

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

85888

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Statement Date:

NDA NUMBER:
85-888

NAME AND ADDRESS OF APPLICANT

Chromalloy Pharm, Inc
Los Angeles, CA 90066

ORIGINAL
AMENDMENT ☒
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

submission of one month stability study

DATE(s) of SUBMISSION(s)
3/28/78

PHARMACOLOGICAL CATEGORY

Antihistamine

NAME OF DRUG

Brompheniramine Maleate

HOW DISPENSED

RX ☒ OTC ☐

DOSAGE FORM

tablet

POTENCY

4 mg.

RELATED IND/NDA/DMF

LABELING

Container label: Satisfactory(JRCarr)
Package insert: " "

BIOLOGIC AVAILABILITY

deferred

ESTABLISHMENT INSPECTION

Chromalloy Pharm. Inc. incompliance

7-26-77

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

active ingredient, and excipients and finished dosage form are tested according to USP/NF spec.

PACKAGING

amber glass bottles
white metal cap

STABILITY

Protocol:

submitted

Exp. Date:

two years

REMARKS AND
CONCLUSION:

approved

JMRoss

REVIEWER:

JSI 4/25/78

CHROMALLOY REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Statement Date

85-888

AF Number

Name and address of Applicant (City and State)

Chromalloy Pharm. Inc.
Los Angeles, CA 90066

Original
Amendment ☒
Supplement
Resubmission
Correspondence
Report
Other

Purpose of Amendment/Supplement

submission of FPL and stability information

Date(s) of Submission(s)

12/12, 19/77

Pharmacological Category

Antihistamine

Name of Drug

Brompheniramine Maleate

Dosage Form(s)

tablet

Potency(ies)

4 mg.

How Dispensed

Rx ☒

OTC

Sterilization

NA

Samples

Related IND/NDA/DMF

Labeling

Container label: Satisfactory (JRCarr)
Package insert: " "

Biologic Availability

DEFERRED

Establishment Inspection

Chromalloy Pharm. Inc. noncompliance

Components, Composition, Manufacturing and Controls

Active ingredient, excipients and finished dosage form are tested according to USP & NF specs

Packaging

Container —

amber glass round bottle

Closure —

white metal cap

Stability
Protocol

submitted

Expiration Date

two exp date requested

Remarks and Conclusion

Requested one-month stability study

REVIEWER

rev w/f J.M. Ross

DATE

2-3-78

**CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT**

Federal Register
Statement Date

NDA Number 85-888

AF Number

Name and Address of Applicant (City and State)

Chromalloy Pharm, Inc.
Los Angeles, CA 90066

Original

Amendment ☒
Supplement ☐
Resubmission ☐
Correspondance ☐
Report ☐
Other ☐

Purpose of Amendment/Supplement

submission of additional control information

Date(s) of Submission(s)

11/1/77

Pharmacological Category

Antihistamine

Name Of Drug

Brompheniramine Maleate

Dosage Form(s)

tablet

Potency

4 mg.

How Dispensed

Rx ☒

OTC ☐

Environmental Impact Analysis
Report

submitted

Samples

Related IND/NDA/MF(s)

Labeling

NA

Biologic Availability

Deferred

Establishment Inspection

Chromalloy Pharm, Inc, in compliance

Components, Composition, Manufacturing and Controls

active ingredient, excipients and finished dosage form are tested according
to USP & NF Specs.

Remarks

Requested: Expand stability protocol
Submit FPL

Conclusion

rev w/f

J.M. Ross

IS/

12-12-77

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date

NDA Number

85-888

AF Number

Name and Address of Applicant (City and State) Chromalloy Pharm. Inc. Chromalloy Labs. Div. Los Angeles, CA 90066		Original Amendment Supplement Resubmission Correspondance Report Other
Purpose of Amendment/Supplement NEW APPLICATION		Date(s) of Submission(s) 6/9/77
Pharmacological Category Antihistamine.	Name Of Drug Brompheniramine Maleate	
Dosage Form(s) tablet	Potency 4 mg.	How Dispensed Rx ☒ OTC ☐
Environmental Impact Analysis Report submitted	Samples	Related IND/NDA/MF(s)

Labeling
Container label: Satisfactory (JRCarr)
Package insert: "

Biologic Availability
Deferred

Establishment Inspection
Chromalloy Pharm Inc, incompliance

Components, Composition, Manufacturing and Controls
active ingredient, excipients and finished dosage form are tested according to USP&NF specs

Remarks
Requested: FPL
1 include reference to 3rd Suppl. for revision of specs for sodium lauryl sulfate, pregeatinized starch, lactose, & dibasic calcium phosphate
3 indicate specs for FD&C Yellow #6/ submit Cert. Anal.
4 Examine FD&C Yellow #5 / F.R. 2/4/77

Conclusion

Reviewer:

rev: w/f

J?M. Ross

15/1/77

Date: