



founded 1881

April 30, 2008

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Advanced notice of proposed rulemaking for Food Labeling: Revision of Reference Values and Mandatory Nutrients. 72 Fed. Reg. 62149 - 62175 (November 2, 2007). Docket No. FDA-2008-N- 0040 [Formerly Docket No. 2006N-0168; RIN 0910-ZA30]

Dear Sir or Madam:

Members of the Consumer Healthcare Products Association (CHPA) Dietary Supplements Committee appreciate the opportunity to provide comments on the advanced notice of proposed rulemaking (ANPR) for revisions to food labeling reference values and mandatory nutrients (72 *Federal Register* 62149-62175). CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplements and over-the-counter medicines. Our comments will address the approach for setting the Daily Values (DVs).

Approach for Setting the Daily Values (DVs)

The United States Food and Drug Administration (FDA) inquired about whether DVs should be set based on estimated average requirements (EARs) for those nutrients for which an EAR has been set or whether DVs should be set based on recommended dietary allowances (RDAs) for those nutrients for which an RDA exists. Additionally, the agency inquired if DVs should be set based on population-coverage or population-weighted EARs and/or RDAs. The CHPA DSC strongly recommends that the DVs continue to be based on RDAs, not EARs. Furthermore, these DVs should be determined based on population-coverage RDAs as opposed to using population-weighted RDAs. For those nutrients without an EAR, daily values should be based on population-coverage adequate intakes (AIs).

One of the goals of the FDA should be to ensure that the greatest number of consumers is likely to meet their nutritional needs. To accomplish this goal, use of population-coverage RDAs should continue to be the basis for establishing DVs. RDAs are determined on a basis of the mean of the population intake for a given nutrient plus two standard deviation units. This

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approach results in appropriate nutritional requirements for approximately 98% of the population. The EARs, however, are defined as intakes covering the nutritional needs for 50% of the population which, by definition, means that 50% of the population will *not* have their nutritional needs met using the EAR approach. Additionally, use of the population-coverage approach is based on the entire target population, not on weighted averages for various population subgroups. As noted by Kretser (2006), not only would a population-weighted EAR result in only 50% of the population meeting their nutritional adequacy at any given time, but the weighted averages would result in even lower EARs or AIs for some nutrients as the reference population (*i.e.*, United States and Canadian populations) ages.¹

There may be concern that in certain cases using a population-coverage based RDA might result in overconsumption of some nutrients. However, in the case of vitamins and minerals, the RDA values do not approach the tolerable upper intake levels (UL) for these substances.^{2,3,4} It should be noted that these ULs are based on total intake from food, water, and supplements, except in the case of magnesium where the UL is based on intake of pharmacological agents and for which intake from food and water is excluded.^{2,3,4} As reflected in Tables 1 and 2 below, depending on the methodology used, increases to the current DVs would occur in relatively few instances. Additionally, these potential increases would still be within the UL for those nutrients for which an upper limit has been established.^{2,3,4} In 2006, Murphy and Barr supported the use of the RDA as the basis for DVs for several reasons, including the potential benefit of using the RDA likely exceeds the potential risk of a higher prevalence of excessive intakes.⁵ The authors also suggested that if manufacturers reduce fortification levels and the levels of nutrients contained in supplements, dietary intakes are likely to decline.⁵ This potential decrease may not be desirable for nutrients that are underconsumed.

In addition to the scientific and public health arguments outlined above for the continued use of basing DVs on RDAs, the agency also should consider the importance of conveying a consistent message about dietary goals amongst the various educational tools currently available to consumers (*e.g.*, Food Guide Pyramid and Dietary Guidelines for Americans 2005).^{6,7} Daily Values have been based on RDAs for years. However, a recent study by Borra (2006) found that in focus groups, many were confused about the percent DV even though these consumers were aware of the food label information.⁸ Changing the basis for setting DVs could potentially make

¹ Kretser, A.J., The new Dietary Reference Intakes in food labeling: the food industry's perspective. *Am. J. Clin. Nutr.* (2006); 83(suppl):1231S-1234S.

² Institute of Medicine (IOM) Dietary Reference Intakes Summary Tables (Vitamins Table). Retrieved on February 26, 2008, from <http://www.iom.edu/Object.File/Master/7/296/webtablevitamins.pdf>.

³ Institute of Medicine (IOM) Dietary Reference Intakes Summary Tables (Elements Table). Retrieved on February 26, 2008, from <http://www.iom.edu/Object.File/Master/7/294/Webtableminerals.pdf>.

⁴ Institute of Medicine (IOM) Dietary Reference Intakes Summary Tables (Summary Tables). Retrieved on February 26, 2008, from <http://www.iom.edu/Object.File/Master/45/134/Dietary%20Reference%20Intakes%20Tables.pdf>.

⁵ Murphy, S.P. and Barr, S.I., Recommended Dietary Allowances should be used to set Daily Values for nutrition labeling. *Am. J. Clin. Nutr.* (2006); 83(suppl): 1223S-1227S.

⁶ United States Agriculture Department (USDA), Mypyramid.gov. Retrieved on February 26, 2008, from <http://www.mypyramid.gov/>.

⁷ United States Department of Health and Human Services, Dietary Guidelines for Americans 2005. Retrieved on February 26, 2008, from <http://www.fda.gov/ohrms/dockets/dockets/06q0458/06q-0458-sup0001-02.pdf>.

⁸ Borra, S., Consumer perspectives on food labels. *Am. J. Clin. Nutr.* (2006); 83(suppl): 1235S.

years of consumer education meaningless.⁹ New programs would be required to re-educate consumers about the appropriate use of the nutrition information at a substantial cost in time and resources.

