

**ADVERTISING STANDARDS AUTHORITY INC.**

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**4 May 2004**

Director of Dockets Management (HFA – 305)  
Food and Drug Administration  
5630 Fishers Lane  
rm. 1061  
Rockville  
MD 20852  
USA      **Attn: Glenn Byrd**

Dear Glenn,

**Docket No 2004D-0042**

I enclose a hard copy of our comments on the "Guidance for Industry- Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" Paper. The comments were also filed via your website today. (Comment Number 2420)

Please contact me if you would like any further information.

Yours sincerely



Glen Wiggs  
**Executive Director**

2004D-0042

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## **Comments of the Advertising Standards Authority (New Zealand)** **on Guidance for Industry Paper “Brief Summary: Disclosing Risk** **Information in Consumer Directed Print Advertisements.”**

### **Background**

The United States and New Zealand are the only two developed countries which allow the advertising of prescription drugs. It is clear from the Guidance Paper and other material that the issues which arise from advertising prescription drugs in the United States are similar to the issues in New Zealand. It may be useful for the FDA to know how those issues are being dealt with in New Zealand and the proposed solutions.

### **Regulatory Environment**

#### **(a) Regulation**

In New Zealand there is underlying legislation in the Medicines Act and Medicines Regulations which have base requirements for prescription drug advertisements. In summary those requirements are:

Advertiser's Name

Advertiser's Address

Active Ingredients

Quantity of Active Ingredients

All Authorised Uses

Appropriate Precautions

All Contra-Indications

All adverse Reactions

Short warnings and Statement such as “Prescription Medicine”

#### **(b) Self-Regulation**

New Zealand has a comprehensive self-regulatory system which is administered by the Advertising Standards Authority (ASA) See [www.asa.co.nz](http://www.asa.co.nz) for full details. Members of the ASA are organisations which represent all media- television, newspapers, radio, magazines, outdoor, cinema, addressed and unaddressed mail, and internet, plus advertisers and advertising agencies. The ASA has Codes of Practice including a Code for Therapeutic Advertising. It funds and resources a separate and

also continue. Australia will have complaint and pre-vetting systems based on the New Zealand model.

There has therefore been the unique opportunity to start afresh and devise requirements which give proper information and warnings to consumers without the clutter.

### **Joint Code**

The new Joint Code is still in draft but is due to be finalised in July 2004. There are provisions for prescription drug advertising which would apply in New Zealand and when permitted in Australia- initially on the internet. The key provisions are

#### **(a) Key Principles**

1. Comply with (new) Therapeutic Products Act.
2. Not mislead
3. High standard of social responsibility

#### **(b) Mandatory Information**

1. "All required statements (listed below) must be prominently displayed or communicated i.e standing out as to be easily read from a normal viewing distance, and/or heard and understood."

2.

"Always read the label"

"Use only as directed"

"If symptoms persist see your doctor"

"Prescription Medicine, consult your doctor to see if this medicine is right for you"

3.

- Trade name
- Indications relevant to advertisement
- Active ingredients (not quantity)

4. "If the product, when used according to directions

- has known serious adverse effects (in terms of severity and clinical importance); or
- is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI),

an appropriate warning of those effects should be given."

5. Where full information can be obtained.

## **Current Australian Situation**

The advertising of prescription medicines to consumers is banned in Australia. As a consequence Disease State Awareness advertising is common. No risk information or warnings are required therefore only the benefits are advertised. Under the current Australian requirement such advertising is not subject to any code, complaint or pre-vetting.

In our view the advertising is of a low standard and does not properly protect and inform the consumer. Disease State Awareness advertising has in effect turned into Unbranded Advertising. Two examples are attached.

However it could well be that this style of advertising has evolved because branded advertising is banned. The proposal to encourage responsible Disease Awareness Advertising alongside branded advertising should not result in the same problem that Australia now has.

## **FTA Agreement**

United States and Australia have recently negotiated a free trade agreement. It is still to be ratified by both Governments. Annex 2-C of the Agreement states:

### **“5 Dissemination of Information**

Each party shall permit a pharmaceutical manufacturer to disseminate to health professionals and consumers via the manufacturer’s Internet site registered in the territory of a Party, and on other Internet sites registered in the territory of a Party linked to that site, truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party’s territory as is permitted under each Party’s laws, regulations and procedures, provided that the information includes a balance of risks and benefits and encompasses all indications for which the Party’s competent regulatory authorities have approved the marketing of the pharmaceuticals”

The effect of the provision is to allow prescription drug Internet advertising in Australia.

Clearly, the question of prescription drug advertising only on the internet will be highly controversial in Australia and other media such as newspapers, radio and television which are responsible and regulated will object to a relatively unregulated media having preference. It is envisaged it will only be a matter of time before they would have equal rights.

## **Australia and New Zealand Therapeutic Harmonisation**

Australia and New Zealand are currently negotiating full harmonisation of regulation of therapeutic goods which includes prescription drugs. In effect the two separate regulators in Australia and New Zealand will be replaced by one which will operate in both countries. It is planned that the new regime will commence on 1 July 2005.

Part of the harmonisation process is a harmonised advertising regulatory regime. There will be a joint advertising code which will operate in Australia and New Zealand which will be underpinned by legislation. The ASA will administer the code in New Zealand and the complaints system will continue. The prevetting system will

independent Advertising Standards Complaints Board to which any member of the public can make a complaint. If a complaint is upheld then the advertiser, agency and media are requested to withdraw the advertisement. To date there has been 100% compliance with this request.

