Council for Responsible Nutrition
1828 L Street, NW, Suite 510 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

October 25, 2011

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Nos. FDA-2000-P-0102; FDA-2000-p-0133; and FDA-2006-P-0033: Food Labeling; Health Claim; Phytosterols and Risk of Coronary Heart Disease; Proposed Rule; Reopening of the Comment Period

The following comments on the U.S. Food and Drug Administration's (FDA) proposal to amend the regulation authorizing a health claim on the relationship between phytosterols and reduced risk of coronary heart disease (CHD), published in the Federal Register on December 8, 2010, are submitted on behalf of the Council for Responsible Nutrition (CRN). CRN is a Washington, D.C. – based trade association representing the dietary supplement industry. Our members include some of the largest and most well-known suppliers, manufacturers, direct sellers, and retailers of dietary supplements and dietary ingredients.

CRN submits these comments in opposition to FDA's abrupt discontinuation of its eight year old policy of enforcement discretion allowing use of the CHD health claim on the label of dietary supplements containing phytosterols in free form. The sudden termination of enforcement discretion based on tentative Agency conclusions disrupts well-founded industry expectations based on the express terms of the original 2003 enforcement discretion letters and fails to take into account the logistical difficulties and associated time involved in launching reformulated and/or relabeled dietary supplements that conform to the Agency's newly announced proposed criteria. The Agency's announcement fails to acknowledge, much less justify, the disparate standards applied to dietary supplements and conventional foods. For these reasons, the termination of enforcement discretion is arbitrary and capricious agency action that cannot stand. To address these concerns, CRN requests that FDA continue to exercise enforcement discretion in accordance with the 2003 letters until the effective date of the final rule, or, at a minimum, until the next uniform compliance date for food of January 1, 2014

A. The Interim Final Rule Authorizing a Health Claim Concerning the Relationship Between Phytosterols Esters and CHD

On September 8, 2000, FDA published an Interim Final Rule (IFR) authorizing use of a health claim on certain foods containing phytosterol and phytostanol esters, based on their ability to reduce low-density lipoprotein cholesterol (LDL-C) and total cholesterol, and thereby reduce the risk of CHD.[1] The impetus for the IFR was two specific health claim petitions submitted by Lipton and McNeil Consumer Healthcare seeking authorization to make a health claim for certain foods containing specified amounts of sterol and stanol esters, respectively. The preamble to the IFR documented FDA's evaluation of over two dozen studies investigating consumption of both esterified phytosterols and free phytosterols on blood cholesterol levels.

Because the IFR was issued in response to two narrow health claim petitions, the resulting regulation, 21 C.F.R § 101.83, authorized use of the health claim only on the particular foods (salad dressings, spreads, snack bars, and soft gel dietary supplements) containing the substances (sterol and stanol esters of specified composition) in the amounts addressed in those petitions. However, the preamble to the IFR stated FDA's conclusion that the free sterol/stanol is the molecule that is incorporated into the intestinal micelles in a manner that prohibits the absorption of cholesterol: "The agency agrees that the active moiety of the plant sterol ester is the plant sterol and has concluded that studies of the effectiveness of free plant sterols in blood cholesterol reduction are relevant to the evaluation of the evidence in the plant sterol esters petition."[2]

The IFR was effective upon publication on September 8, 2000, pursuant to the Food and Drug Modernization Act (FDAMA) provisions authorizing FDA to make proposed health claims immediately effective, pending consideration of public comment and publication of a final regulation, if necessary for public health reasons.[3] In determining that the relevant statutory standard was satisfied, FDA explained:

> FDA has concluded that there is significant scientific agreement that plant sterol/stanol esters reduce blood total and LDL cholesterol levels. The reported reductions in blood total and LDL cholesterol levels are significant and may have a profound impact on population risk of CHD if consumption of plant stanol esters becomes widespread. The agency has determined that issuance of an interim final rule is necessary to enable consumers to be informed promptly and effectively of this important new

---

1 *Food for human consumption: Food Labeling; Plant Sterol/Stanol Esters and Coronary Heart Disease; Health Claims,* 65 Fed. Reg. 54685 (Sept. 8, 2000).

