

Was the dietary ingredient marketed in the U.S. before October 15, 1994? (See IV.A.5 and IV.A.8.)

Yes

Have there been any proposed or implemented changes to the manufacturing process for the dietary ingredient?

Yes

Does the new manufacturing process change the identity of the ingredient (e.g., different chemical structure or composition, use of extraction, use of a different starting material, such as a different part of a botanical)? (See IV.A.11.)

Yes

Was the dietary ingredient, in its revised form, marketed as a dietary ingredient in the U.S.A. before October 15, 1994?

Yes

Not Sure

No

Pre-DSHEA Dietary Ingredient. **No NDI notification required.** Adulteration standard in 21 USC 342 (f)(1)(B)) does not apply.

The manufacturing change may have created an NDI. NDI notification may be required. **Consult with FDA.**

No

New Dietary Ingredient (NDI).

Has the NDI been present in the food supply as an article used for food? (See section IV.B.)

Yes

No

Has the notifier submitted a notification to FDA for a product containing the same NDI with the same or lower NDI intake level, same composition, and same or narrower conditions of use? (See IV.B.1.)

Yes

No

Will the manufacturing process for the new product change the identity of the NDI (e.g., different chemical structure or composition, use of extraction, use of a different starting material, such as a different part of a botanical)? (See IV.B.4.)

No

Yes

NDI adulteration standard (21 USC 342(f)(1)(B)) applies. **No NDI notification required.**

NDI notification required.

Has the NDI been chemically altered from its conventional food form*?

* Examples of processes that do not chemically alter an ingredient are minor loss of volatile components, dehydration, lyophilization, milling, or formation of tincture, aqueous solution, slurry, powder, or solid in suspension. See IV.B.3.

Examples of changes that chemically alter an ingredient (see IV.B.4 for more details and additional examples):

New process makes or breaks chemical bonds.

New solvents (except tincture or water) or post-extraction processing that changes chemical composition of mixture.

New manufacturing method (e.g., new agricultural or fermentation conditions) that significantly changes chemical composition.

Changes in particle size that also alter chemical properties

New starting materials (e.g., different part of a plant) that change the chemical composition of the ingredient.

The NDI may have been chemically altered. If so, NDI notification will be required. **Consult with FDA.**

Not Sure

No to All

Yes to Any

Is NDI intake level under the intended conditions of use, the same as, or lower than the intake from conventional food use of the NDI? (See IV.B.2.)

Yes

No

The NDI has been probably chemically altered. If so, **NDI notification required.**

Regulatory status of the NDI is unchanged. NDI adulteration standard (21 USC 342(f)(1)(B)) applies. **NDI notification not required.**

NDI adulteration standard (21 USC 342(f)(1)(B)) applies. **NDI notification not required, but recommended.**