

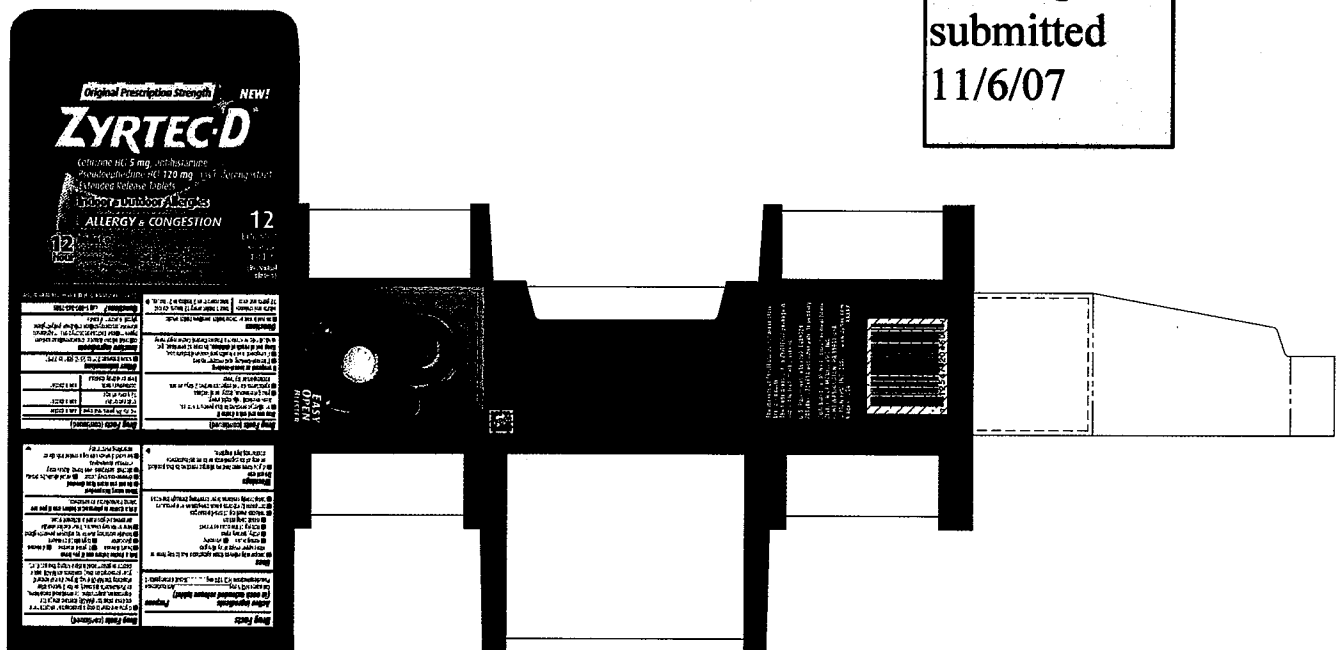
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

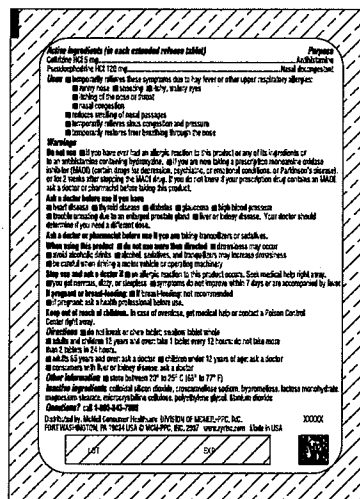
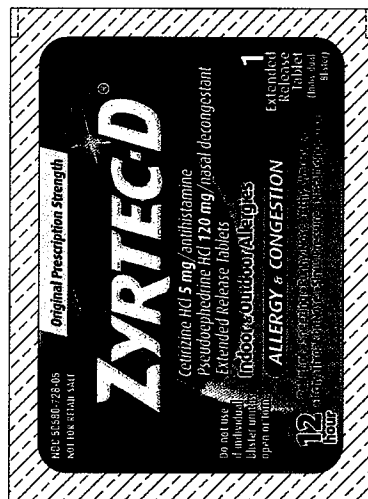
APPLICATION NUMBER:
21-150/S007

LABELING

Supplemental NDA 21-150/S-007: Zyrtec-D (Cetirizine HCl 5 mg/Pseudoephedrine HCl 120 mg)
Over-the-Counter (OTC) Use
Amendment to Pending Application

