

FDA Presentation – AOD-9604

Presented by:

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AOD 9604

- Synthetic, orally active lipolytic peptide fragment of hGH
- AOD 9604 appears to enhance lipolysis in mice by upregulating beta-3 adrenergic receptors
- Increases fat oxidation

Ng FM, et al. Metabolic studies of a synthetic lipolytic domain (AOD9604) of human growth hormone. Horm Res. 2000;53(6):274-8.

Heffernan MA, Jiang WJ, Thorburn AW, Ng FM. Effects of oral administration of a synthetic fragment of human growth hormone on lipid metabolism. Am J Physiol Endocrinol Metab. 2000;279(3):E501-507.

AOD 9604

- How is AOD 9604 generally used by the medical community? Adjunct for weight management support
- **4 preclinical animal and 2 human clinical trials of significance**
- Reported safe in human studies
 - Human GRAS status in USA as dietary supplement



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AOD 9604 Human Safety Study

SAFETY AND TOLERATIBILITY STUDY – IV and PO

- 2013 meta-analysis = six randomized, double-blind, placebo-controlled trials n= 900 adult subjects
- Reported no effect on serum IGF-1 levels
- AOD 9604 has no negative effect on carbohydrate metabolism (in contrast to hGH) – oral carb test
- No anti-AOD 9604 antibodies detected in any of the patients selected for antibody assay
- Authors concluded that AOD 9604 displays a very good safety and tolerability profile indistinguishable from placebo, with none of the adverse effects associated with full-length hGH treatment

Stier H, et al. Safety and tolerability of the hexadecapeptide AOD9604 in humans. J Endocrinol Metab. 2013;3(1-2):7-15.

AOD 9604 Level of Evidence

	Level of Evidence	Description
	Level 1	FDA Approved Drug studies
	Level 2	Evidence obtained from systematic review and/or meta-analyses of studies including RCTs and other human studies
X	Level 3	Evidence obtained from <u>a</u> RCT
	Level 4	Evidence obtained from a study without randomization
	Level 5	Evidence obtained from case reports
X	Level 6	Evidence obtained from <i>in vitro</i> human studies
X	Level 7	Evidence obtained from laboratory animal studies
X	Level 8	Evidence obtained from Opinions or Reviews

6 RCT using AOD 9604 for weight management support reported

AOD 9604 Dispensing Data

- Community Pharmacy dispensing data
- 158,989 doses of AOD 9604 dispensed, including:
 - Injection
 - Troche
 - Cream
 - Capsules