ALLERGAN
SURGICAL

2525 Dupont Drive, P.O. Box 19534, Irvine, California, USA 92623-9534 Telephone: (714) 246-4500 Website: www.allergan.com

October 1, 2001

3002 '01 OCT -2 P1:35

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Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff

On behalf of Allergan, I am respectfully submitting the following comments on the above-cited draft guidance document released for comment on July 18, 2001.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 However, we feel that the following modifications to the draft guidance are necessary to protect the rights of sponsors.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 The draft guidance states that FDA intends to release the publicly available documentation to the public one business day before the panel meeting is scheduled to occur.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

C 2

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

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

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

FedEx® Express

Express Shipping Request

For use by PowerShip Customers only

8279 6318 3441

Form I.D. No. 0205 0181682408

410

WCSL 01 PART 155822 Rev. 10/00 ©1994-2000 FedEx

Sender's FedEx Account Number 0900-1170-7

8279 6318 3441 Form I.D. No. 0205

From M. Yaross, TL-11 Ship Date 10-1-01

ALLERGAN INC
2525 DUPONT DR
IRVINE, CA 92612-1599

To *To "Hold" at FedEx location, print FedEx address here. We cannot deliver to P.O. boxes or P.O. ZIP codes.*

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

Release No. Phone No.

Reference Info 200120035

Special Handling ☐ HOLD Weekday at FedEx Location ☐ HOLD Saturday at FedEx Location ☐ SATURDAY Delivery ☐ SUNDAY Delivery ☐ Dangerous Goods ☐ Dry Ice

Weight	Declared Value	Services	FedEx Priority Overnight	FedEx Standard Overnight	FedEx 2Day	FedEx First Overnight	FedEx Express Saver	FedEx Extra Hours	FedEx 1Day Freight	FedEx 2Day Freight	FedEx 3Day Freight
	NDV		☒ FedEx Envelope ☐ FedEx Box ☐ FedEx Pak ☐ FedEx Tube ☐ Other Pkg.	☐ FedEx Envelope ☐ FedEx Box ☐ FedEx Pak ☐ FedEx Tube ☐ Other Pkg.	☐ FedEx Envelope ☐ FedEx Pak ☐ Other Pkg.	☐ FedEx Envelope ☐ Other Pkg.	☐ FedEx Envelope ☐ FedEx Pak ☐ Other Pkg.	☐ FedEx Envelope ☐ FedEx Box ☐ FedEx Pak ☐ FedEx Tube ☐ Other Pkg.	☐ Other Pkg.	☐ Other Pkg.	☐ Other Pkg.

ALLERGAN, INC
COMPANY MAIL DEPT.
18555 TELLER AVE.
IRVINE CA 92612-1599
(714)246-4753

SHIP DATE: 01OCT01
ACC # 0900011707

ACTUAL WGT: 1 LBS MAN-WT

SEE ADDRESS LABEL ON PACKAGE FOR
THIS SHIPMENT TO MD 20852

8279 6318 3441 FedEx®

8279 6318 3441

REF: 2001200035

PRIORITY OVERNIGHT TUE

cad # 0011834 01OCT01

Deliver by 02OCT01

TRK# 8279 6318 3441 FORM 0201

IAD AA

20852 -MD-US XA GAIA

153078 MAY 7/01

Align bottom

Select FedEx Letter or FedEx Envelope/Letter on your shipping document.