In the Matter of John Matthew Dwyer III, a/k/a Matthew Dwyer

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT
File No. 122 3287

connection with the manufacturing, labeling, advertising, promotion, offering for sale, and sale or distribution of any Covered Product.

Part IV provides a safe harbor for representations permitted under any tentative final or final standard promulgated by the Food and Drug Administration ("FDA"), any new drug application approved by the FDA, or FDA regulations pursuant to the Nutrition Labeling and Education Act of 1990 or the FDA Modernization Act of 1997.

Triggered when the human clinical testing requirement in Part II applies, **Part V** of the proposed order requires Dwyer to secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with