

SECTION FOUR

The level of the new dietary ingredient in the dietary supplement.
See 21 CFR Section 190.6 (b)(3)(i)

The distributor will market creatine from creatine ethyl ester HCl as a new dietary ingredient and more available source of creatine in dietary supplement products at a recommended and suggested level of use of 500 mg to 3 grams per day, consumed in a single or divided daily dose.

Currently marketed creatine monohydrate products are offered for muscle health and improved physical performance. For that purpose, creatine is typically acutely loaded with 20 grams per day (or 0.3 gm per kg) for 5 days followed by a maintenance dose of 2 or more grams (0.03 grams per kg,) daily. See Jellin JM, Gregory P, Batz F, Hitchens, K et al. Pharmacist's Letter/ Prescriber's Letter Natural Medicines Comprehensive Database. 3rd ed. Stockton Ca: Therapeutic Research Faculty; 2000: pp.345-346; and PDR for Nutritional Supplements 1st ed., Medical Economics, Creatine, pp. 114-117, enclosed as Attachments 4 and 5.