

4:36 99 MAY 11 P4:07

**Docket No. 99N-0554**

**Implementation of Sections 303 and 304 of the  
Food and Drug Administration Modernization Act:  
Health Claims and Nutrient Content Claims  
Based on Authoritative Statements**

**Comments Submitted to the  
Food and Drug Administration**

**On Behalf of**

**General Mills, Inc.**

**By  
Patton Boggs LLP**

**May 11, 1999**

*99N-0554*

*c5*

**PATTON BOGGS LLP**  
ATTORNEYS AT LAW

May 11, 1999

**VIA COURIER**

Dockets Management Branch (IFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: *Docket No. 99N-0554*  
*Implementation of Sections 303 and 304 of the Food and Drug Administration*  
*Modernization Act; Food Claims Based on Authoritative Statements*

Dear Sir or Madam:

General Mills, Inc. ("General Mills") appreciates the opportunity to comment on the Food and Drug Administration's ("FDA's") implementation of the Food and Drug Administration Modernization Act ("FDAMA") sections 303 and 304 permitting health claims and nutrient content claims based on authoritative statements of federal health agencies or the National Academy of Sciences.<sup>1</sup> General Mills is a major packaged-food manufacturer engaged for over 50 years in the development and production of food products including flour, ready-to-eat breakfast cereals, cake and other dessert mixes, snacks, and numerous other products.

General Mills supports Congress's efforts through FDAMA to expand the use of food labeling claims, and recognizes that the proper implementation of the FDAMA provisions is crucial to achieving this goal. General Mills looks forward to working with FDA to ensure that FDA implements these FDAMA provisions in a manner that furthers the goal of promoting public health through accurate and informative food labeling and that reflects

---

<sup>1</sup> Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, title 3, secs. 303, 304, §§ 403(r)(3)(codified as amended at 21 U.S.C. § 343(r)(3)(1997)).

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 2

Congress's intent to achieve this goal through the use of health claims and nutrient content claims based on authoritative statements ("authoritative statement claims").

### **I. Congress Enacted Sections 303 and 304 of FDAMA to Provide a Streamlined Alternative to Current Procedures for Labeling Foods with Health Claims and Nutrient Content Claims**

Congress made clear its intent for FDAMA sections 303 and 304 to provide a simple, efficient, and broad alternative to the existing burdensome and limited claim process which evolved from the restrictive regime set forth in the Nutrition Labeling and Education Act.<sup>2</sup> The House Report recognized that FDA has approved only ten health claims and stated that "(t)he perception of a time-consuming process without predictability of end point is widely believed to serve as a disincentive to the proposal of new claims."<sup>3</sup> The Senate Report speaks of the current "inefficient" system for health claim approvals.<sup>4</sup> The House Report also recognized that limiting nutrient content claims to those for which FDA has promulgated a regulation, hinders the dissemination of nutrition information to consumers.<sup>5</sup> Thus, Congress clearly recognized that the current nutrient content claim requirements are extremely limited, and the current health claim requirements entail a lengthy approval process that can prevent valuable claims from reaching the market in a timely and productive manner.

---

<sup>2</sup> Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

<sup>3</sup> H. Rept. 105-306, at 7 (1997). The report cited, as important evidence of the need for an alternative method for making claims, the history of the folic acid and neural tube defects health claim. In 1992, the Centers for Disease Control and Prevention estimated that the incidence of neural tube defects could be reduced by 50 percent if women of child-bearing age consumed 0.4 mg folic acid per day. Four months later, in January 1993, FDA published a rule prohibiting a health claim about the relationship, but then in October 1993, proposed to permit the claim. Not until March 1996 did FDA approve the claim. The House Committee expressed remorse that many children likely suffered neural tube defects because consumers were unaware of the relationship between the disease and adequate consumption of folic acid.

<sup>4</sup> S. Rept. 105-43, at 49 (1997).

<sup>5</sup> Id.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 3

The House Report states the intention to permit claims to assist consumers in “maintaining healthy dietary practices” and to enable consumers to “be more promptly and effectively informed of beneficial levels of nutrients in foods for which Daily Values have not been established.”<sup>6</sup> The Conference Report referred to the FDAMA provisions as making “streamlined procedures available for the Secretary to permit more scientifically sound health and nutrient content claims.”<sup>7</sup> Furthermore, the Conference Report modified the House’s version of the provisions to expedite the process by which FDA processes the claim notifications (from 150 days to 120 days).<sup>8</sup> Thus, through the FDAMA provisions, Congress intended to permit more food claims to reach the market by providing an alternative to the current food claim requirements.