2 65 Fed. Reg. at 54690, 54693. The agency reached the same conclusion regarding stanol esters and stanols. 65 Fed. Reg. at 54691.

3 65 Fed. Reg. at 54713; *see* 21 U.S.C. § 343(r)(7).

> knowledge regarding the nutritional and health benefits of plant sterol/stanol esters. The agency has also determined that issuance of an interim final rule is necessary to ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible.[4]

The IFR solicited public comment and stated that FDA would "address comments and confirm or amend the interim rule in a final rule."[5]

B. FDA Response to Comments on the IFR and Determination to Allow the CHD Claim on a Broad Range of Foods, Including Dietary Supplements, Through the Exercise of "Enforcement Discretion"

The IFR generated significant interest, and the Agency received many comments during the 75 day comment period, raising "numerous complex issues."[6] Several comments requested that FDA allow foods containing free phytosterols to bear the health claim. Many other comments requested that FDA broaden the categories of foods eligible to bear the health claim. Comments also addressed the daily intake levels specified in the IFR. In October 2001, FDA formally reopened the comment period, citing two previous requests that the comment period be extended, the significant substantive issues raised by comments submitted to date, and international developments raising various questions about the use of phytosterols. The Federal Register Notice sought comment on several specific issues including use of the health claim on foods containing free phytosterols, the effects of various food matrices on the activity of free phytosterols, the daily intake levels of free and esterified sterols and stanols that are effective in reducing the risk of CHD, and use of the health claim on foods containing mixtures of sterols and stanols.[7]

In January 2003 Cargill Heath & Food Technologies requested that FDA issue a letter stating the Agency's intent not to enforce certain requirements of the IFR, based on scientific evidence indicating that a broader range of phytosterol containing foods effectively reduce cholesterol and should therefore be eligible to bear the health claim.[8] In response, FDA issued a letter on February 14, 2003 identifying the specific circumstances under which FDA

---

4 65 Fed. Reg. at 54714.

5 65 Fed. Reg. at 54714.

6 *Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease,* Interim Final Rule; notice of extension of period for issuance of final rule, 66 Fed. Reg. 30311, 30312 (June 6, 2001).

7 *Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease,* Interim Final Rule; reopening of comment period, 66 Fed. Reg. 50824, 50825 (Oct. 5, 2001).

8 *See* Letter to C. Taylor, Ph.D. from F. Shinnick, Ph.D. (Jan. 6, 2003), attached hereto as Exhibit [INSERT].

would consider the exercise of enforcement discretion.[9] This "enforcement discretion letter" permitted use of the health claim on products, including dietary supplements, containing free sterols and stanols as long as they delivered at least 0.8 g/day divided over two daily doses and contained a sterol/stanol blend of a certain composition.[10]

The Agency explained that its decision to exercise enforcement discretion was driven by the scientific evidence:

> We received many comments in response to the IFR and to a notice reopening the comment period (66 FR 50825; October 5, 2001). These comments have brought to FDA's attention substantial additional scientific evidence regarding the cholesterol-lowering efficacy of phytosterols that has been published in peer-reviewed scientific journals since issuance of the IFR. The IFR authorized a health claim for only plant sterol esters and plant stanol esters, the substances that were the subjects of the two health claim petitions. Comments and supporting scientific evidence now suggest that currently available scientific support extends to a broader range of phytosterol substances.[11]

The enforcement discretion letter unequivocally stated that enforcement discretion would remain in effect until issuance of a final rule:

- "Pending completion of the final rule, FDA believes that it would be appropriate to consider the exercise of enforcement discretion with regard to use of the health claim on a wider range of foods."
- "Based on preliminary review of the comments and additional scientific evidence, FDA intends to consider the exercise of enforcement discretion, pending publication of the final rule, with respect to certain requirements of the health claim."
- "The agency cautions manufacturers that the final rule may differ from the broadened criteria listed above and that manufacturers would then be required to change their labels to conform to the final rule."[12]

---

[9] *See* FDA Letter Regarding Enforcement Discretion with Respect to Expanded Use of an Interim Health Claim Rule About Plant Sterol/Stanol Esters and Reduced Risk of Coronary Heart Disease (Feb. 14, 2003), available at: http://www.fda.gov/Food/LabelingNutrition/LabelClaims/HealthClaimsMeetingSignificantScientificAgreementSSA/ucm074779.htm.

