

CENTER FOR DRUG EVALUATION AND RESEARCH

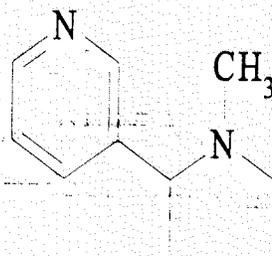
APPLICATION NUMBER: 74-507

CHEMISTRY REVIEW(S)

1. CHEMIST'S REVIEW NO. 7
2. ANDA # 74-507
3. NAME AND ADDRESS OF APPLICANT
 Circa Pharmaceuticals, Inc.
 Attention: Joyce Anne DelGaudio
 33 Ralph Avenue
 P.O. Box 30
 Copiague, NY 11726-0030
4. LEGAL BASIS for ANDA SUBMISSION
 Listed drug is Nicorette® (Marion Merrel Dow, NDA#18612)
 Exclusivity for NCE expired 1/13/94 and for new product
 (NDA# 20066) expired 6/8/95. Exclusivity 2/9/99.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME None
7. NONPROPRIETARY NAME Nicotine Polacrilex Gum USP
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:
Firm:
 06/16/94: Date of submission
 06/23/94: Original amendment
 08/15/94: Original amendment (bioequivalence)
 03/14/95: Original amendment
 08/01/95: Response to field inspection report
 08/04/95: Labeling Amendment
 03/27/96: Bio amendment
 04/23/96: Original amendment
 08/09/96: Original amendment
 08/15/96: New correspondence
 02/15/97: New correspondence
 08/14/97: Major amendment
 09/12/97: Response to bio request (chew-out study)
 05/05/98: Facsimile Amendment
 07/29/98: Amendment
 10/5/98: New correspondence
 11/5/98: New correspondence
 1/8/99: Minor amendment
 2/5/99: New correspondence
 2/25/99: New Correspondence
 3/3/99: Label amendment
 3/9/99: Label amendment
 3/10/99: Label amendment
FDA:
 01/18/95: NA letter #1
 05/10/96: Bio letter - acceptable, old formulation
 03/06/97: NA letter #2 (Chem & label)
 05/28/97: Bio letter - request for Chew-out study
 01/28/98: Bio waiver granted for 2 mg
 04/16/98: NA Fax #3 (Chem & label)
 05/18/98: NA Fax (label)
 12/30/98: TA granted
 1/22/99: Phone call by C. Hoppes
 2/4/99: Label review/deficiency

2/16/99: Label review/deficiency
3/11/99: Acceptable Label review & Chem review completed

10. PHARMACOLOGICAL CATEGORY
Ganglionic Stimulating Agent
Use: Smoking deterrent
11. Rx or OTC
OTC
12. RELATED IND/NDA/DMF(s): See element #37 for list of DMFs
13. DOSAGE FORM
Chewing Gum
14. POTENCY
2 mg
15. CHEMICAL NAME AND STRUCTURE



Nicotine

$C_{10}H_{14}N_2$ Mol.Wt. 162.23

1-methyl-2-(3-pyridyl)pyrrolidine

16. RECORDS AND REPORTS:
None

17. COMMENTS

- a. EER submitted on 12.23.94; a 483 was issued, the sponsor's response to the 483 was submitted to the ANDA on 8.1.95. EER issued again on 2/11/97. Acceptable 12/29/98.
- b. Biowaiver issued; letter dated 1/28/98.

18. CONCLUSIONS AND RECOMMENDATIONS

No outstanding chemistry deficiencies; ANDA is approvable. Labeling review acceptable as of 3/11/99.

19. REVIEWER:

Radhika Rajagopalan, Ph.D.

DATE COMPLETED:

3/11/99

3/11/99