

products collected between November 1999 and February 2000, including information from labels of products purchased from retail establishments and information taken from mail-order catalogs and Internet sites. In selecting dietary supplement products, RTI used the definition of "dietary supplement" from the Dietary Supplement Health and Education Act of 1994 (Public Law 103-417), which includes, among other things, vitamins, minerals, herbs and other botanicals, and amino acids (section 201(ff) of the act (21 U.S.C. 321(ff))). RTI included only information available to consumers at the point-of-sale.

The RTI sampling procedure was designed to include the maximum number of different products and different ingredients, which led to a relatively greater variety of products than would be representative of consumer purchase patterns. In order to get as many products as possible with different characteristics, RTI over-sampled health food stores. This led to an over-sample of herbals and botanicals, which, according to the database, are more likely to contain sodium. Thus, the design of the survey (e.g., how the products were sampled) would be likely to lead to an overestimate of the percentage of dietary supplements that contain sodium.

FDA recognizes that the RTI database cannot be used to make precise, quantitative estimates of dietary supplement characteristics; nevertheless, in the absence of other available data, FDA used these data to estimate the proportion of dietary supplement products that might be affected by permitting the second-tier sodium requirements to take effect for the term "healthy." FDA found these data useful as they allow for a conservative estimate of the impact of the proposed rule on dietary supplement products, because it is likely that a smaller proportion of products will be impacted than the proportion calculated under this assessment. FDA requests comments on this assessment of dietary supplement products that may contain sodium and welcomes any additional available data concerning dietary supplements.

To estimate the proportion of dietary supplement products in this dataset that contain sodium, FDA reviewed the ingredient information in the RTI database, which includes information on the first 30 ingredients contained in the product. The agency searched for ingredients containing either the term "salt" (sodium chloride), the most common source of sodium in foods, or the term "sodium" (e.g., sodium

benzoate). This process would not have identified ingredients containing other sources of sodium (i.e., ingredients that include sodium-containing components that do not include sodium in their name). FDA identified 133 dietary supplement products in this dataset (4 percent) containing the terms "sodium" or "salt" in one or more of the first 30 ingredients.

To estimate the proportion of dietary supplement products in this dataset that may contain sodium and also bear a claim for "healthy," FDA reviewed the database for brand names, product names, and claims on the 133 dietary supplement products. The agency found 1 product with the term "health" in the brand name, 1 product with the term "health" in the product name and also in the product claim, and 32 products with claims containing the terms "health" or "healthy." Most of the claims on the products were structure/function claims under 21 CFR 101.93(f) (e.g., "Helps promote bone health") or health claims under 21 CFR 101.14 (e.g., "Enough calcium helps maintain good bone health and reduce the risk of osteoporosis"); such claims would not be considered "healthy" claims under § 101.65(d). FDA did, however, identify 11 products in this dataset (0.4 percent) bearing "healthy" claims under § 101.65(d) either as part of the brand or product name or as a separate claim on the product (Ref. 8). Since this dataset over-sampled products that are more likely to contain sodium, it is likely that less than one percent of dietary supplement products would potentially be affected by requiring individual foods bearing the claim "healthy" to meet the proposed, second-tier sodium requirement.

In addition to the relatively small proportion of dietary supplement products overall that contain sodium and bear "healthy" claims, judging from our sample of 11 products in this dataset, the amount of sodium contained in these dietary supplement products is probably quite limited for a variety of reasons. Since ingredients are listed on product labels in descending order of predominance by weight (21 CFR 101.4), the amount of sodium in dietary supplement products is likely to be small because the sodium-containing ingredients tend to be minor ingredients (Ref. 8). Furthermore, dietary supplement products tend to have small serving sizes (e.g., pills, capsules, packets, teaspoons).

In addition, only a small proportion of most sodium-containing dietary supplement ingredients is actually sodium. For example, salt (sodium chloride) is the ingredient with the

highest proportion of sodium, about 40 percent. The agency calculated the percentage of sodium for the other sodium-containing ingredients about which the agency had sufficient information, and these other ingredients contain a significantly smaller proportion of sodium, varying from around 12 to 27 percent (Ref. 8). Thus, dietary supplements are likely to contain limited amounts of sodium because the sodium-containing ingredients themselves contain limited amounts of sodium.

An example may help to illustrate how the two factors discussed work in tandem to limit the amount of sodium in dietary supplement products. Only one of the 11 products bearing a healthy claim listed salt as an ingredient. This product lists salt as the 14th ingredient in order of predominance. Thus, the amount of sodium in that particular dietary supplement product is likely to be small since it is only 40 percent of a very minor ingredient.

Also, unlike conventional food products that use salt to improve taste, dietary supplement products are taken to supplement the diet and are not generally consumed for their taste. Most dietary supplement products are in pill, tablet, or capsule form (Ref. 8) and are swallowed without chewing. Therefore, since taste is not a factor for most of these products, manufacturers selecting ingredients for their dietary supplement products can easily avoid sodium-containing ingredients if they are trying to limit the sodium content in order to make "healthy" claims.

Thus, given the foregoing information and observations based on the RTI data sample, FDA does not anticipate that the sodium content of dietary supplement products will have an impact on their ability to qualify for "healthy" claims. Furthermore, the agency received no comments to the ANPRM from dietary supplement manufacturers indicating that dietary supplement products currently making "healthy" claims would be affected. Thus, FDA does not believe that changing the sodium content requirement for individual foods bearing "healthy" claims will adversely affect dietary supplement manufacturers wishing to make such claims. The agency requests comments on whether its assessment regarding dietary supplement products is accurate and whether or not the availability of dietary supplement products bearing a "healthy" claim would be adversely affected by this rulemaking. FDA requests specific information on such products, including the numbers and types of products affected, the current