Zyrtec-D
labeling
submitted
11/6/07





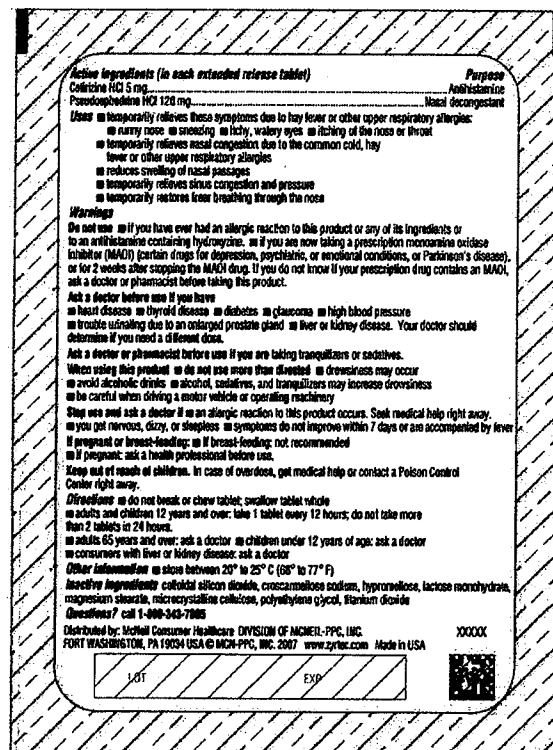
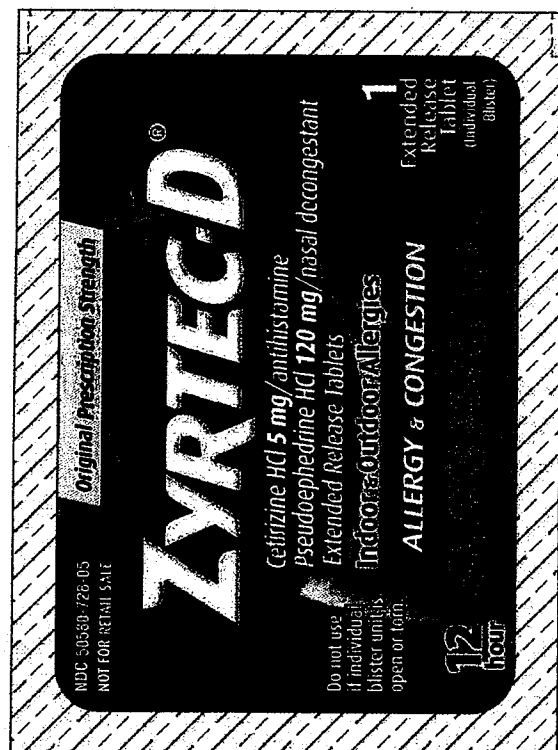
Submission C

**Zyrtec-D
labeling
submitted
10/30/07**

labeling
submitted
10/30/07

mission B

Commission B



Zyrtec-D 5 mg/antihistamine	
1. Indications and Usage	2. Dosage and Administration
3. Contraindications	4. Warnings and Precautions
5. Adverse Reactions	6. Drug Interactions
7. Clinical Studies	8. How Supplied
9. Marketing Commitment	10. Other Information
11. Zyrtec-D 5 mg/antihistamine	12. Zyrtec-D 5 mg/antihistamine
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NEW!

Original Prescription Strength

ZYRTEC-D

Cetirizine HCl 5 mg/antihistamine
Pseudoephedrine HCl 120 mg/nasal decongestant
Extended Release Tablets

Relief of:
Sneezing
Runny Nose
Nasal Congestion
Itchy Throat
Itchy Eyes
Itchy Ears
Itchy Skin

50
100 mg/120 mg
100 mg/120 mg
100 mg/120 mg

EASY OPEN

FREE SAMPLES
NOT FOR RESALE

Indoor/Outdoor Allergies
ALLERGY & CONGESTION

NEW!

Original Prescription Strength

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Cetirizine HCl 5 mg/antihistamine
Pseudoephedrine HCl 120 mg/nasal decongestant
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Indoor/Outdoor Allergies
ALLERGY & CONGESTION

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/s/

Andrea Segal
11/9/2007 10:37:28 AM