

Policy on Use of EDTA

Adopted 1/7/04

The administration of EDTA (ethylenediaminetetraacetic acid) in a clinical setting by delivering the medicine through parenteral or non-parenteral routes beyond its FDA approved clinical indications of laboratory documented heavy metal poisoning/intoxication/toxicity, without support of scientifically valid evidence (as opposed to anecdotal evidence) of its effective use in the treatment of a disease or medical condition for which a licensee uses it may be considered to be violation of RSA 329:17, VI. *

That the advertising of EDTA's administration in any matter to prevent or cure diseases or medical conditions other than laboratory documented heavy metal poisoning/intoxication/toxicity, without support of scientifically valid evidence (as opposed to anecdotal evidence) of its effective use in the treatment of a disease or medical condition for which a licensee advertises it may be consider to be violation of RSA and/or the rules promulgated pursuant thereto.

However, EDTA may be used in the clinical setting when a licensee experienced in clinical investigations has applied for and received written approval from a US Department of Health and Human Services, Office for Human Research Protection certified Institutional Review Board under Code of Federal Regulations, Title 45, Part 46 Protection of Human Subjects (45 CFR 46); for a carefully controlled clinical investigation of its effectiveness in treating diseases or medical conditions other than those approved by the FDA, under a protocol satisfactory to the Institutional Review Board.

*** Note:** Scientific evidence of clinical effectiveness comes from research published in the peer-reviewed literature, and reflects rigorous and methodologically valid studies using research design (such as clinical trials) that will yield unbiased results. The use of expert opinion, case series, anecdotal evidence, or other uncontrolled and methodologically weak studies, even if published in the literature, does not constitute scientific evidence of effectiveness.