[10] *Id.* Specifically, the mixtures of phytosterol substances were to contain at least 80 percent beta-sitosterol, campesterol, stigmasterol, sitostanol, and camperstanol (combined weight).

[11] *Id.*

[12] *Id.*

FDA promptly posted the enforcement discretion letter on its website in the area devoted to health claims meeting the significant scientific agreement standard and issued a similar letter to another free phytosterol manufacturer.[13] In reliance upon the enforcement discretion letters and the strength of the science that supports them, the dietary supplement industry developed and marketed many phytosterol-containing products that would otherwise be ineligible to bear the health claim, was the narrow limitations in the IFR still in effect. In fact, the majority of phytosterol supplements contain phytosterols in free form, due to technical limitations associated with formulation of phytosterol esters into dietary supplements in tablet/capsule form. The dietary supplement industry has marketed products bearing the health claim in accordance with the limitations expressed in the enforcement discretion letters for almost eight years.

C. FDA's December 2010 Proposed Rule and Determination to Make Dietary Supplements Containing Free Phytosterols Ineligible for the CHD Claim Predicated on "Tentative Conclusion" Regarding Scientific Evidence

On December 8, 2010, without any notice to industry that it was considering premature discontinuation of enforcement discretion or issuance of a new proposed rule years after the close of the comment period, FDA announced significant, almost-immediately-effective changes to the circumstances under which phytosterol-containing dietary supplements may be labeled with the CHD health claim. Specifically, FDA published a proposed rule to amend the regulation authorizing a health claim on the relationship between phytosterol esters and reduced risk of CHD, 21 C.F.R. § 101.83, and summarily announced that, beginning on February 21, 2011, FDA would no longer exercise its enforcement discretion based on the February 2003 letters. [14] Instead, FDA announced its intent to exercise its enforcement discretion when a health claim is made in a manner consistent with the requirements of the newly proposed rule.[15] In a Federal Register Notice published on February 18, 2011, FDA extended the deadline by one year, stating that the previously announced termination of the 2003 enforcement discretion letters would go into effect on February 21, 2012.[16]

---

[13] *See* Letter to Forbes Medi-Tech Inc. from C. Taylor, Ph.D. (Feb. 26, 2003), attached hereto as Exhibit [INSERT].

[14] *Food Labeling; Health Claim; Phytosterols and Risk of Coronary Heart Disease; Proposed Rule,* 75 Fed. Reg. 76526 (Dec. 8, 2010). Specifically, FDA indicated it would no longer exercise enforcement discretion based on the terms of the February 2003 letters starting 75 days from the date that the proposed rule publishes, *i.e.,* February 21, 2011. 75 Fed. Reg. at 76546.

[15] 75 Fed. Reg. at 76546.

[16] *Health Claim; Phytosterols and Risk of Coronary Heart Disease* (Extension of Enforcement Discretion), 76 Fed. Reg. 9525 (Feb. 18, 2011). CRN and others had requested that FDA allow more time to accomplish the numerous tasks associated with reformulating and relabeling products, as would be required by the December 8, 2010 Notice.