## **II. FDA Should Implement the FDAMA Provisions In Accordance with FDAMA’s Express Language and Congress’s Intent**

In the Federal Register announcement of the May 11, 1999, public meeting, FDA posed a series of relevant questions to aid FDA in implementing FDAMA sections 303 and 304. The responses to these questions must reflect the express language of the FDAMA provisions. Where the provisions do not contain express language, FDA must implement the provisions so that they reflect Congress’s intent to provide a simpler alternative to the current food claim regulatory scheme. Set forth below are General Mill’s responses to the FDA’s questions about how it should implement the provisions.

---

<sup>6</sup> *Id.* at 15, 17.

<sup>7</sup> H. Conf. Rept. 105-399, at 98 (1997).

<sup>8</sup> *See id.*

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 4

## **A. The Scientific Basis for Claims**

### **1. What is an "authoritative statement"?**

Under FDAMA, a statement shall be regarded as an authoritative statement only if the statement (1) is published by an appropriate scientific body, and (2) is not a statement of an employee of the scientific body made in the individual capacity of the employee.<sup>9</sup> Although FDAMA sets forth the characteristics of an authoritative statement, FDA has created other required characteristics for an authoritative statement. FDA has stated that an authoritative statement must also (1) reflect a consensus within the identified scientific body if published by a subdivision of one of the Federal scientific bodies, and (2) be based on a deliberative review by the scientific body of the scientific evidence. Thus, FDA exceeds FDAMA's scope by requiring that an authoritative statement possess characteristics beyond the two cited in FDAMA.

To base a claim on an authoritative statement, FDAMA requires that the authoritative statement is currently in effect, and either is about the nutrient/disease relationship referred to in the proposed authoritative statement health claim, or identifies the nutrient level referred to in the proposed authoritative statement nutrient content claim.<sup>10</sup> FDA, however, imposes numerous additional requirements that the statement must (1) not reflect inconclusive or preliminary findings; (2) not indicate that the health relationship or nutrient level should be the subject of ongoing scientific study; (3) not indicate merely direction for future research; and (4) be within the realm of acceptable pronouncements (e.g., the Surgeon General's authoritative statements would ordinarily be found only in the Surgeon General Reports).<sup>11</sup> Nowhere in FDAMA nor in the legislative history did Congress indicate that it intended for FDA to analyze statements and prohibit claims based on these requirements. In fact,

---

<sup>9</sup> 21 U.S.C. 343(r)(3)(C) and (r)(2)(G) (hereinafter all references to section 343 are to title 21).

<sup>10</sup> 343(r)(3)(C)(i) and 343(r)(2)(G)(i).

<sup>11</sup> Food and Drug Administration, "Guidance for Industry: Notification of a Health Claim or a Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body," June 11, 1998.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 5

Congress enacted these provisions based on concerns that FDA would subject future claims to the intense scrutiny and delay experienced by the folic acid/neural tube defects health claim. Thus, Congress clearly did not intend for the provision to permit FDA to conduct such an extensive review or to deny a claim if the authoritative statement reflects the need for additional research.

However, statements that satisfy FDAMA's limited requirements must still be "authoritative". FDA imposed its own requirements because neither FDAMA nor the legislative history defines "authoritative". General Mills instead proposes an interpretation of "authoritative" that remains true to Congress's intent in enacting the position. An "authoritative" statement means a statement that provides direction and advice from the scientific body to the public. Thus, a statement from NIH that it should conduct research on whether antioxidants can help prevent cancer, does not speak authoritatively to provide dietary guidance to the public. However, consumers would benefit from the advice contained in a statement such as: "although the research concerning a cancer relationship is still not conclusive, NIH recommends consuming more foods containing antioxidants". Such a statement although not conclusive, as proposed by FDA, is nonetheless authoritative.

