

SECTION FIVE

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

The distributor of the new dietary ingredient creatine ethyl ester HCL will recommend the use of the dietary ingredient creatine ethyl ester HCL as a more available source of creatine for use in the manufacturing of dietary supplement products and as a single source product that are offered and marketed to supplement the daily diet with creatine for the maintenance of muscular health.

The targeted population for the dietary ingredient creatine ethyl ester HCL is adults and children over the age of eighteen years of age.

Creatine ethyl ester HCL will be recommended for adults only and will not be intended for use by pregnant or lactating women; individuals at risk for renal or hepatic dysfunction; individuals that have been medically prescribed Disulfuram (Antibuse); or individuals with known hypersensitivity to any of the components of creatine ethyl ester HCL.