As the Agency is well aware, this abrupt termination and change in enforcement discretion criteria has had a dramatic impact on the dietary supplement industry. Unlike the February 2003 enforcement discretion letters, which permit use of the health claim on all supplements containing free phytosterols that contain a sterol/stanol blend of specified composition, the proposed rule prohibits use of the health claim on all dietary supplements containing free phytosterols, regardless of phytosterol composition, regardless of formulation, and regardless of the form of the supplement (*i.e.,* tablet, capsule, chewable, powder, granule, liquid, gummy, bar, etc).[17]

FDA proposed this dramatic change despite its "extensive re-evaluation of the scientific evidence regarding the relationship between consumption of phytosterols and the risk of CHD"[18] and subsequent confirmation that free phytosterols are the active component of the ester and free phytosterols effectively lower blood cholesterol levels.[19] According to the Agency, the results of the three published studies on the efficacy of supplements containing free phytosterols it considered were inconsistent. Specifically, FDA concluded that one study showed that a particular supplement had no impact on blood cholesterol levels, whereas two studies on a different formulation were positive.[20] Based on this information, FDA stated that the particular formulation of the supplement is critical. In the words of FDA:

> The available scientific evidence for the cholesterol-lowering effects of phytosterols in dietary supplements shows that formulation of the supplement product is an important factor in the effectiveness of the product in lowering cholesterol and that esterifying the phytosterol is one way to ensure effectiveness.
>
> * * * * *
>
> We **tentatively conclude** that the available evidence is insufficient to establish what factors are key in predicting which nonesterified phytosterol formulations will be effective and which will not be when consumed as ingredients in dietary supplements.[21]

---

17 75 Fed. Reg. 76540, 76555 (21 C.F.R. § 101.83(c)(2)(iii)(B) (proposed)).

18 Specifically, FDA considered those intervention studies published since 2000 that satisfied FDA criteria and were located by FDA and the Agency for Healthcare, Research and Quality. 75 Fed. Reg. at 76528-29.

19 75 Fed. Reg at 76528, 76530, 76531. With respect to products containing free phytosterols, FDA evaluated the five studies on free sterols/stanols it previously considered in issuing the IFR as well as an additional twelve studies conducted and published since that time. 75 Fed. Reg. at 76530-31.

20 75 Fed. Reg. at 76540.

21 75 Fed. Reg. at 76540, 76529 (emphasis supplied).

FDA further explained that it is "difficult" "to predict the effectiveness of nonesterified phytosterols in lowering cholesterol when consumed as ingredients in dietary supplements."[22] Because the results of the free sterol/stanol studies were inconsistent, FDA also "**tentatively conclude[d]**" that the evidence for a relationship between dietary supplements containing free phytosterols and CHD does not meet the significant scientific agreement standard.

Despite its summary termination of the enforcement discretion letters that had established an important category of dietary supplements and concomitant declaration that a CHD claim for such products would be unlawful, FDA acknowledged the importance of public comment on the proposal:

> Because the agency has not provided a formal opportunity for public comment on the modifications proposed to current Sec. 101.83, and because of the time that has elapsed since publishing the IFR, the agency has decided to issue a proposed rule to amend current Sec. 101.83 rather than finalizing, with modification, the IFR. This approach provides an opportunity for public comment prior to issuance of the final rule.[23]

FDA also specifically acknowledged the importance of industry comments on the Agency's tentative conclusions concerning dietary supplements containing free phytosterols; FDA invited submission of additional data on the cholesterol-lowering efficacy of free phytosterol supplements and data bearing on the propriety of using USP standards to determine whether a supplement may bear the health claim. The Notice expressly states that FDA would "reevaluate its tentative conclusion regarding the eligibility of dietary supplements containing both esterified and nonesterified phytosterols in light of any additional data received."[24]

FDA has already received many submissions objecting to the proposed rule, including comments and petitions addressing the Agency's tentative conclusions and rationale concerning supplements containing free phytosterols and summary termination of enforcement discretion. The Agency recently published a Federal Register Notice reopening the comment period.[25] The Notice invites further comment on the proposal, acknowledges that the final rule may be different from the proposal in light of comments submitted to the docket, and cautions industry that such changes may necessitate additional label changes:

---

[22] 75 Fed. Reg. at 76540.

