CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 17-892/S-034

ADMINISTRATIVE DOCUMENTS

REGULATORY PROJECT MANAGER
LABELING REVIEW

Date: June 13, 2003
Drug: Halcion (triazolam) 0.125 mg and 0.25 mg Tablets
NDA: 17-892
Sponsor: Pharmacia & UpJohn
Indication: Insomnia
Supplements:

NDA	Supplement	Dated	Action
Halcion (triazolam) 0.125 mg and 0.25 mg Tablets			
17-892	SLR-034	8-20-98	AE Letter Dated 10-22-02; Sponsor submitted Complete Response in Submission dated 1-21-03
17-892	SLR-033	3-7-95	AP Letter Dated 4-4-96

Notes of Interest

- The last approved labeling supplement was SLR-033 which was approved in an Agency letter dated 4-4-96.

REVIEW

17-892/SLR-034
Date: 8-20-98, and amended on 1-21-03
CBE: No, Prior Approval
Label Code: 0812110831
Reviewed by Medical Officer/OCPB: Original Submission Reviewed

This supplement provides for revisions to the **CLINICAL PHARMACOLOGY** section and the addition of a new section under **PRECAUTIONS** entitled **Geriatric Use** to add additional information on geriatric use and to comply with a Federal Register notice dated August 27, 1997.

- The sponsor has revised the labeling, verbatim, as requested in our 10-22-03 AE letter.

CONCLUSIONS

1. The supplement only provides for changes as outlined in the submission when compared to the last approved labeling supplement, NDA 17-892/SLR-033. Attached is an annotated copy of the labeling when compared to the last approved labeling, SLR-033.

2. Since the sponsor has revised the labeling, verbatim, as requested in our 10-22-02 AE letter, I recommend that this review, alone, should be sufficient to issue an AP action.

Paul David, R.Ph.,
Senior Regulatory Project Manager

Robbin Nighswander, R.Ph.,
Supervisory Regulatory Health Officer

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/s/

Paul David
7/10/03 10:53:06 AM
CSO

Robbin Nighswander
7/10/03 10:54:54 AM
CSO

REGULATORY PROJECT MANAGER
LABELING REVIEW

Date: October 4, 2002
Drug: Halcion (triazolam) 0.125 mg and 0.25 mg Tablets
NDA: 17-892
Sponsor: Pharmacia & UpJohn
Indication: Insomnia
Supplements:

NDA	Supplement	Dated	Action
Halcion (triazolam) 0.125 mg and 0.25 mg Tablets			
17-892	SLR-034	8-20-98	Open Supplement
17-892	SLR-033	3-7-95	AP Letter Dated 4-4-96

Notes of Interest

- The last approved labeling supplement was SLR-033 which was approved in an Agency letter dated 4-4-96.

REVIEW

17-892/SLR-034
Date: 8-20-98
CBE: No, Prior Approval
Label Code: N/A
Reviewed by Medical Officer/OCPB: Yes.

This supplement provides for revisions to the **CLINICAL PHARMACOLOGY** section and the addition of a new section under **PRECAUTIONS** entitled **Geriatric Use** to add additional information on geriatric use and to comply with a Federal Register notice dated August 27, 1997.

- The OCPB reviewer recommends an approvable action with minor changes to the sponsor's proposed labeling.
- The clinical reviewer also finds the labeling acceptable.

CONCLUSIONS

1. The supplement only provides for changes as outlined in the submission when compared to the last approved labeling supplement, NDA 17-892/SLR-033.

2. I recommend that an approvable letter issue outlining the revisions requested by the OCPB reviewer.

Paul David, R.Ph.,
Senior Regulatory Project Manager

Robbin Nighswander, R.Ph.,
Supervisory Regulatory Health Officer

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/s/

Paul David
10/16/02 08:44:32 AM
CSO

Robbin Nighswander
10/16/02 08:50:00 AM
CSO