

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**85888**

**MEDICAL REVIEW**

REVIEW OF RESUBMISSION

DATE COMPLETED: 1-6-78

ANDA #: 85-888

CO. NAME & ADDRESS:  
Chromalloy Pharmaceuticals, Inc.  
Los Angeles, CA 90066

NAME OF DRUG: Brompheniramine Maleate Tablets, 4 mg

DATE OF SUBMISSION: 12-12-77

TYPE OF SUBMISSION: Resubmission

CLINICAL EVALUATION:

1. Review of studies: None submitted
2. Review of labeling:
  - a. Container labels for containers of 100 and 1000 tablets - satisfactory
  - b. Package insert: satisfactory

CONCLUSION: The labeling for this drug is acceptable

RECOMMENDATIONS: The company is to be so notified

JS  
J.R. Carr, D.D.S.

cc:  
Dup  
JRCarr/m1b/1-6-77

REVIEW OF ANDA

DATE COMPLETED: 7-11-77

ANDA #: 85-888

CO. NAME: Chromalloy Pharm., Inc.  
Los Angeles, CA 90066

F.R. DATE: 3-19-73

NAME OF DRUG: Brompheniramine Maleate Tablets, 4 mg.

DATE OF SUBMISSION: 6-9-77

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: Bioavailability requirement is deferred for this drug.
2. Review of Labeling:
  - a) container label: draft copies for containers of 100 and 1000 tablets - satisfactory.
  - b) insert labeling: draft copy - satisfactory

CONCLUSION: The draft labeling for this is satisfactory. Have the firm send in FPL identical in content.

RECOMMENDATIONS: The company is to be so notified.

cc:dup  
JRC/wlb/7-13-77

JS  
~~J.H. Carr, D.D.S.~~