[23] 75 Fed. Reg. at 76528.

[24] 75 Fed. Reg. at 76541.

[25] *Food Labeling; Health Claim; Phytosterols and Risk of Coronary Heart Disease; Reopening of the Comment Period,* 76 Fed. Reg. 49707 (Aug. 11, 2011).

Following receipt of comments on this document, FDA intends to publish a final rule, which will amend § 101.83. The reopening of the comment period may result in the submission of additional information that may cause the Agency to reconsider its proposed amendments to the phytosterols and risk of coronary heart disease health claim. The Agency notes that a final rule may vary from the proposal. To the extent that manufacturers have labeled their products consistent with the proposed requirements, and the final requirements differ from what the Agency proposed, manufacturers will be required to change their labels to conform to the final rule.[26]

D. CRN Comments

CRN offers the following comments on the impact to the dietary supplement industry of the Agency's stated approach to the CHD health claim; the requirements of the Administrative Procedure Act as they relate to discontinuation of enforcement discretion under the 2003 letter and finalization of the health claim; and means by which the Agency may address the deficiencies in the current approach.

(1) Adverse Impact on the Dietary Supplements Containing Free Phytosterols

The Agency's summary termination of enforcement discretion in accordance with the February 2003 letters has created an untenable situation for the dietary supplement industry, which has for years relied in good faith on terms outlined in those letters. As reflected in our previous comments, reformulation and relabeling are extremely complex undertakings, entailing multiple steps, and typically requiring at least 18 months. Many reformulated and/or relabeled products will have different universal product codes, different prices, different counts, and/or changes in dosages. With such changes, a product cannot simply be stocked in place of the former product it is to replace; instead shelf tags must be changed and retailers must work within their systems for an orderly inventory transition. Retailers change their planogram[27] at most twice a year, and the timing of the change is different for each retailer. Most in the dietary supplement industry will not be able to ship newly reformulated and/or relabeled product in time to coincide with planogram changes scheduled to occur before the current February 22, 2012 termination of enforcement discretion in accordance with the 2003 letters. In these circumstances, many products may have to be considered for discontinuation and reintroduction at the next planogram change. Any company that does manage to ship new product to coincide with near-term planogram changes would have likely maintained substantial inventory of current product in case new product was not available in time. This abrupt change will cause many companies to be faced with costly

---

[26] 76 Fed. Reg at 49707-08.

[27] A planogram is diagram of a retail store that specifies, in detail, how and where every product should be placed, *i.e.,* which aisle, which shelf, how many facings are allocated to each SKU.

returns from retailers. And all of this must occur while the industry awaits FDA's evaluation of comments on the "tentative conclusions" that underpin the newly proposed rule.

As FDA made clear in its most recent Federal Register Notice, the final rule may well differ from the December 2010 proposal, and this is the essence of notice and comment rulemaking. Thus, companies that make changes to align their products with the criteria in the proposed rule may have to go through this arduous process a second time to conform to requirements of the final rule. In light of this uncertainty, many companies may simply discontinue their phytosterol supplements. Those that opt to reformulate and/or relabel may be forced to pass along increased costs to consumers.[28] Either outcome, discontinued products or higher costs, harms consumers. FDA has long recognized the public health significance of CHD (21 C.F.R. § 101.83(b)(1)) as well as the tangible public health benefits associated with the phytosterol health claim, which enables consumers to select phytosterol containing foods in lieu of alternatives that do not reduce the risk of CHD.[29]

(2) "Enforcement Discretion" Does Not Abrogate the Requirements of the Administrative Procedure Act

With all due respect to FDA's efforts to address the existing body of published data on this important category of products, the December 2010 summary termination of the February 2003 enforcement discretion letters, represents the kind of arbitrary and capricious decision making that has long been condemned.

> "'No, no!' said the Queen. 'Sentence first - verdict afterwards.' 'Stuff and nonsense!' said Alice loudly. 'The idea of having the sentence first!'"

