flexibility indicated and have the nutrition label precede the ingredient statement horizontally.

FDA is proposing in § 101.4(g) to require that the ingredient list be preceded by the word ''Ingredients,'' unless some ingredients (i.e., dietary ingredients or sources of dietary ingredients) are identified within the nutrition label, in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words ''Other Ingredients.'' FDA is proposing that the word ''Ingredients'' precede the list of ingredients so that the appearance of this aspect of the label is as consistent as possible with the labeling of other foods. As stated above, consistency in the presentation of food labeling information enhances consumer understanding. FDA is proposing that the term ''Other Ingredients'' be used to indicate to consumers that some ingredient information appears in the nutrition information that precedes the ingredient list.

Proposed § 101.4(g) also requires that ingredients that are not, or do not contain, dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, be listed in the ingredient statement. The agency acknowledges that a 1942 Trade Correspondence identified as TC-387 (Ref. 5) exempted ''excipients, fillers, binders, and other fabricating ingredients'' from complete ingredient declaration when used in manufacturing dietary supplements (i.e., labels could list ''excipients'' rather than listing excipients by name). As explained in the final rule on ingredient labeling (58 FR 2850 at 2869, January 6, 1993), however, although TC–387 has not been officially revoked, its position has been overturned by more recent agency statements of policy on this subject, as expressed in the Federal Register of August 2, 1973 (38 FR 20730), the Federal Register of March 16, 1979 (44 FR 16005), and in subsequent correspondence with industry (Refs. 6 and 7). These more recent statements of policy make it clear that the label for dietary supplements must contain a list of nutrients and a full statement of ingredients (except those exempted under section 403(i)(2) of the act), declared by their common or usual name. At this time, because TC–387 expresses a position contrary to the agency's policy since 1973, the agency is revoking TC–387.

In proposed § 101.36(d)(1), the agency is providing that source ingredients in dietary supplements be identified in accordance with § 101.4 that addresses ingredient labeling for all food products. A basic requirement of this section is that ingredients be listed by common or usual name (see § 101.4(a)). To help ensure correct identification of herbs or other botanicals, including algae and fungi, the agency is proposing in § 101.4(h)(1) that the botanical name in Latin binomial form be included in parentheses following the common or usual name. Proper scientific reference to a species is done with its Latin binomial, representing the genus in which the species has been placed and the species epithet, followed by the designation of the author or authors who published the name. When an author has moved a species from one genus to another, the name of the original author is enclosed in parentheses followed by the author who made the transfer. To ensure that there is consistency and clarity in declaration, the agency is proposing that any botanical name declared should be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature* (Ref. 8). The agency requests comments on this issue.

FDA recognizes that it is possible to have more than one acceptable botanical name in Latin form (i.e., a synonym). FDA advises manufacturers to choose the name that is most currently used in commerce and in appropriate references and, in cases of confusion, to consult with the agency.

Section 403(s)(2)(C) of the act, which was added by the DSHEA, provides that a dietary supplement is misbranded if it contains an herb or other botanical, and the label or labeling of the supplement fails to identify any part of the plant from which the dietary ingredient is derived. Accordingly, FDA is proposing in § 101.4(h)(2) that this information be provided as part of the required ingredient information. While nothing in the act requires that information on the part of the plant from which a botanical is derived be in a particular place on the label, FDA tentatively finds that it would be in the interest of consumers if the information were presented as part of the ingredient information because it would ensure that all the identifying information about the herb or other botanical (i.e., common or usual name, Latin binomial, and part of plant from which it is derived) is presented in one place.

FDA is proposing in § 101.4(h)(2) to require that the part or parts of the plant (e.g., leaf, flower, root, fruit, seed, or bark) be presented in parentheses immediately following the Latin binomial name of the botanical ingredient. This manner of presentation is consistent with the way other clarifying information is presented in ingredient statements (see § 101.4(d) and (e)). Whenever information on the part of the plant is presented on the label or in labeling, FDA is proposing to require that the name of the part of the plant be expressed in English. FDA tentatively concludes that pharmaceutical names such as ''flos'' for flower, ''radix'' for root, or ''fructus'' for fruit should not be used because they are not recognized in botanical nomenclature, and their meanings would not be commonly understood by American consumers. When an entire plant is used, the label should specify ''entire plant'' to meet the requirements of the act.

The requirements of proposed § 101.4(h)(1) and (2) apply whether the botanical ingredient is listed in an ingredient statement or in the nutrition label as provided by proposed § 101.36(d). However, inasmuch as section 403(i) of the act does not require ingredients to be listed when the food contains only one ingredient, FDA is proposing in § 101.36(h)(3) that for single-ingredient dietary supplements, the Latin binomial name and the part of the plant from which the dietary ingredient is derived may be prominently placed on the principal display panel or the information panel, or included in the nutrition label.

In proposed § 101.36(d)(2), the agency is requiring that when two or more sources are listed within a parentheses, they be listed in descending order by weight, which is consistent with the way ingredients are to be listed in § 101.4. This listing of ingredients in descending order by weight will provide consumers with an indication of the relative amount of each ingredient in the absence of information on their actual amounts. As discussed elsewhere in this preamble, the agency is not proposing that other dietary ingredients be listed in descending order by weight because the amounts of these dietary ingredients are required to be listed.

In proposed § 101.36(d)(3), the agency is providing that representations that a source ingredient conforms to an official compendium may be included such as by a reference to the compendium (e.g., ''Calcium (from calcium carbonate USP)''). This provision is consistent with the discussion in the preamble of the 1994 dietary supplement final rule that explained that the agency would not object to the use of the U.S.P. symbol in the ingredient list to identify those ingredients that are U.S.P. grade (59 FR 354 at 369), as long as the ingredients meet FDA's compliance requirements in § 101.9(g)(4), which are discussed below under *Compliance and*