of optimizing peak bone mass. The claim may also state that adequate intake of calcium, or when appropriate, adequate intake of calcium and vitamin D, is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss for persons with a family history of the disease, post-menopausal women, and elderly men and women.

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between calcium and osteoporosis:

Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

(f) *Model additional health claims for calcium and vitamin D.* The following model health claims may be used in food labeling to describe the relationship between calcium, vitamin D, and osteoporosis:

Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

Dated: September 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA–2008–N–0341]

Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to require that the holder of a new drug application (NDA) submit certain information regarding authorized generic drugs in an annual report. We are taking this action as part of our implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA requires that FDA publish a list of all authorized generic drugs included in an annual report since 1999, and that the agency update the list quarterly. We are using direct final rulemaking for this action because the agency expects that there will be no significant adverse comment on the rule. In the proposed rule section of this issue of the **Federal Register**, we are concurrently proposing and soliciting comments on this rule. If significant adverse comments are received, we will withdraw this final rule and address the comments in a subsequent final rule. FDA will not provide additional opportunity for comment.

DATES: This direct final rule is effective February 11, 2009. Submit written or electronic comments on or before December 15, 2008. If we receive no timely significant adverse comments, we will publish a notice in the **Federal Register** before January 12, 2009, confirming the effective date of the direct final rule. If we receive any timely significant adverse comments, we will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule before February 11, 2009.