

**LACHMAN CONSULTANT SERVICES, INC.**  
Westbury, NY 11590

# **ATTACHMENT D**

**DIFFERENCES BETWEEN THE LABELING FOR  
CETIRIZINE ORALLY DISINTEGRATING TABLETS AND THE LABELING FOR  
ZYRTEC®(TABLETS, CHEWABLE TABLETS, AND ORAL SYRUP)**

1. The name ZYRTEC was removed throughout the package insert and was replaced with either Cetirizine, Cetirizine Hydrochloride, or Cetirizine Hydrochloride Orally Disintegrating Tablets.
2. The DESCRIPTION section was revised to include Cetirizine Hydrochloride Orally Disintegrating Tablets and remove the three paragraphs describing ZYRTEC® Tablets, ZYRTEC Chewable Tablets, and ZYRTEC Syrup.
3. The DOSAGE AND ADMINISTRATION section was revised to remove the Subsection "Children 6 months to less than 2 years" because this patient group is dosed with 1/2 teaspoon of Syrup daily and this petition does not involve the syrup form of the product. Since the orally disintegrating tablet will be marketed in 5 mg and 10 mg strengths, and since the package insert states that the tablet should not be broken, the insert does not include a recommended dosage for this patient population. In addition, the same holds true for the children's age group, 2 to 5 years. Therefore, the paragraph relating to syrup under the subheading "Children 2 to 5 Years" was removed and replaced with the statement: "The recommended initial dose of Cetirizine Hydrochloride Orally Disintegrating Tablets in children aged 2 to 5 years is 5 mg once a day."
4. Revisions were made to the INDICATIONS: "Perennial Allergic Rhinitis" and "Chronic Urticaria" subsections. As discussed above, the petition does not apply to the syrup form of the product. Thus, the reference to children below the age of 2 years has been deleted and replaced with, "children 6 months of age and older" in both subsections.

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