Finally, there is a risk of diminishing consumer confidence in the ability of FDA and industry to convey nutritional information if the basis for setting DVs is modified. The proposed changes for establishing DVs would result in different levels for many, if not all, nutrients listed on the nutrition and/or supplement facts panels (see Tables 1 and 2 below). The magnitude of these changes would be greatest using the EAR as a basis for revisions, particularly the population-weighted EAR. It is unclear whether or not consumers would be cognizant of any changes to the DVs listed on the food labels. However, those that *are* aware of the changes may question the reliability of the label information (and past label information) as only the standard-setting methodology, and not necessarily new scientific data, would be the basis for much of the change.

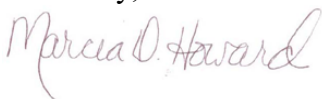
Summary

CHPA DSC members appreciate the FDA's consideration of their comments on the proposed ANPR for revisions to food labeling reference values and mandatory nutrients. We hope the agency accepts our proposal to base Daily Values on population-coverage RDAs (or population-coverage AIs for those nutrients for which RDAs have not been established). In summary, CHPA DSC members believe this approach would:

- provide appropriate guidance on nutritional requirements to the greatest number of consumers;
- minimize possible confusion amongst consumers about the meaning and proper use of DVs due to potential changes in the label values;
- minimize re-education programs needed for consumers, teachers, and healthcare professionals if the DVs were modified based on changes to standard-setting procedures; and
- maintain public confidence in the ability of FDA and industry to appropriately interpret, utilize, and convey the best available scientific data on nutrition.

Thank you for considering our position. Please contact me if you have any questions.

Sincerely,



Marcia D. Howard, Ph.D.
Director, Regulatory & Scientific Affairs

MDH/04-30-08

⁹ United States Food and Drug Administration (FDA), How to Understand and Use the Nutrition Facts Label. Retrieved April 20, 2008, from <http://www.cfsan.fda.gov/~dms/foodlab.html>.

Table 1: Current and projected DVs using population-weighted RDAs and EARs as basis for determining the DVs.

Nutrient	Current DV (100%)	New DVs (100%) (Highest RDA)	New DVs (100%) (Weighted RDA)	New DVs (100%) (Highest EAR)	New DVs (100%) (Weighted EAR)
Vitamin A IU	5000	3000	2511	2100	1768
Vitamin C mg	60	90	74	75	61
Vitamin E IU ¹⁰	30	22.4	20.9	17.9	16.4
Thiamin mg	1.5	1.2	1.1	1	0.9
Riboflavin mg	1.7	1.3	1.1	1.1	0.9
Niacin mg	20	16	14	12	11
Vitamin B6 mg	2	1.7	1.3	1.4	1.1
Folate µg	400	400	378	330	304
Vitamin B12 µg	6	2.4	2.3	2	1.9
Iron mg	18	18	11	8	6
Phosphorus mg	1000	1250	769	1055	640
Iodine µg	150	150	144	95	91
Magnesium mg	400	420	341	350	283
Zinc mg	15	11	9.1	9.4	7.7
Selenium µg	70	55	52	45	43
Copper mg	2	0.9	0.8	0.7	0.7
Molybdenum µg	75	45	45	42	34

Table 1 reflects modifications to Table 11A in the *Federal Register* notice (pages 62162 – 62163) comparing the current Daily Values (DVs) with DVs based on population-weighted recommended daily allowances (RDAs) and estimated average requirement (EARs).¹¹ Except for the current DV which was provided in international units (IU) in Table 11A, Vitamin E values were converted from mg α -tocopherol to IU using the conversion factor provided by the National Institutes of Health (NIH) Office of Dietary Supplements (1 mg α -tocopherol Vitamin E = 1.49 IU).¹⁰ Projected DVs calculated according to the highest RDA are represented as follows: values in green are unchanged from current DVs, values listed in blue represent a projected decrease from current DVs, and values listed in black italics represent a projected increase from current DVs.

¹⁰ National Institute of Health (NIH) Office of Dietary Supplements Vitamin E Dietary Supplement Fact Sheet. Retrieved April 19, 2008, from <http://ods.od.nih.gov/factsheets/vitamine.asp>.

¹¹ *Federal Register* notice volume 72, No. 212, pages 62149 - 62175 (November 2, 2007). Advance notice of proposed rulemaking. Food Labeling: Revision of Reference Values and Mandatory Nutrients. Retrieved on April 16, 2008, from <http://www.fda.gov/OHRMS/DOCKETS/98fr/07-5440.pdf>.

Table 2: Current and projected DVs using highest and weighted AIs as basis for determination of the DVs.

Nutrient	Current DV (100%)	New DVs (100%) (Highest AI)	New DVs (100% DV) (Weighted AI)
Vitamin D IU	400	<i>600</i>	280
Vitamin K µg	80	<i>120</i>	95
Biotin mcg	300	30	28
Pantothenic Acid mg	10	5	5
Calcium mg	1000	<i>1300</i>	1091
Manganese mg	2	<i>2.3</i>	1.9
Chromium µg	120	35	27
Chloride mg	3400	2300	2150
Potassium mg	3500	<i>4700</i>	4622
Choline mg	550	550	460

Table 2 reflects modifications to Table 11B in the *Federal Register* notice (page 62163) comparing the current Daily Values (DV) with DVs based the highest and weighted adequate intakes (AIs).¹¹ Projected DVs based on the highest AI are represented as follows: values in green are unchanged from current DVs, values listed in blue represent a projected decrease from current DVs, and values listed in black italics represent a projected increase from current DVs.