CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

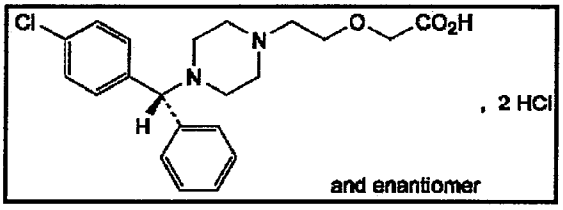
19-835/S022

21-621/S005

CHEMISTRY REVIEW(S)

Chemistry Review # 1	ONDQA Division IV- Branch VII	2. NDA Number 19-835
3. Name and Address of Applicant Pfizer Inc., 235 East 42nd Street, New York, NY 10017		4. Supplement# Date SE6-022 15-JAN-2007 GOAL 11/16/07
5. Name of Drug Zyrtec® Tablets	6. Nonproprietary Name Cetirizine hydrochloride	
7. Supplement Provides for: for the OTC marketing of this product with the same strength, dose, duration of use, dosage form, population and route of administration as the approved prescription NDA drug product.		8. Amendment(s) S/A 31-JUL-2007
9. Pharmacological Category Antihistamine	10. How Dispensed Tablet	11. Related Documents NDA 21-621/S-005 DMF [redacted] NDA 21-150/S-007 NDA 22-155 (20-346)* Also DMFs [redacted]
12. Dosage Form Tablet	13. Strength 5 mg and 10 mg	

14. Chemical Name and Structure: (±)-[2-[4-(p-chloro-α-phenylbenzyl)-1-piperazinyl]ethoxy] acetic acid dihydrochloride



15. Comments: This is a PA submission. This is the lead submission (i.e., lowest NDA number in the bundle of submissions) for the tablet dosage forms (i.e., see format item 11 above). While a number of DMFs are referenced, it is realized that they support the Rx drug product so they are assumed to be acceptable without additional assessment. One, DMF [redacted] has been reviewed (i.e., Chemistry Review #2 date of 28-AUG-2007) relative to this specific supplement since it is of interest to clearly understand the basic controls used [redacted]. It is adequate. Another DMF [redacted] was checked for information [redacted], but no review was written owing to poor information organization.

* This syrup dosage strength is not part of this specific bundle that is for just the related tablet dosage forms. Refer to [redacted] for a background perspective of the filing relationships between the related dosage forms.

File N19835_S22W(27-AUG)

16. Conclusions and Recommendations: Send an approval letter for this NDA 19-835/S-022. Include the other bundled supplements involved.

17. Name **Signature** **Date 30-AUG-2007**

Stuart Zimmerman (ONDQA, Division IV, Branch VII)

Dr. James Vidra, PhD, Branch Chief (ONDQA, Division IV, Branch VII)

22 Page(s) Withheld

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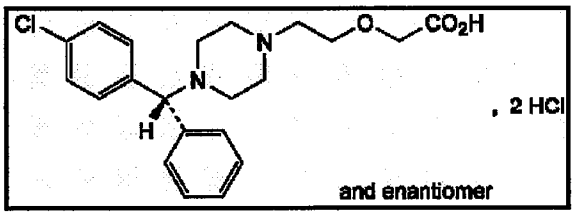
/s/

Stuart Zimmerman
9/5/2007 01:05:54 PM
CHEMIST

Jim Vidra
9/5/2007 03:08:16 PM
CHEMIST

Chemistry Review # 1	ONDQA Division IV- Branch VII	2. NDA Number 21-621
3. Name and Address of Applicant Pfizer Inc., 235 East 42nd Street, New York, NY 10017		4. Supplement# Date SE6-005 15-JAN-2007 GOAL 11/16/07
5. Name of Drug Zyrtec® Chewable Tablets	6. Nonproprietary Name Cetirizine hydrochloride	
7. Supplement Provides for the OTC marketing of this product with the same strength, dose, duration of use, dosage form, population and route of administration as the approved prescription NDA drug product.		8. Amendment(s) S/A 31-JUL-2007
9. Pharmacological Category Antihistamine	10. How Dispensed Rx	11. Related Bundled Documents ((Tablets): NDA 19-835/S-022 NDA 21-150/S-007 DMFs ———
12. Dosage Form Chewable Tablet	13. Strength 5 mg and 10 mg	

14. Chemical Name and Structure: (±)-[2-[4-(p-chloro-α-phenylbenzyl)-1-piperazinyl]ethoxy] acetic acid dihydrochloride



15. Comments: This is a PA submission. This NDA is part of a bundle of related supplements as noted in Section 11 above. The reference to the CMC section of this supplement was reported to be found in Summary Volume 2 (pages 456 through 458). It was indicated that there are no drug substance or drug product changes from the current NDA. CMC topic sections of special interest in this review deal with the container-closure system and its related stability consequencies. These control aspects were not initially addressed in the supplement so queries provided more information. There is also reference to the operation of another testing site that has been approved by OC (i.e., see report in Review Notes).

16. Conclusions and Recommendations: Send an approval letter for this NDA 21-621. Include the other bundled supplements involved in a joint action letter.

17. Name **Signature** **Date 30-AUG-2007**
Stuart Zimmerman (ONDQA, Division IV, Branch VII)

Dr. James Vidra, PhD, Branch Chief (ONDQA, Division IV, Branch VII)

File N21621_S-005_W(21-AUG-2007)

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