---

[28] Comments submitted by Cargill to these dockets discuss in detail the economic impact on consumers. *See* Letter from J. van de Ligt, Ph.D. (Feb. 18, 2011).

[29] In explaining its decision to issue an immediately-effective IFR in 2000, FDA described the benefits of the phytosterol health claim as follows:

> The agency agrees with the plant sterol ester and plant stanol ester petitioners that authorizing the health claim immediately will help consumers develop and maintain healthy dietary practices. As discussed above, FDA has concluded that there is significant scientific agreement that plant sterol/stanol esters reduce blood total and LDL cholesterol levels. The reported reductions in blood total and LDL cholesterol levels are significant and may have a profound impact on population risk of CHD if consumption of plant stanol esters becomes widespread. The agency has determined that issuance of an interim final rule is necessary to enable consumers to be informed promptly and effectively of this important new knowledge regarding the nutritional and health benefits of plant sterol/stanol esters. The agency has also determined that issuance of an interim final rule is necessary to ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible.

65 Fed. Reg. at 54714; *see also* 75 Fed. Reg. at 76548-49; 21 C.F.R. § 101.83(b)(1).

FDA's declaration that "the act's enforcement provisions commit complete discretion to the Secretary of Health and Human Services"[30] to summarily declare illegal products made lawful over eight years ago stands the Administrative Procedure Act and the Constitutional concept of due process on their head. FDA cannot create enforcement discretion "Wonderland" and then administer it like the Queen of Hearts.

An agency decision will be set aside under the Administrative Procedure Act (APA) if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). FDA's termination of enforcement discretion runs afoul of the APA in at least two respects.

First, FDA's termination decision, effectively banning the CHD claim on dietary supplements containing free form phytosterols, imposes different standards on the dietary supplement and conventional food industries, in contravention of the APA. FDA has an absolute obligation to apply its regulatory standards even-handedly among all similarly situated firms. In *Bracco Diagnostics, Inc. v. Shalala*, plaintiffs challenged FDA's decision to subject their applications for injectable contrast imaging agents to different, more onerous, standards of review than were applied to another similar product. The court granted plaintiffs' motions for preliminary injunction, holding that FDA's unexplained failure to treat similarly situated products in the same way was arbitrary and capricious in violation of the APA. The court determined that FDA could either regulate the products as drugs or devices, but could not impose disparate standards on the two products.

> What the FDA is not free to do, however, is to treat them dissimilarly and to permit two sets of similar products to run down two separate tracks, one more treacherous than the other, for no apparent reason.

963 F.Supp. 20, 27-8 (D.D.C. 1997).[31]

Despite the court's clear holding in *Bracco v. Shalala,* FDA has imposed its health claim standard for phytosterols in a highly disparate manner, forcing the dietary supplement industry down a "more treacherous" and onerous track than producers of conventional foods. FDA's summary termination of the 2003 letters and new policy of enforcement discretion for products formulated and labeled in accordance with the proposed rule amounts to a requirement for clinical data specifically establishing the efficacy of free phytosterols when

---

[30] 75 Fed. Reg. at 76546.

[31] *See also United States v. Diapulse Corp.*, 748 F.2d 56 (2d Cir. 1984) (holding that FDA must "apply its scientific conclusions evenhandedly" and cannot "'grant to one person the right to do that which it denies to another similarly situated'." (citation omitted)); *Allergan, Inc. v. Shalala,* No. 94-1223, 6 Food and Drug Rep. 389 (D.D.C. Nov. 10, 1994) (holding that FDA enforcement must be conducted in a fair and even handed manner against similarly situated parties; otherwise agency conduct is arbitrary and capricious in violation of the APA); *Green Country Mobilephone, Inc. v. FCC*, 765 F.2d 235, 237-38 (D.C. Cir. 1985) ("once an agency agrees to allow exceptions to a rule, it must provide a rational explanation if it later refuses to allow exceptions in cases that appear similar").

