



TAP PHARMACEUTICAL PRODUCTS INC.

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Lake Forest IL 60046

May 17, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Comments on Docket No. 2004D-0042
Brief Summary: Disclosing Risk Information in Consumer-Directed Print
Advertisements**

To Whom It May Concern:

TAP Pharmaceutical Products Inc. (TAP) would like to provide the following comments to Docket No. 2004D-0042 on the draft guidance for Industry entitled: **Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements.**

TAP would like to thank the Agency for issuing this draft guidance, as we believe that this will increase the probability that consumers will read this important information.

Our comments pertain to a request for clarification of the following section:

B. Highlights (Lines 206-227)

1. Before the Proposed Rule Becomes Effective

Unless and until the proposed rule becomes effective, FDA does not intend to object to a consumer-directed print advertisement for a prescription drug ...if it includes the risk information that would appear in the Highlights section of **FDA-approved labeling** (emphasis added) for the product, including information addressing the following risks:

- Contraindications: all
- Warnings: all
- Precautions: the major precautions, including...
- Adverse Reactions: the 3-5 most common...

Comment:

In those cases where the FDA-approved professional labeling does not include an FDA approved highlights section, TAP presumes that it is FDA's intention not to object to industry using a consumer-friendly brief summary, which was created based on an industry drafted, not FDA approved, highlights section that follows the proposed rule (65 FR 81082, December 22, 2000) and includes information addressing the risks bulleted above.

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Because the guidance includes the statement "**FDA-approved labeling**" this could be interpreted to mean that the highlights section used to create the brief needs to be pre - approved by FDA before using, notwithstanding the fact that the proposed rule is not effective.

Please call me if this request for clarification is unclear as I appreciate that this is a difficult point to communicate.

Thank you and best regards,

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