***2. Who decides if a particular statement is an "authoritative statement"?***

Although FDA cannot define "authoritative statement," FDA must implement and enforce the definition of "authoritative statement" set forth by FDAMA. Therefore, FDA must decide if a statement is authoritative by FDAMA's standards. However, if FDA plans to allow other agencies and scientific bodies to determine if statements are authoritative, then the decision will not be FDA's and will not be based solely on FDAMA's requirements.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 6

FDA has initiated a plan to consult with scientific bodies to determine if their statements are authoritative.<sup>12</sup> In fact, in reviewing the nine authoritative statement claims submitted by Weider Nutrition International, Inc.,<sup>13</sup> FDA consulted the scientific bodies that made the cited statements. In FDA's interim final rules on the claims, FDA repeatedly cited these bodies' responses that the statements were not authoritative.<sup>14</sup> FDA has stated also that it will consult other federal scientific bodies with public health responsibilities to determine the authoritative nature of a statement.<sup>15</sup> However, nowhere did Congress indicate that any scientific bodies would determine whether a statement is authoritative. Congress determined the requirements for authoritative statements in FDAMA and FDA cannot request that a scientific body impose its own standards and its own analysis to determine if the statement meets the FDAMA requirements.<sup>16</sup>

***4. Is the "context" of a statement in the publication in which it appears relevant to that determination? If so, how?***

FDA has stated that it will consider the context of a statement in determining whether the scientific evidence about a health relationship or nutrient level is preliminary or inconclusive.<sup>17</sup> However, as discussed above, whether a statement is preliminary or inconclusive is not a requirement for an authoritative statement. Thus, to determine whether a statement qualifies as authoritative, FDA need only consider the context of the statement if it clarifies whether the statement is published and whether it is made by an individual employee in their individual capacity.

---

<sup>12</sup> See, e.g., letter from Donna E. Shalala, Secretary, Health and Human Services, to Dan Glickman, Secretary of Agriculture, March 17, 1998.

<sup>13</sup> 63 Fed. Reg. 34083 (June 22, 1998).

<sup>14</sup> *Id.*

<sup>15</sup> Food and Drug Administration, "Guidance for Industry," supra note 10.

<sup>16</sup> Note that FDA could conceivably consult with a scientific body regarding the specific FDAMA requirements, such as to determine if the statement is current.

<sup>17</sup> 63 Fed. Reg. at 34085.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 7

FDA also can use the statement's context to determine if the claim and statement meet other FDAMA requirements. For example, FDA can consider context when verifying the nutrient/disease relationship for an authoritative statement health claim,<sup>18</sup> or when verifying that the statement is current. FDA can also consider the context in determining whether the claim accurately represents the authoritative statement, as required by FDAMA.<sup>19</sup> Thus, if the context of the statement indicates the need for more research, or indicates that the research is inconclusive, the claim, or the context of the claim, should so indicate.<sup>20</sup>

***5. How does the significant scientific agreement standard apply to health claims based on authoritative statements?***

FDAMA does not refer to the "significant scientific agreement" standard in the authoritative statement claim provisions. However, the Senate Report on the bill states that, "the standards and criteria for health claims prescribed by section 403(r)(3) and implementing regulations, including the significant(t) scientific agreement standard, would be fully applicable."<sup>21</sup> FDA has advised that a statement does not meet the significant scientific agreement standard if it is inconclusive or intended to guide future research.<sup>22</sup> Congress did not provide, however, for FDA to conduct an analysis of whether the statement is inconclusive or preliminary to determine that the claim meets the standard. A claim recommending increased consumption of a nutrient based on a potential nutrient/disease relationship could well be supported by significant scientific agreement even if the relationship has not yet been deemed conclusive.

---

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* (required by 343(r)(3)(C)(iv) and (r)(2)(G)(iv)).

<sup>20</sup> Although FDA has stated it will not permit such claims, such a use of the statement's context in the claim accords with both FDAMA and with the recent court case, Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).

<sup>21</sup> S. Rept., supra note 3, at 51.

<sup>22</sup> Food and Drug Administration, "Guidance for Industry," supra note 10.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 8

The House Report stated that claims based on authoritative statements have a “presumption of validity.”<sup>23</sup> Thus, if a claim is appropriately based on an authoritative statement, it should be presumed to meet the “significant scientific agreement standard”. The claim would not be valid if the statement and the claim do not meet the other specified requirements (published by an appropriate body, not made by an employee acting in their individual capacity, currently in effect, about a nutrient/disease relationship or a nutrient level, and accurately representing the authoritative statement).

