



October 1, 2001

3022 01 OCT -2 P135

Dockets Management Branch (HFA-305)
Division of Management Systems and Policy
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 01D-02975
Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff

On behalf of Allergan, I am respectfully submitting the following comments on the above-cited draft guidance document released for comment on July 18, 2001.

We support FDA's efforts to make the Advisory Committee process more transparent to both sponsors and to the public. The detailed guidance on the appropriate processes for compiling panel packages is very helpful in this regard. However, we feel that the following modifications to the draft guidance are necessary to protect the rights of sponsors.

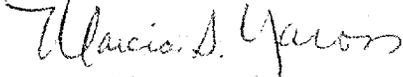
- Timing of public availability. The draft guidance states that FDA intends to release the publicly available documentation to the public one business day before the panel meeting is scheduled to occur. We believe that release should only be concurrent with the meeting. Meetings can be cancelled or postponed for unforeseen reasons on very short notice; public release in advance of a postponed meeting cannot be reversed. We therefore believe that the release should only be concurrent with public discussion at a convened open meeting. This concern also applies to the inclusion of names of sponsors in Federal Register notices of open meetings; if the sponsor has not previously publicly acknowledged submission of an application to FDA, the firm's competitive position may be irreparably harmed should the meeting be cancelled or postponed.
- Content of publicly available panel packages. FDA has proposed that clinical, preclinical, and statistical protocols may generally be released to the public without redaction. We strongly disagree. While summaries of such studies may be releasable without undue harm to sponsors, the detailed protocols provided to the Agency in premarket applications contain detailed methodologies and know-how held as confidential by the sponsors; their disclosure is likely to cause substantial harm to the competitive position of the submitter and must be considered confidential commercial information under 21 CFR 20.61(b).

01D-0297

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Thank you for the opportunity to comment on this draft guidance document. Please feel free to contact me at 1-714-246-2362 should you require further information or clarification.

Sincerely yours,



Marcia S. Yaross, Ph.D.
Director, Worldwide Regulatory Affairs
and Medical Compliance

cc: Sara Thornton, Executive Secretary, Ophthalmic Devices Advisory Panel

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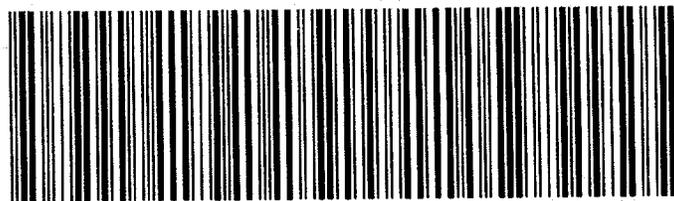
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