

## **Analysis of Proposed Consent Order to Aid Public Comment**

unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

**Part II** prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety, or side effects of any covered product, unless the representation is 2 (a)(c)(e)(b) TTTpffi co.d(a)(nc)(e)(at)(ar)-

Respondents control and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which Respondents have delivered a copy of the order.

**Part X** requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. **Part XI** contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. **Part XII** contains other requirements related to the Commission's monitoring of Respondents' order compliance. **Part XIII** provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.