CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-429

PHARMACOLOGY REVIEW(S)

PHARMACOLOGY/TOXICOLOGY FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 22-429 **Applicant:** Banner Pharmacaps Inc. **Stamp Date:** July 31, 2008

Drug Name: Cetirizine HCl Capsules, 10 mg & 5 mg **NDA Type:** 505(b)(2)

Background:
Banner Pharmacaps Inc. (BPI) is seeking approval for over the counter (OTC) marketing of its proposed drug product, Cetirizine HCl, Capsules, 10 mg & 5 mg. This is an application that will rely on the Agency's finding of safety and efficacy for the reference listed drug (RLD), Zyrtec® Tablets, 10 mg & 5 mg, the subject of NDA 19-835, held by McNeil Consumer Healthcare. The proposed indications are temporarily relief of symptoms due to hay fever or other upper respiratory allergies. The proposed dosage is one capsule (10mg) or one to two capsules (5mg) once daily.

On initial overview of the NDA application: There are no outstanding pharmacology/ toxicology issues since this NDA refers to the finding of safety for NDA 19-835. No additional information was submitted under this NDA that belongs in the pharmacology/toxicology section.

	Content Parameter	Yes	No	Comment
1	On its face, is the pharmacology/toxicology section of the NDA organized (in accord with 21 CFR 314 and current guidelines for format and content) in a manner to allow substantive review to begin?			N/A- this is a 505(b)(2). The referenced NDA is NDA 19-835
2	Is the pharmacology/toxicology section of the NDA indexed and paginated in a manner allowing substantive review to begin?			N/A –see 1
3	On its face, is the pharmacology/ toxicology section of the NDA legible so that substantive review can begin?			N/A –see 1
4	Are all required (*) and requested IND studies (in accord with 505 b1 and b2 including referenced literature) completed and submitted in this NDA (carcinogenicity, mutagenicity*, teratogenicity*, effects on fertility, juvenile studies, acute and repeat dose adult animal studies*, animal ADME studies, safety pharmacology, etc)?			N/A –see 1
5	If the formulation to be marketed is different from the formulation used in the toxicology studies, have studies by the appropriate route been conducted with appropriate formulations? (For other than the oral route, some studies may be by			N/A –see 1

PHARMACOLOGY/TOXICOLOGY FILING CHECKLIST FOR A NEW NDA/BLA

	Content Parameter	Yes	No	Comment
	routes different from the clinical route intentionally and by desire of the FDA).			
6	On its face, does the route of administration used in the animal studies appear to be the same as the intended human exposure route? If not, has the sponsor submitted a rationale to justify the alternative route?			N/A –see 1
7	Has the sponsor submitted a statement(s) that all of the pivotal pharm/tox studies have been performed in accordance with the GLP regulations (21 CFR 58) or an explanation for any significant deviations?			N/A –see 1
8	Has the sponsor submitted all special studies/data requested by the Division during pre-submission discussions with the sponsor?			N/A –see 1
9	Are the proposed labeling sections relative to pharmacology/toxicology appropriate (including human dose multiples expressed in either mg/m2 or comparative serum/plasma levels) and in accordance with 201.57?			N/A –see 1
10	If there are any impurities – etc. issues, have these been addressed? (New toxicity studies may not be needed.)			N/A –see 1
11	Has the sponsor addressed any abuse potential issues in the submission?			N/A –see 1
12	If this NDA is to support a Rx to OTC switch, have all relevant studies been submitted?			N/A –see 1
13	From a pharmacology/toxicology perspective, is the NDA fileable? If ``no`` please state below why it is not.	x		

Cindy Li — April 3, 2009

Reviewing Pharmacologist — Date

Paul Brown — April 3, 2009

Team Leader/Supervisor — Date

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/s/

Xinguang Li
4/9/2009 12:19:17 PM
INTERDISCIPLINARY

PM suggested to still put in for the checklist since wcompleted anyway. Thanks!

Paul Brown
4/10/2009 03:19:49 PM
PHARMACOLOGIST

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY REVIEW AND EVALUATION

NDA NUMBER:	**22-429**
SERIAL NUMBER:	**000**
DATE RECEIVED BY CENTER:	**July 31, 2008**
PRODUCT:	**Cetirizine HCl Capsules, 10 mg & 5 mg**
INTENDED CLINICAL POPULATION:	**Temporarily relief of symptoms due to hay fever or other upper respiratory allergies**
SPONSOR:	**Banner Pharmacaps Inc.**
DOCUMENTS REVIEWED:	**Vol. 1**
REVIEW DIVISION:	**Division of Nonprescription Clinical Evaluation (HFD-560)**
PHARM/TOX REVIEWER:	**Cindy Li, Ph.D.**
PHARM/TOX SECONDARY REVIEWERS:	**Wafa Harrouk, Ph.D.** **Paul Brown, Ph.D.**
DIVISION DIRECTOR:	**Andrea Leonard-Segal, M.D.**
PROJECT MANAGER:	**Janice Adams-King, RPM**

Date of review submission to Division File System (DFS):

EXECUTIVE SUMMARY

A. Recommendation on approvability

This is a 505(b)(2) application. The applicant is relying on the Agency's finding of safety and efficacy for the reference listed drug (RLD), Zyrtec® Tablets, 10 mg & 5 mg, which is the subject of NDA 19-835 held by McNeil Consumer Healthcare. Based on the Agency's previous finding of safety for Zyrtec, NDA 22-429 can be approved from the pharmacology/toxicology perspective provided the clinical and clinical pharmacology/biopharmaceutics reviewers find that an adequate clinical bridge has been established between the two products.

B. Recommendation for nonclinical studies

There are no outstanding pharmacology/ toxicology issues.

