



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 90-254

Perrigo R&D Company  
Attention: Vallerie Gallagher  
Associate Director, Regulatory Affairs  
515 Eastern Avenue  
Allegan, MI 49010

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 19, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Children's Cetirizine Hydrochloride Oral Solution (Allergy) and Children's Cetirizine Hydrochloride Oral Solution (Hives-Relief), 1 mg/mL (OTC).

Reference is also made to your amendments dated February 26, February 28, and March 17, 2008.

We have completed the review of this ANDA, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted over-the-counter (OTC) labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Children's Cetirizine Hydrochloride Oral Solution (Allergy) and your Children's Cetirizine Hydrochloride Oral Solution (Hives-Relief), 1 mg/mL, to be bioequivalent to the reference listed drug, Children's Zyrtec Oral Solution (Allergy) and Children's Zyrtec Oral Solution (Hives-Relief), respectively, 1 mg/mL, of McNeil Consumer Healthcare.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Robert L. West  
4/9/2008 11:17:00 AM  
Deputy Director, for Gary Buehler