







4. Articles intended for use as a component of any article specified in clause 1, 2, or 3 above; but does not include devices or their components, parts, or accessories.

F. **“Essentially Equivalent Product”** means a product that contains the identical

ingredients, except for inactive ingredients (*e.g.*, binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (*e.g.*, orally, sublingually), as the Covered Product; provided that the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the relevant field indicates that the amount and combination of additional ingredients are unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

G. **“Food”** means, as defined in Section 15 of the FTC Act, 15 U.S.C. § 55:

**ORDER**

**I. PROHIBITED REPRESENTATIONS: SUBSTANCE OR OPIOID USE AND WITHDRAWAL CLAIMS**

IT IS ORDERED that Defendants, Defendants' officers, agents, and employees, and all other Persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, marketing, promotion, offering for sale, sale, or distribution of any Covered Product

are hereby permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that such product:

- A. Alleviates or significantly alleviates the symptoms of withdrawal relating to opioid dependence or addiction, opioid use disorder, or any other substance dependence.

















contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For any test conducted, controlled, or sponsored, in whole or in part, by Defendants, Defendants must establish and maintain reasonable procedures to protect the confidentiality,

accuracy, and integrity of any information collected, stored, transmitted, or otherwise processed

by Defendants.

procedures shall be documented in writing and shall contain administrative, technical, and physical safeguards appropriate to Defendants' size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.











**DONE AND ORDERED** in Chambers in West Palm Beach, Florida, this 7th day of  
July, 2016.



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DONALD M. MIDDLEBROOKS  
UNITED STATES DISTRICT JUDGE