''high potency'' claim. The exclusion of these nutrients will not necessarily help consumers to engage in healthy dietary practices.

Having tentatively concluded that some nutrients may be present in a ''high potency'' multinutrient dietary supplement at less than 100 percent of the RDI or DRV, the agency must determine what percentage of nutrients must be present in the product at 100 percent of the RDI or DRV for the product to qualify to make a ''high potency'' claim. A logical starting point is determination of: (1) How many nutrients have had RDI's and DRV's established for them, and (2) of those nutrients, how many cannot, or should not, be expected to be present at 100 percent of the RDI or DRV for technological reasons or because of public health concerns.

In the RDI/DRV final rules published on January 6, 1993 (58 FR 2206), FDA established RDI's in § 101.9(c)(8)(iv) for 19 vitamins and minerals (i.e., vitamin A, vitamin C, calcium, iron, vitamin D, vitamin E, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, and copper) and DRV's in § 101.9(c)(9) for eight nutrients (i.e., total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, and protein). In addition, in a companion document entitled ''Food Labeling: Reference Daily Intakes'' published elsewhere in this issue of the Federal Register, FDA is establishing RDI's for six additional vitamins and minerals (i.e., vitamin K, selenium, chloride, manganese, chromium, molybdenum). Thus, there are a total of 33 nutrients for which RDI's or DRV's have been established. Of these 33 nutrients, 4 (i.e., calcium, phosphorus, magnesium, and fiber) have already been mentioned as being difficult to include in dietary supplements in amounts equal to 100 percent of the DV because of technological problems related to their bulk.

Other nutrients that should not be expected to be present at 100 percent of the DV include total fat, saturated fat, cholesterol, and sodium. It would be nonsensical to associate the term ''high potency'' with these nutrients because, as discussed earlier, dietary guidelines recommend that intake of these nutrients be limited or moderated in the diet (Ref. 8). In addition, it is not useful to include chloride at high levels in multinutrient supplements. Salt is the primary source of dietary chloride, and the typical American diet already contains significant levels of chloride because of high intakes of salt (Refs. 6 and 10). (See the discussion of the exemption of chloride in § 101.3(e)(4)(ii) in the final rule entitled ''Food Labeling: Reference Daily Intakes'' published elsewhere in this issue of the Federal Register.) Lastly, as discussed earlier, potassium would be considered a drug at such high levels, so it should not be included in dietary supplements at 100 percent of the DRV.

Therefore, FDA tentatively concludes that there are 11 nutrients (calcium, phosphorus, magnesium, dietary fiber, total carbohydrate, total fat, saturated fat, cholesterol, sodium, chloride, and potassium) for which it would be impracticable or imprudent to require that, when present in a multinutrient product, they be present at levels at or above 100 percent of the RDI or DRV for the product to qualify for the use of the nutrient content claim ''high potency.'' This amounts to one-third of the nutrients for which RDI's and DRV's have been established (11 out of 33 nutrients). Accordingly, the agency believes that it would be reasonable to expect that the remaining two-thirds of the nutrients for which RDI's and DRV's have been established could be present at 100 percent of the RDI or DRV in a ''high potency'' multinutrient dietary supplement product that contained all 33 nutrients for which RDI's and DRV's have been established.

FDA finds merit in the comment that suggested that not all nutrients need be present at or above the RDI for the product to qualify for the claim. This comment suggests that the agency establish a standard for ''high potency'' that applies to supplements that do not contain all of the 33 nutrients for which RDI's and DRV's have been established as well as those that do. FDA tentatively concludes that two-thirds represents a reasonable standard; it provides flexibility for supplements that do not contain all 33 nutrients, and it provides a consistent standard for all supplement products. Finally, it is a familiar fraction that is easy to use. With a two-thirds standard, the manufacturer would have latitude to decide, in formulating a product that will qualify to bear a ''high potency'' claim, which nutrients to include at 100 percent of the RDI or DRV. The alternative would be to require that any of the 22 nutrients that can be present at 100 percent of the DRV be present at that level if the supplement is to bear a ''high potency'' claim. FDA is concerned, however, that such a requirement would set too high a standard and not provide appropriate flexibility. Comment is requested on the agency's tentative conclusion.

Based on these factors, the agency is proposing in § 101.54(f)(2) that the term ''high potency'' may be used on the label or in the labeling of a dietary supplement to describe the product (e.g., ''High potency multivitamin, multimineral dietary supplement tablets'') if the product contains 100 percent or more of the RDI or DRV for at least two-thirds of the vitamins, minerals, protein, and dietary fiber present in the product. This proposed requirement will mean that each nutrient (i.e., vitamin, mineral, protein, or dietary fiber) in a dietary supplement containing only one or two nutrients will have to be present at 100 percent or more of the RDI or DRV because two-thirds of one or two nutrients does not result in a whole number that is different from the original number (e.g., 2 times 2/3 equals 1.34; the product 1.34 indicates that more than one nutrient is needed to meet the criterion; therefore both nutrients would have to meet or exceed 100 percent of the RDI or DRV).

The agency recognizes that dietary supplements that consist of an assortment of dietary ingredients are widely available in the marketplace. FDA agrees with the comment that stated that the presence or absence of dietary ingredients for which RDI's or DRV's have not been established (e.g., omega-3 fatty acids, choline, boron) (hereinafter referred to as ''other dietary ingredients'') should not affect the claim so long as those nutrients with RDI's or DRV's are present at levels required for the claim. The presence or absence of other dietary ingredients for which RDI's and DRV's have not been established is immaterial to the claim, and, therefore, the agency finds no basis for proposing alternate requirements for such products. It is important to note that because the definition that FDA is proposing is based on the presence of a nutrient at 100 percent of the RDI or DRV, dietary supplements that do not contain nutrients for which RDI's or DRV's have been established will not be able to use the term ''high potency.''

c. *Disclosure requirement.* One comment stated that the label of a ''high potency'' multivitamin product should disclose the names or number of nutrients that are present at high levels. For example, the comment suggested that the label could carry an asterisk next to the claim, with the following disclosure: ''contains high levels of [number] vitamins.''

The agency rejects this comment. The agency tentatively concludes that such a requirement for the label or labeling of a ''high potency'' multinutrient dietary supplement is not needed to prevent consumers from being misled by the claim. Section 403(s) of the act, added by the DSHEA, states that a dietary