If authoritative statements are not considered presumptively to meet the significant scientific agreement standard, FDA will have to conduct a full investigation into the scientific evidence as FDA does for health claim petitions; a result clearly contradicting that intended by Congress. For example, the Senate Report indicates that the authoritative statement health claim provision provides an alternative to a system that “fails adequately to benefit from the deliberative processes in which authoritative scientific bodies engage in issuing statements on matters of public health.”<sup>24</sup> The Report states that the provision “maintains the rigorous scientific standard health claims must meet under existing law but streamlines the procedure for making health claim when the scientific basis for a claim has been developed by an authoritative scientific body outside FDA.”<sup>25</sup> Thus, the authoritative statement claim provisions provide a means for determining that the claim meets the standard without FDA conducting a lengthy health claim petition review.

General Mills recognizes an additional question that may aid in FDA’s implementation of the FDAMA provisions:

---

<sup>23</sup> H. Rept., *supra* note 2, at 16.

<sup>24</sup> S. Rept., *supra* note 3, at 49.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 9

**6. *How closely must a claim resemble the authoritative statement?***

FDAMA states that an authoritative statement claim must be “stated in a manner so that the claim is an accurate representation of the authoritative statement referred to.”<sup>26</sup> The claim must also be stated so that it “enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.”<sup>27</sup> FDA has stated that an authoritative statement should use the word “may” to characterize the relationship between the nutrient and the disease or health-related condition, so as to indicate that the disease or health-related condition is caused by many factors.<sup>28</sup>

General Mills asserts that, to comply with FDAMA, a claim need not mimic the authoritative statement, but the claim must provide the same message to consumers as the authoritative statement. Thus, although FDA should not require that a claim use the term “may”, in order to convey the same message as a statement, depending on the authoritative statement, a claim may need to use “may” or a similar term, or may need to provide additional qualifying information. Furthermore, depending on the statement and its context, the claim or the claim’s context may need to state other important elements of the diet (*e.g.*, “a low fat diet including. . .”). General Mills suggests that authoritative statement claims should be modeled on current health and nutrient content claim regulations in that the notification should identify the authoritative statement and a model claim. Just as claims other than the model are permissible as long as they comply with the existing regulation, authoritative statement claims that differ from the model would be lawful as long as they accurately reflect the authoritative statement.

---

<sup>25</sup> *Id.*

<sup>26</sup> 343(r)(3)(C)(iv) and (r)(2)(G)(iv).

<sup>27</sup> *Id.*

<sup>28</sup> Food and Drug Administration, “Guidance for Industry,” *supra* note 10.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 10

Finally, FDA has stated that the authoritative statement health claim should not refer to a single brand name product, or the claim would be misleading.<sup>29</sup> However, FDA should clarify that the claim can identify a particular brand name product as an example, as long as the claim also identifies the general substance. By referencing the general substance along with the specific example, the claim would satisfy FDAMA's requirement that the claim refer to the "nutrient."<sup>30</sup>

## **B. Existing Regulatory Requirements**

*1. What requirements of 21 CFR 101.13 and part 101, subpart D should we apply to nutrient content claims based on authoritative statements?*

*2. What requirements of 21 CFR 101.14 should we apply to health claims based on authoritative statements?*

FDAMA specifies that authoritative statements must comply with section 403(r)(2)(A), (r)(2)(B), (r)(3)(A)(ii), and paragraph (a) and section 201(n).<sup>31</sup> FDA has stated that foods bearing health claims based on an authoritative statement should comply with 21 C.F.R. 101.14, and foods bearing nutrient content claims based on an authoritative statement should comply with 21 C.F.R. 101.13.<sup>32</sup> FDA's regulations at 21 C.F.R. 101.13, part 101 subpart D, and 101.14, implement the statutory requirements cited by FDAMA. Therefore, General Mills agrees that FDA should apply these regulatory requirements to authoritative statement claims, without applying the health petition process. FDA should amend its regulations so health claims are not limited to those approved by FDA through a petition, and so nutrient content claims are not limited to those provided for by regulation.

---

<sup>29</sup> *Id.*

<sup>30</sup> 343(r)(3)(B)(i).