PHARMACOLOGY/TOXICOLOGY REVIEW

NDA number: 22-429
Review number: 1
Sequence number/date/type of submission: SN000/ 07/31/2008 /NDA
Information to sponsor: Yes () No (x)
Sponsor and/or agent: Banner Pharmacaps Inc.

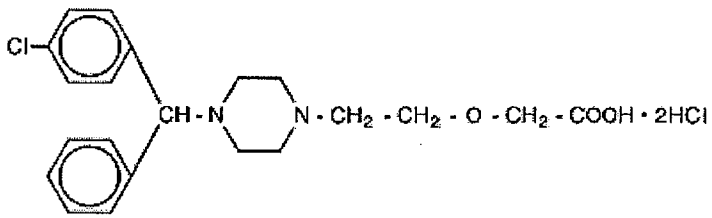
Reviewer name: Cindy Li, Ph.D.
Division name: DNCE, Office of Nonprescription Products (ONP)
HFD #: 560
Review completion date: 4/2/2009

Drug: Cetirizine HCl Capsules, 10 mg & 5 mg
Drug class: Antihistaminic agent

Intended clinical population: temporarily relief of symptoms due to hay fever or other upper respiratory allergies
Route of administration: Oral capsule

Drug:

Trade name: Cetirizine HCl
Chemical name: (RS)-2-[2-[4-[(4-Clorophenyl)phenylmethyl] Piperazin-1-yl]ethoxy]acetic acid dihydrochloride
CAS registry number: 83881-52-1
Molecular formula: C12H27Cl3N2O3
Molecular weight: 461.8
Structure:



Relevant INDs/NDAs/DMFs:
NDA 19-835, ——, 21-150, 22-155, 20-346, 21-621 and supplements. b(4

Background:
Banner Pharmacaps Inc. (BPI) is seeking approval for over the counter (OTC) marketing of its proposed drug product, Cetirizine HCl, Capsules, 10 mg & 5 mg. This is an application that will rely on the Agency's finding of safety and efficacy for the reference listed drug (RLD), Zyrtec® Tablets, 10 mg & 5 mg, the subject of NDA 19-835, held by McNeil Consumer Healthcare. The proposed indications are temporarily relief of

symptoms due to hay fever or other upper respiratory allergies. The proposed dosage is one capsule (10mg) or one to two capsules (5mg) once daily.

Pharmacology/Toxicology Review:

This is a 505(b) (2) submission and the sponsor is referring to the Agency's previous finding of safety for NDA 19-835 for all nonclinical support. No additional information was submitted under this NDA that belongs in the pharmacology/toxicology section.

OVERALL CONCLUSIONS AND RECOMMENDATIONS
On overview of the NDA application: there are no outstanding pharmacology/ toxicology issues.

Unresolved toxicology issues (if any): None

Recommendations: Based on the Agency's previous finding of safety for Cetirizine HCl (5 & 10 mg) (Zyrtec) tablets in addition to previous human experience with this entity, NDA 22-429 can be approved from the nonclinical perspective.

Reviewer Signature: Cindy Li, Ph.D.

Supervisor Signature: Paul Brown, Ph.D. Concurrence Yes X No ___

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/s/

Xinguang Li
4/3/2009 01:19:26 PM
INTERDISCIPLINARY

Please sign.Thanks!

Paul Brown
4/10/2009 03:17:15 PM
PHARMACOLOGIST

LABELING FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 22-429	**Applicant:** Banner Pharmacaps Inc.	**Stamp Date:** 09/26/2008
Drug Name: **Cetirizine HCL Capsules**	**NDA Type:** NDA Amendment (N-000-BL)	

On **initial** overview of the NDA application for RTF:

	Content Parameter	Yes	No	Comments
1	Is Index sufficient to locate necessary labeling?	X		
2	Has labeling for all SKUs been submitted (e.g., blister card, pouch, immediate container, carton label and package insert labeling, etc)?	X		
3	Does the submission contain the annotated specifications for the "Drug Facts" label?	X		
4	Is a new trade name being proposed? If multiple trade names, is the RLD trade name identified?		X	

Any Additional Comments:

This is an amendment to the filling checklist DFS on 09/29/ 2008. The submission did contain the annotated specifications for the "Drug Facts" label.

Ayana K. Rowley, Pharm.D. — 10/07/2008

Reviewing Interdisciplinary Scientist — Date

Supervisor/Team Leader — Date

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/s/

Ayana Rowley
10/7/2008 11:24:28 AM
PHARMACIST

Marina Chang
10/7/2008 11:27:17 AM
INTERDISCIPLINARY

LABELING FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: **22-429**	**Applicant:** Banner Pharmacaps Inc.	**Stamp Date:** 09/26/2008
Drug Name: **Cetirizine HCL Capsules**	**NDA Type:** NDA Amendment (N-000-BL)	

On **initial** overview of the NDA application for RTF:

	Content Parameter	Yes	No	Comments
1	Is Index sufficient to locate necessary labeling?	X		
2	Has labeling for all SKUs been submitted (e.g., blister card, pouch, immediate container, carton label and package insert labeling, etc)?	X		
3	Does the submission contain the annotated specifications for the "Drug Facts" label?		X	
4	Is a new trade name being proposed? If multiple trade names, is the RLD trade name identified?		X	

Any Additional Comments:

Ayana K. Rowley, Pharm.D. — 09/29/2008

Reviewing Interdisciplinary Scientist — Date

Supervisor/Team Leader — Date

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/s/

Ayana Rowley
9/30/2008 02:26:40 PM
PHARMACIST

Debbie Lumpkins
9/30/2008 02:53:32 PM
INTERDISCIPLINARY