ingested in supplement form. Yet, the very same policy allows use the CHD health claim on all types of conventional foods containing either esterified or free forms of phytosterols, even though there is *no* clinical data establishing the cholesterol-lowering efficacy of phytosterols in each of the many categories of conventional foods, much less clinical trial data establishing efficacy of *both* the esterified and free forms in each of these food categories. By way of example, FDA regulations establish forty-three separate categories of conventional foods, for purposes of food additive regulation. 21 C.F.R. § 170.3(n)(1) – (43).[32] The specific dietary interventions in the studies relied upon by FDA fall into only a handful of these food categories,[33] but the Agency has not chosen to limit the health claim to those specific food categories studied. FDA has also not used those particular phytosterol studies finding no cholesterol lowering effect to conclude that certain food categories should be barred from making the health claim. Instead, at least with respect to conventional foods, FDA has proposed a broad approach, authorizing the health claim based on the wealth of evidence establishing that phytosterols reduce cholesterol. FDA's summary determination and proposal to take a contrary approach for dietary supplements which, unlike many categories of conventional foods, have been the subject of successful clinical trials, is arbitrary and capricious.

Second, courts have long held that agency action based on change in settled policy is arbitrary and capricious unless the agency formally announces the change in policy and supplies a reasoned explanation for the change of course. In *FCC vs. Fox Television Stations, Inc*. 556 U.S. 502, 129 S.Ct. 1800 (2009) the Supreme Court explained this requirement, emphasizing that an agency must provide a reasoned explanation for a change in policy and must taken into account any reliance on the former policy:

> To be sure, the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position. An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books. See *United States* v. *Nixon*, 418 U. S. 683, 696 (1974). And of course the agency must show that there are good reasons for the new policy. But it need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates. This means that the agency need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate. Sometimes it must—when, for example, its new policy rests upon factual findings that contradict

---

[32] The food additive regulations represent just one example of the manner in which conventional foods could be categorized. Other types of categorization schemes might be more appropriate, were the Agency to move to a food-category-based model for the CHD health claim.

[33] Table I in the proposed rule identifies the particular type of phytosterol-containing conventional food tested in each of the studies relied upon by the Agency. 75 Fed. Reg. at 76556-69.

> those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account. *Smiley* v. *Citibank (South Dakota), N. A.*, 517 U. S. 735, 742 (1996). It would be arbitrary or capricious to ignore such matters. In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.

129 S.Ct. at 1811.[34]

Agency action is likewise arbitrary and capricious if the agency failed to consider the relevant factors or made a clear error of judgment. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402,416 (1971) (citations omitted). The APA requires an agency to "examine the relevant data and articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983).

Here, the agency has revoked enforcement discretion that it originally said would continue until issuance of a final rule based solely on a "tentative" conclusion that the Agency reached after reviewing a docket on which the comment period closed over nine years ago.[35] FDA offered no explanation for the decision to disregard its express commitment to continue enforcement discretion until issuance of the final rule, nor does the termination reflect any Agency consideration of the tremendous impact of declaring products relying on the enforcement discretion letters unlawful. The record is devoid of any Agency acknowledgement that industry had, for almost eight years, relied upon both the eligibility criteria stated in the 2003 enforcement discretion letter and the promise that those criteria would remain in effect until publication of the final rule. There is no meaningful analysis regarding the nature of the products manufactured and sold under those criteria or the economic impact of the action.[36] FDA's approach upsets well-founded expectations and

---

[34] *See also Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 57 (1983) ("an agency changing its course by rescinding a rule must supply a reasoned analysis"); *Bell Atlantic Tel. Co. v. FCC*, 206 F.3d 1, 8 (D.C. Cir. 2000) (vacating and remanding because of commission's failure to provide "real explanation" for change in policy).

[35] The comment period closed in November 2001. *Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease,* 66 Fed. Reg. 50824 (Oct. 5, 2001).