<sup>31</sup> 343(r)(2)(G)(iii) and (r)(3)(B)(iii).

<sup>32</sup> Food and Drug Administration, "Guidance for Industry," supra note 10.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 11

### **C. Procedural and Definitional Issues**

#### ***1. Which agencies should we identify as scientific bodies of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition under section 40(r)(2)(G)(i) and (r)(3)(C)(i) of the act?***

FDAMA specifies that, for purposes of the claim provisions, an authoritative statement must be published by a “scientific body of the United States with official responsibility for public health protection or research directly related to human nutrition . . . or the National Academy of Sciences or any of its subdivisions.”<sup>33</sup> The FDAMA provisions give the National Institutes of Health and the Centers for Disease Control and Prevention as examples of qualifying United States scientific bodies.<sup>34</sup> In its guidance document, FDA states that it considers the Surgeon General within the Department of Health and Human Services, and the Department of Agriculture’s Food and Nutrition Service, Food Safety and Inspection Service, and Agricultural Research Service, to qualify under the provisions. General Mills agrees that these bodies meet the FDAMA definition, but FDA should clarify that the scientific bodies are not limited to those bodies listed by FDAMA and FDA; Congress wrote this provision broadly to ensure that other existing bodies, as well as newly formed bodies, can qualify.

Just as FDA acknowledges the qualification of the Department of Agriculture’s services, other individual subdivisions, such as those within the Centers for Disease Control and Prevention and the National Institutes of Health, should qualify as sources for authoritative statements. The Conference Report states that the Committee neglected to include these subdivisions because the Committee desired that statements issued by the agencies reflect consensus within the agency.<sup>35</sup> However, these subdivisions often publish important authoritative statements about areas in which they have specific expertise. In fact,

---

<sup>33</sup> Codified at 21 U.S.C. 343(r)(2)(G)(i) and 343(r)(3)(C)(i).

<sup>34</sup> Id.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 13

General Mills agrees that FDA may need to examine the context of a statement to determine whether it complies with FDAMA's specific requirements. However, because many of the authoritative statements appear in large reports to which FDA has access, General Mills suggests that FDA not require that the submission include the entire document. Instead, the submitter can include the document if FDA can not easily obtain the document, or if FDA specifically requests the document after submission.

***3. Should we require that you submit with a notification an analytical methodology for measuring the substance that is the subject of your submitted claim?***

FDA's guidance document states that FDA believes that the notification should contain an analytical methodology for the nutrient that serves as the subject of the claim. Because FDAMA does not require an analytical method as part of the submission, FDA should not require it. However, General Mills recognizes FDA's need for standardized methodologies to be associated with each claim. Therefore, General Mills recommends that FDA maintain this suggestion in a guidance document, which provides a flexible means by which FDA can advise industry on the means by which FDA can most efficiently implement FDAMA's mandate. FDA should explain that if FDA does not already employ a standardized methodology, the submitter would benefit from providing FDA with an appropriate methodology so that FDA can more easily prevent improper and misleading use of the claim.

***4. What is a "balanced presentation of the scientific literature" relating to the subject to which a claim refers that is required under section 403(r)(2)(G)(ii)(III) and (r)(3)(C)(ii)(III) of the act?***

FDA's guidance document suggests that a balanced presentation of the scientific literature should be a "bibliography of the scientific literature on the topic of the claim" and a "brief, balanced account or analysis of how this literature either supports or fails to support

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 14

the authoritative statement.”<sup>40</sup> Although FDAMA does not specify the components of a balanced representation, Congress recognized that a bibliography may prove helpful for FDA’s review.<sup>41</sup> General Mills concurs with FDA that these suggestions should remain in a guidance document so that industry can consistently provide FDA with the appropriate materials to aid FDA in determining that the statement is current and accurate.

***5. Should FDA keep notifications confidential for 120 days after the date of their submission or should we place them in a public docket upon receipt?***

FDAMA does not address whether FDA must keep notifications confidential during the 120 days after submission. However, Congress intended the FDAMA provisions to provide a means for more accurate and informative food claims to reach the market. Therefore, FDA should implement the provisions in a manner that provides the most incentive for industry to develop claims and submit notifications.

