



Electronic Retailing Association
Leaders in Direct-to-Consumer Commerce

THE FTC'S NEW HIGHER "FENCE"
Electronic Retailing Association
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On July 14, 2010, the Federal Trade Commission announced settlements with Nestle Health Care Nutrition, Inc. and Iovate Health Sciences USA, Inc. Both settlements imposed “fencing in requirements” (standards for the sort of substantiation an advertiser needs in order to make certain claims) that go beyond what FTC has traditionally required.

FTC COMPLAINTS

- FTC sued Nestle over claims that the drink Boost Kid Essentials prevents upper respiratory tract infections, reduces the duration of acute diarrhea, protects against colds and flu by strengthening the immune system and reduces absences from daycare and school due to illness.

- FTC sued Iovate over claims that its products could help consumers lose weight or treat colds and other illnesses.

SUBSTANTIATION/FENCING IN

- Usual standard for health-related claims in FTC “fencing in” orders is: “At the time of making the representation, advertiser must possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific field when considered in light of the entire body of relevant and reliable scientific evidence to substantiate that the representation is true. For purposes of this Order, competent and reliable scientific

evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.”

NESTLE

- The Nestle Order, for some claims, went far beyond the usual “fencing in” language quoted above. The Order provided that, in connection with the marketing of any drink product containing probiotics or other nutritionally complete drink, Nestle could not claim that the product prevents or reduces the risk of upper respiratory tract infections, including, but not limited to, cold or flu viruses, unless the

representation was specifically permitted in labeling for such products by regulations promulgated by the FDA under the Nutrition Labeling and Education Act of 1990. This removes the notion of “substantiation” and substitutes a determination by a sister agency.

For the sale of nutritionally complete beverages in connection with claims that the beverages reduce the duration of acute diarrhea in children up to the age of 13 or reduce absences from daycare or school due to illness, Nestle must have as substantiation “at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted by different researchers, independently of each other, that

conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.”

- For all other claims made by Nestle, they are required to have “competent and reliable scientific evidence” defined in the usual way.

INOVATE

Inovate got an Order that is quite similar. With respect to claims that its drugs are dietary supplements that would reduce the risk, incidents or frequency of colds or flu, prevent colds or flu, reduce the severity or duration of colds or flu or provide relief from hay fever or environmental

allergies, lovate must have a product that is subject to a final OTC drug monograph promulgated by the FDA for such use and conform to the condition of such use, or have a product that is covered by a tentative final OTC drug monograph and adopt the conditions of such use or be the subject of a new drug application for such use approved by the FDA and conform to the conditions of use. In other words, like Nestle, lovate cannot make certain claims, even if they have substantiation, unless such claims for such a product have been approved by the FDA.

- Weight loss claims by lovate must be supported by “competent and reliable scientific evidence” which, as with Nestle, is defined as “at least two adequate and well-controlled human clinical studies” of the products sold,

“conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.”

- All other health-related claims must be supported by “competent and reliable scientific evidence” of the usual type traditionally required by the FTC.

SUMMARY

In both Nestle and Iovate, the Commission has imposed three levels of regulatory hurdles for the marketer who wishes to make certain claims. The highest, in each case, is FDA approval of the claims. The second level, for certain other claims, is the requirement for two human studies, the conditions of which are fully defined in the Order, that prove that the claims are true. The third, and least burdensome requirement for all other claims not subject to the first two levels of proof, is the traditional “competent and reliable scientific evidence:” standard used by the FTC.



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A BRAVE NEW WORLD...?

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SOME INITIAL OBSERVATIONS

- Both orders issued together -- Not an accident
- Designed to send a message to the industry
- Consistent with recent enforcement practices
 - Requirement of clinical studies
 - Consensus in scientific community
 - Testing on product rather than ingredients

SOME INITIAL OBSERVATIONS

- Differences between a food and a dietary supplement
- Three different standards for substantiation
- Definition of equivalent product

WHAT DOES THIS MEAN?

- When is FDA approval required?
- Are double blind clinical studies always required?
- What standards apply to the clinical studies?

WHEN IS FDA APPROVAL REQUIRED

- For supplements -- FDA approval is required for any disease claim
 - No change from current enforcement policy
 - Change is -- when making a disease claim without FDA approval; FTC enforcement more likely now
 - No longer just a risk of FDA warning letter

WHEN IS FDA APPROVAL REQUIRED

– Food products

- Note distinction between respiratory claim and reduction of the duration of acute diarrhea claim
- Is the claim one likely to be covered by NLEA

WHEN ARE CLINICAL STUDIES REQUIRED?

- Supplements:
 - Note two different standards in the order:
 - Weight Loss
 - Other Health Related Claims
 - FTC: Two double blind clinicals will always be required for weight loss claims for supplement
 - For other health related claims, will depend on what experts in the field consider necessary to support
 - Is the claim a novel one?
 - Is the delivery mechanism novel?
 - Is there a wide body of evidence supporting the claim?

WHEN ARE CLINICAL STUDIES REQUIRED?

- Foods
 - Trickier -- depends on nature of the claim
 - Is it the type of claim NLEA would likely cover

STANDARDS FOR CLINICAL STUDIES

- Two independent researches
- Double blind
- Placebo controlled UNLESS placebo difficult to administer
- Studies must be conducted on the product itself or equivalent product
 - Definition of equivalent consistent with recent enforcement policy

WHAT TO DO NOW

- Carefully review current advertising
- Have you crossed the line between structure function and disease claims
- If weight loss, do you have 2 independent studies
- For other health related claims?
 - What is the body of evidence
 - How novel is the product/the claim



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The Electronic Retailing Self-Regulation Program

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August 5, 2010

ERSP Goals and Procedures



- Restore consumer confidence in electronic retailing
- Discontinue egregious unsupported claims quickly
- Demonstrate the direct response industry's commitment to legal compliance to the FTC
- Primary and core claims
- Does substantiation appear reasonable on its face



FTC complaint when it has reason to believe law has been violated and it appears that proceeding is in public interest



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Dietary Supplement Maker to Pay \$5.5 Million to Settle FTC False Advertising Charges

FTC Challenges Claims that Supplements Cause Weight Loss and Treat or Prevent Colds, Flu, Allergies, and Hay Fever



Accelis - 2006 ERSP Inquiry



- One study on primary ingredient was insufficient to support establishment claims
- Unqualified “fast” and “rapid” weight loss claims were unsupported
- Claims that the product “works immediately” and that it was the only “corosolic acid” based weight loss product were inaccurate

Cold MD - 2007 NAD Inquiry



- Single clinical study “not sufficiently reliable” to provide support for strong efficacy claims
- Quantified performance and establishment claims regarding immune system not adequately substantiated
- Claims that Cold MD “works fast” and is “doctor formulated and approved” should be discontinued

Key points in FTC definition of “competent and reliable scientific evidence”

- Two human clinical studies;
- evaluated in light of the entire body of scientific evidence; and
- conducted on a product with identical active ingredients to the advertised product and in the same dosage and administration unless there is reason to believe that the differences are unlikely to affect product efficacy.