

# FDA Draft Guidance

Good Reprint Practices for the  
Distribution of Medical Journal Articles  
and Medical or Scientific Reference  
Publications on Unapproved New Uses  
of Approved Drugs and Approved or  
Cleared Medical Devices

# A scientific or medical journal article that is distributed should:

- be peer-reviewed
- be published by an organization that requires full disclosure of all conflicts of interest and has an editorial board with independent experts who have demonstrated expertise in the subject of the article
- not be a special supplement or publication funded by manufacturers of the product that is the subject of the article

# The scientific or medical reference publication should not be:

- primarily distributed by a manufacturer, but should be generally available in bookstores or other independent distribution channels
- written, edited, excerpted, or published specifically for, or at the request of, a manufacturer
- edited or significantly influenced by a manufacturer or any individuals having a financial relationship with the manufacturer

The information contained in the publication should:

- address adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and experience to evaluate the safety or effectiveness of the product

# The information/publication should not:

- be false or misleading, be inconsistent with the weight of credible evidence, be withdrawn by the journal or disclaimed by the author, or discuss a clinical investigation FDA has previously informed the company is not adequate and well-controlled
- pose a significant risk to the public health
- be in the form of a letter to the editor or an abstract
- be a report of Phase 1 trials in healthy subjects
- be a reference publication with little or no substantive discussion of the relevant investigation or data

# Information that is distributed should be:

- unabridged
- accompanied by the approved labeling
- accompanied by a comprehensive bibliography
- disseminated with a representative publication that reaches contrary or different conclusions
- distributed separately from promotional information



# Information that is distributed should not be:

- marked, highlighted, summarized, or characterized
- physically attached to any promotional material a sales representative uses or delivers during an office visit
- discussed during a sales visit
- distributed in promotional exhibit halls or during promotional speakers' programs (as opposed to medical or scientific conferences in settings appropriate for scientific exchange)

The publication should be accompanied by a prominently displayed and permanently affixed statement disclosing:

- that the uses described in the information have not been approved or cleared by FDA
- the manufacturer's interest in the product
- any author the manufacturer knows has a financial connection to the product/manufacturer
- any person the manufacturer knows has provided funding for the study
- any significant risks or safety concerns the manufacturer knows that are not discussed in the journal article or reference text