If FDA makes notifications public as soon as FDA receives them, then the submitter’s competitors can prepare to use the claim as soon as FDA indicates its acceptance of the claim or the 120 days expire, without the competitors investing any resources in preparing the notification. Because others in industry would receive a “free-ride” from the submitter, FDA should keep the notification confidential during this time so that only the submitter can prepare to immediately implement the claim. When the claim enters the market, the submitter gains an advantage from having submitted the notification, introduced it into the market first, and being the sole user of the claim for the period while others prepare to implement it. Thus, companies will have incentive to submit notifications for appropriate claims and the public will benefit from the use of more scientifically sound nutrition information.

---

<sup>40</sup> Food and Drug Administration, “Guidance for Industry,” supra note 10.

<sup>41</sup> H. Conf. Rept., supra note 6, at 98.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 15

FDA should recognize that the submitter only receives this advantage if, during the 120-day review period, the submitter can prepare to market products with labels bearing the claim. Thus, during the 120-day period in which FDA reviews the notification, FDA should keep the submitter reasonably apprised of the status of the notification. Such communication will permit FDA to request information or materials that may assist FDA in reviewing the notification, and will encourage efficient review of the notification. Such communication also would follow Congress's intent in FDAMA to make FDA more accessible to industry and to encourage cooperative FDA-industry relations.

***6. If a notification is incomplete or does not support a claim, should we respond to it by letter or by issuing a regulation, and what should be the legal effect of letters were we to use them?***

FDAMA states that after 120 days, the claim can be used until such time as FDA issues a regulation prohibiting or modifying the claim, or finding that the requirements are not met (including that the notification is not complete).<sup>42</sup> FDA has stated that it will notify the submitter as soon as possible within the 120 days that the notification does not comply with FDAMA.<sup>43</sup> FDA stated that the submitter may revise the notification and resubmit it, at which point FDA may restart the 120 days.<sup>44</sup>

FDAMA does not require that FDA promulgate a regulation during the 120 days to deem a notification incomplete. However, in keeping with Congress's intent for a more efficient system which enable more claims, FDA should notify the submitter by letter of an incomplete notification as soon as possible during the 120 days, so that the submitter can supplement the notification. The letter should request that the submitter notify FDA as to whether it will supplement the notification. If the submitter responds that it will not

---

<sup>42</sup> 343(r)(3)(D), (r)(2)(H).

<sup>43</sup> Food and Drug Administration, "Guidance for Industry," supra note 10.

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 16

supplement the notification, or if a certain amount of time passes and the submitter does not respond, then FDA should consider the notification withdrawn and publish a notice rejecting the notification and explaining the insufficiency. This notice will enable others in industry to become aware of the failed notification and the insufficiency, and to submit a more complete notification for that claim. The information might also prove useful for others in industry in preparing notifications for different claims.

If the submitter notifies FDA that it will supplement the notification, the 120 days should restart only if the notification lacks components explicitly required by FDAMA. Furthermore, if FDA determines that the notification is complete but rejects it, FDA should notify the submitter by letter and publish a notice in the Federal Register so that others become aware and do not expend resources on the same claim unless they can address FDA's problems with the claim. Note that if the submitter withdraws the notification before FDA responds to the submitter or makes any decisions on the notification, then the notification should remain confidential because FDA has not acted or made statements that others in industry should know about.

The following question may also prove beneficial in FDA's implementation of the FDAMA provisions:

***7. When should FDA deny an authoritative statement health claim because it is equivalent to one FDA has already authorized?***

FDAMA provides that an authoritative statement claim must be one "which is not authorized by the Secretary in a regulation."<sup>45</sup> The Senate Report states that "(o)nce FDA regulations governing health claims concerning a particular diet/disease relationship (e.g., calcium and osteoporosis) have become effective, no claim concerning that diet/disease

---

<sup>44</sup> *Id.*

<sup>45</sup> 343(r)(3)(C), (r)(2)(G).

Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 17

relationship based on the statement of an authoritative scientific body could be made unless it is consistent with the FDA regulation."<sup>46</sup> Thus, the FDAMA provision is intended to address authoritative statement claims that are equivalent to existing claims; *i.e.*, that discuss the same diet/disease relationships.

