



PERFORMANCE - ENHANCING PRODUCTS

An FTC Regulatory Perspective

January 8, 2002

***A Conference on the Science and Policy of
Performance - Enhancing Products***

NIH, Bethesda, MD

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FTC'S ROLE

- ❑ Consumer Protection Mission
- ❑ Section 5 of the FTC Act prohibits deceptive and unfair acts and practices in commerce
- ❑ Claims made in advertising must be truthful, not misleading and substantiated
- ❑ Focus of FTC in PEP area has been on unproven safety claims in advertising. Law also requires that efficacy claims are truthful and substantiated

ENFORCEMENT ACTIONS

- ❑ FTC priority with sports products has been explicit safety claims for supplements that present serious health risks
- ❑ Recent actions have involved explicit safety claims for androgen products (AST and Met-Rex (consents))
- ❑ Some of the products also contained ephedra and caffeine
- ❑ FTC challenged safety/no side effects claims. Required strong warning statements about risks of steroid hormones, and about ephedra in labeling and advertising.

Basic Principles of FTC Ad Law

- All claims made by an ad – express and implied – must be truthful, non misleading and substantiated

Basic Principles of FTC Ad Law

- ❑ Substantiation means competent and reliable scientific evidence
 - ❑ Starting point is always well controlled human clinical studies
 - ❑ Look to what experts in relevant field consider adequate
 - ❑ Studies must relate to the product
 - ❑ Claims must reflect strength of the science (“may” is not an adequate qualifier)
 - ❑ Consumer anecdotes never a substitute for science

Basic Principles of FTC Ad Law

- ❑ Include any material information that qualifies a claim
 - ❑ Significant side effects/safety risks
 - ❑ Emerging Science
 - ❑ Limits on Efficacy/Conditions of Use

Basic Principles of FTC Ad Law

- ❑ Disclosures must be clear and prominent
 - ❑ Use direct and unambiguous language
 - ❑ Do not hide disclosures in fine print
 - ❑ Place disclosures close to claims being qualified



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