The advertiser's organisation administers a pre-vetting system. The media will not accept an advertisement for a prescription drug (also non-prescription drugs, herbal remedies and dietary supplements) unless it has been pre-vetted.

The entire regulatory system is voluntary and has the backing of all major advertisers (including multi-nationals). In particular pharmaceutical companies are enthusiastic in their support.

### **ASA Therapeutic Code**

The ASA Therapeutic Code has a Principle and Guideline approach. In brief the Code states.

Principle 1. Comply with law

- Medicines Act and Regulations

Principle 2. High Standard of Social Responsibility

- There are certain warnings that must be given such as "Use strictly as Directed. "Prescription Medicine, consult your doctor"
- The Complaints Board in various Decisions has ruled, in interpreting the Principle, that "serious adverse effects should be obvious to the reader, viewer or listener" of the advertisement and in "language easily understood"
- The Complaints Board has specifically disallowed the lengthy small-print styled information as currently occurs in the United States in print advertisements on the grounds that so much information (much of it technical) is confusing to the reader and does not meet the test of a "high standard of social responsibility."
- The advertisement must state where full information of the drug can be easily obtained.

- Principle 3

- Not mislead

- Principle 4

-Scientific Information clearly presented in understandable manner.

- Principle 6

-Endorsements and testimonials must be valid, current and typical.

### **Problems**

The problems arising are similar to those that concern the FDA. The main issue is too much clutter in the advertisement and as a result important warnings are not seen. In particular information about serious adverse effects gets mixed up with minor side effects, names and address of advertisers and quantities of active ingredients all of which are of doubtful relevance to the consumer.

6. If there is a charge (unsubsidised) this should be clear.

### **Effect of provisions**

The purpose of the proposed provisions to keep the mandatory information to a minimum but to ensure all of it is communicated to the consumer.

In particular these are specific warnings/risks relating to serious adverse effects which must be clear.

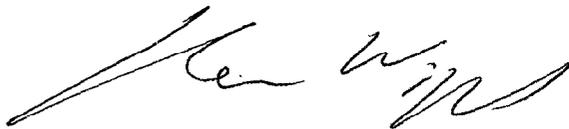
In essence the provisions are not too dissimilar to those proposed in the Guidance Paper.

### **Conclusion**

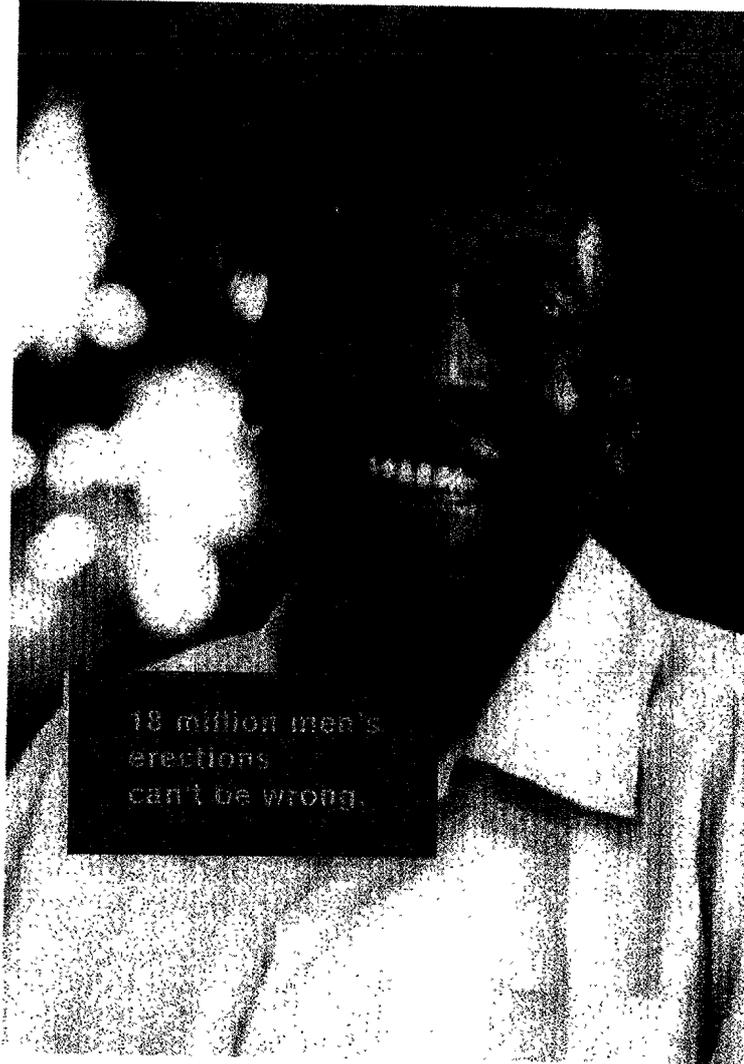
It is interesting that both the draft Joint Code and the Guidance Paper are simultaneously addressing the same issues. At this point we do not know whether we have the perfect answer nor does the FDA in its Guidance Paper.

Hopefully, the mandatory information which must be included in advertisements in the Joint Code will be useful to the FDA. We recommend you consider the provision about serious adverse effects. Prescription drug advertising in New Zealand has been adopting this line in the past year and or so and we have found it works. The problem is the mandatory unimportant information, which causes clutter.

If the FDA would like to discuss any aspect with us please do not hesitate to contact us. Also, as United States and New Zealand are the only countries which currently allow prescription drug advertising an exchange of information on what works and does not work would be advantageous to both of us.



Glen Wiggs  
**Executive Director**



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