[36] The proposed rule states "FDA does not have any information on how many labels would have to be redesigned, or the number of products that would be reformulated because of the proposed rule." 75 Fed. Reg. at 76547. Despite this admitted total lack of relevant information, the preamble includes several faulty assumptions concerning the number of dietary supplements impacted by the action. *Id.* at 76547-48. One need only look at the opening sentence of FDA's dietary supplement discussion to appreciate the significant flaws in the Agency's "analysis" – that sentence acknowledges that FDA based its supplement industry estimates on data from a report that issued in 1999, *four years before* issuance of the enforcement discretion letters permitting use of the CHD claim on dietary supplements and one year before publication of the IFR that permitted the claim on a narrow category of conventional foods. *Id.* at 76547.

imposes this damage on the dietary supplement industry based on what the FDA admits is merely a "tentative" conclusion. This is the essence of arbitrary and capricious action; particularly so given that FDA reached its "tentative" conclusion based on an extremely outdated docket and without the benefit of comment on this unexpected change concerning eligibility of dietary supplements containing free phytosterols to bear the health claim.[37]

(3) Proposed Cure

CRN believes the following actions can help mitigate the infirmities and potentially irreparable damage associated with the current approach and allow for an orderly transition to dietary supplements labeled and formulated in accordance with the criteria that are established for the CHD health claim when 21 C.F.R. § 101.83 is made final.

The optimal approach – and the only approach that is consistent with the procedural and due process requirements of the Administrative Procedure Act on the Agency's exercise of enforcement discretion – is for the Agency to announce an extension of the time during which it will continue to exercise enforcement discretion under the 2003 letters until such time as the CHD final rule becomes effective. Extending enforcement discretion under the 2003 letters in this manner would allow companies to make changes to their products in an orderly fashion in a manner that coincides with retailer planogram changes, minimizing product discontinuations and costly returns. Equally important, companies would be assured that only one reformulation and label change will be required, minimizing costs and marketplace disruptions associated with successive changes.[38]

---

[37] According to the preamble to the proposed rule, FDA considered those intervention studies published since 2000 that satisfied FDA criteria and were located by FDA and the Agency for Healthcare, Research and Quality. 75 Fed. Reg. at 76528-29. Unpublished studies and studies too new to have yet published were necessarily excluded.

[38] At a bare minimum, FDA should continue to exercise enforcement discretion until the next Uniform Compliance date for food of January 1, 2014. *Uniform Compliance Date for Food Labeling Regulations,* 75 Fed. Reg. 78155 (12/15/2010). While discontinuation of enforcement discretion was first announced at the tail end of the previous uniform compliance date period, it is appropriate to use the current date of January 1, 2014 because companies may reformulate and relabel in response to FDA's announcement, and reformulation presents time consuming technical challenges not associated with relabeling.

FDA establishes uniform compliance dates to ensure that label changes take effect in a timely manner, while minimizing the economic impact of changes, were companies required to respond separately to each labeling change as it occurs. Internal company labeling procedures already revolve around established uniform compliance dates; accordingly, establishing the same date for health claim-related changes eases the burden on companies. The January 1, 2014 date would also be a much more reasonable target than February 22, 2012 for those companies seeking to ship newly reformulated and/or relabled product in a manner that coincides with retailers' planogram change schedules.

We note that the Agency has allowed product labeled before the effective date of a label change to be sold through after that date.[39] CRN requests that the Agency clarify that it intends to continue this practice with respect to the lifting of enforcement discretion. Specifically, if the Agency declines to change the February 21, 2012 date, the Agency should clarify that enforcement discretion will extend to products labeled prior to that date, even if shipped after that date. This clarification is essential to enable affected companies to manage inventory in a reasonable manner that avoids costly returns, destruction of printed labels, and market interruptions associated with the inability to launch reformulated/relabeled product in advance of this date.

Respectfully submitted,

Council for Responsible Nutrition
Vice President, Scientific and Regulatory Affairs

---

[39] *See, e.g., Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation*, 62 Fed. Reg. 49826, 49842-43 (Sept. 23, 1997); Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance (Oct. 2006), available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059116.htm.