Consistent with the language of FDAMA and the Senate Report, General Mills asserts that FDA should interpret the FDAMA provision narrowly to allow for claims that are similar to existing claims, though not equivalent. Thus, an authoritative statement health claim is the same as an already existing claim only if the proposed claim references the same substance and the same disease as the existing claim. For example, if a claim differs by referencing a food rather than a nutrient, or citing a similar, but different, disease, then the claims are different claims and FDA should not prevent the authoritative statement claim from being used. This interpretation will enable legitimate claims that are supported by authoritative statements to enter the market without undergoing the lengthy process of amending the existing health claim regulation.

FDA should also recognize that similar claims may have a different emphasis or convey a different message, and thus, the claims are different. For example, in the interim final rules, FDA rejected Weider Nutrition International, Inc.'s proposed claim: "calcium consumption by adolescents and adults increases bone density and may decrease the risk of fractures."<sup>47</sup> FDA rejected the claim, stating that it was a calcium/osteoporosis claim authorized by § 101.72, but that it did not comply with the regulation because the proposed claim mischaracterized the mechanism by which calcium consumption reduces the risk of osteoporosis; while the regulation recognizes the reduction of bone loss in older adults, the authoritative statement claim recognizes the increased bone density in adolescents and young

---

<sup>46</sup> S. Rept., *supra* note 3, at 51.

<sup>47</sup> 63 Fed. Reg. at 34101.

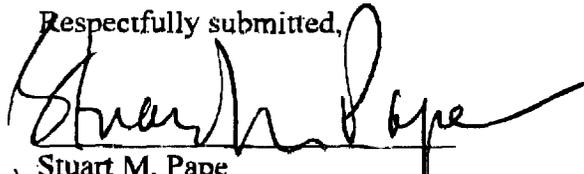
Docket No. 99N-0554  
Comments of General Mills, Inc.  
Page 18

adults.<sup>48</sup> Furthermore, FDA stated that the authoritative statement claim's "risk of fractures" is not synonymous with the existing claim's "osteoporosis" nor with "fractures related to osteoporosis."<sup>49</sup>

Under General Mills's interpretation, the FDAMA provision would not prohibit the proposed claim, because the proposed claim differs from the existing claim; the existing claim references the advantage of calcium to older adults, while the proposed claim targets adolescents' and young adults' calcium consumption. FDA could then conclude that claim does not accurately reflect the authoritative statement if the statement's context indicates that the claim should instead state "calcium consumption by adolescents and young adults increases bone density and thus, may later help decrease the risk of osteoporosis and fractures associated with osteoporosis." By utilizing an interpretation of this FDAMA provision that avoids the lengthy health claim regulations amendment process, FDA would preserve agency resources and fulfill Congress's intent to provide an efficient method to permit more health claims to enter the market.

General Mills appreciates the opportunity to offer these comments and looks forward to working with FDA to appropriately implement FDAMA's authoritative statement claim provisions.

Respectfully submitted,



Stuart M. Pape,  
Patton Boggs LLP, on behalf of  
General Mills, Inc.

---

<sup>48</sup> Id. at 34103.

<sup>49</sup> Id.

**PATTON BOGGS LLP**  
ATTORNEYS AT LAW

2550 M Street, NW  
Washington, DC 20037-1350  
202-457-6000

Facsimile 202-457-6315

---

**To: Jenny Butler**  
**Company: FDA - Docket Management**  
**Fax Number: 301-827-6870**  
**Phone Number: 301-827-6860**

---

**Total Pages**  
**Including Cover: 20**

---

**From: Jennifer Spokes**  
**Sender's Direct Line: 202-457-6472**  
**Date: May 11, 1999**  
**Client Number: 1780.102**

---

**Comments:**

- ANCHORAGE
- DALLAS
- DENVER
- GREENSBORO
- SEATTLE
- WASHINGTON, D.C.

**Confidentiality Note:** The documents accompanying this facsimile contain information from the law firm of Patton Boggs LLP which is confidential and/or privileged. The information is intended only for the use of the individual or entity named on this transmission sheet. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this facsimile is strictly prohibited, and that the documents should be returned to this Firm immediately. If you have received this facsimile in error, please notify us by telephone immediately so that we can arrange for the return of the original documents to us at no cost to you.

If you did not receive all of the pages or find that they are illegible, please call 202-457-5689.