

OLSSON, FRANK AND WEEDA, P. C.

PHILIP C OLSSON
RICHARD L FRANK
DAVID F WEEDA (1948-2001)
DENNIS R JOHNSON
ARTHUR Y TSIEN
JOHN W BODE*
STEPHEN D TERMAN
MARSHALL L MATZ
MICHAEL J O'FLAHERTY
DAVID L DURKIN
NEIL F O'FLAHERTY
PAMELA J FURMAN
BRETT T SCHWEMER

ATTORNEYS AT LAW
SUITE 400
1400 SIXTEENTH STREET, NW
WASHINGTON, D C. 20036-2220
(202) 789-1212
FACSIMILE (202) 234-3550

Sender's Direct Phone (202) 518-6318
Sender's Direct Facsimile (202) 234-3537

TISH E PAHL
ROBERT A HAHN
NAOMI J L HALPERN
STEPHEN L LACEY
EVAN P PHELPS
VALERIE B SOLOMON
OF COUNSEL
JUR. T STROBOS
JACQUELINE H EAGLE
KENNETH D ACKERMAN
MARK L ITZKOFF
SR GOVERNMENT AFFAIRS ADVISOR
JOHN R BLOCK
BRIAN E JOHNSON
SALLY S DONNER

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA
IS LIMITED TO MATTERS AND PROCEEDINGS
BEFORE FEDERAL COURTS AND AGENCIES

October 7, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004P-0324 – Comment On Petition As Amended August 30, 2004

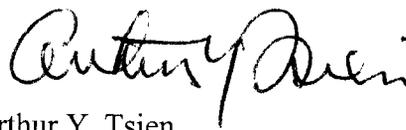
Dear Food and Drug Administration:

This comment responds to the amendment to the citizen petition submitted by Dey, L.P. on August 30, 2004. In that amendment, Dey amended the relief sought "to request written confirmation from FDA that Eon's ANDA 76-867 for a generic version of DuoNeb® is subject to a 30-month stay of final approval," based on a factual scenario set forth in Dey's citizen petition amendment.

We respectfully request that Dey's petition, as amended, be summarily denied by FDA. As a matter of longstanding practice, FDA does not make decisions, or publicly disclose information, regarding possible 30-month delays of ANDA final approval until the issuance of a tentative or final ANDA approval letter. Regardless of whether the factual scenario posited by Dey in its petition amendment is correct, any effort by FDA to address the underlying issue on which Dey seeks relief would result in the public disclosure of information to which Dey would not otherwise be entitled. The agency must not allow Dey to use the citizen petition process to subvert longstanding agency policies and restrictions on the public disclosure of information.

We appreciate the agency's consideration of this comment.

Respectfully submitted,



Arthur Y. Tsien

AYT:cr

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