

ROUTING SLIP
GENERATED BY: HF-40
DATE: JUN 27, 2002

FDA CONTROL NUMBER: 02 3506

TRACER # OS #:

DATE OF CORRESPONDENCE: 05/28/02

DATE INTO FDA: 06/27/02

TO: LESTER M CRAWFORD HF-1

FROM: EUGENE S PEISER, CONSULTANT TO THE FDA REGULATED INDUSTRIES

SYNOPSIS: MEETING REQUEST WITH DR. CRAWFORD TO DISCUSS THE FILED PETITION
"EXPIRATION DATING OF UNIT REPACKAGE1 DRUG PRODUCTS" (DOCKET
NUMBER 02P=01126/CP 1)

LEAD OFFICE: HF-1

HOME OFFICE: HF-40

CONTACT/PHONE#: KIMBERLY K KLINE 301-827-4447

COPIES: GENERAL DISTRIBUTION
HF-1 LESTER M CRAWFORD
HF-10
HF-2 MURRAY M LUMPKIN
HF-40 LAJUANA D CALDWELL
HFD-1
HFA-305

COORDINATION: HF-40 WANDA G RUSS
HF-40 WALTER D OSBORNE

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO

ACTION

DUE DATE

.....
HF-1

CRIMC

NECESSARY ACTION

ACTION

Peiser & Associates, Inc.
PO Box 774
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Palm Harbor, Fl. 34682
1-800-367-4313 Fax: (727) 785-9941 epeiser@aol.com
Consultants to the FDA Regulated Industries

May 28, 2002

Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

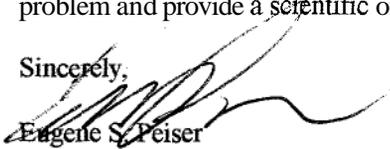
Dear Sir:

We filed a Petition to amend Sect 480.200 Expiration Dating of Unit Dose Repackaged Drug Products on March 29, 2002. It was received at the FDA on 3/20/02 and assigned docket number 02P-01126/CP 1 and was ~~filed~~ on 3/20/02.

We are now requesting a meeting with the proper departments of the agency to discuss this petition and to inform and **notify** the agency on how its position is affecting the economic welfare of those companies forced to comply with the FDA's present interpretation of a Drug Repackager versus a noncomplying repackager operating outside the agency's scrutiny.

~~Please~~ have someone contact me as soon as possible to arrange a face to face meeting to discuss this problem and provide a scientific or reasonable explanation for the agencies position.

Sincerely,


Eugene S. Peiser
Doctor of Pharmacy
Consultant

02-3506