

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-175

PHARMACOLOGY REVIEW

Barry N. Rosloff, Ph. D.
5/16/00

PHARMACOLOGIST REVIEW OF NDA 21-175
ORIGINAL SUMMARY

Sponsor: Department of the Army
Office of the Surgeon General
504 Scott St.
Fort Detrick
Frederick, MD

Drugs: atropine and pralidoxime chloride (i.m.)

Category: antidote for (anticholinesterase) nerve agent poisoning

Related NDAs:

- 1) NDA 17-106 (marketed atropine autoinjector)
- 2) NDA 18-986 (marketed pralidoxime chloride autoinjector)

SUMMARY/EVALUATION:

The present product combines the above 2 drugs; they are injected sequentially through a single needle.

No animal studies were submitted; none were required for this product.

The following comments concern the proposed labeling:

RECOMMENDATION:

This NDA is approvable.

Comments on the proposed labeling are made above.

/S/

Barry N. Rosloff, Ph. D.

cc: NDA 21-175, original submission + division file

Rosloff
Fitzgerald **/S/** 5/17/00
Nighswander