

SECTION FIVE

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The conditions of use recommended or suggested in the labeling of the dietary supplement. See 21 CFR § 190.6(b)(3)(ii).

The manufacturer and U.S. distributor of the new dietary supplement CVT-E002 will recommend the use of CVT-E002 for adults and children 12 years or older for the specific intended use of strengthening the immune system. The product labeling will recommend that individuals who have serious health conditions or are taking other medications, or pregnant, or lactating women consult a health care professional before use. Based on the fact that CVT-E002 is a derivative of North American ginseng, the labeling will recommend that individuals with allergies to ginseng should not use the product and that the recommended daily dose of 400 mg must not be exceeded.

The manufacturer and U.S. distributor of the new dietary supplement CVT-E002 has substantiation that the structure/function claim "strengthens the immune system" for CVT-E002 is truthful and not misleading and is in accord with the requirements of Section 403(r)(6) of the FDC Act and the FDA regulation at 21 CFR § 101.93. The product labeling for marketing CVT-E002 as a dietary supplement in the U.S. will comply with 21 CFR § 101.36.