

**ATTACHMENT 2**



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**REQUEST FOR WAIVER OF PEDIATRIC STUDIES**



## REQUEST FOR WAIVER OF PEDIATRIC STUDIES

**Product Name** Clarithromycin Extended Release Tablets 1000mg

**Suitability Petition number:** 2003P-0238/CP1

**Sponsor:** THE WEINBERG GROUP

### Indications(s):

Adults:

Clarithromycin extended release tablets are indicated for the treatment of adults with mild to moderate infection caused by susceptible strains of the designated microorganisms in the conditions listed below:

Acute maxillary sinusitis due to *Haemophilus influenzae*, *Moraxella catarrhalis*, or *Streptococcus pneumoniae*

Acute bacterial exacerbation of chronic bronchitis due to *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, or *Streptococcus pneumoniae*

Community-Acquired Pneumonia due to *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, *Streptococcus pneumoniae*, *Chlamydia pneumoniae* (TWAR), or *Mycoplasma pneumoniae*

THE EFFICACY AND SAFETY OF CLARITHROMYCIN EXTENDED RELEASE TABLETS IN TREATING OTHER INFECTIONS FOR WHICH OTHER FORMULATIONS OF CLARITHROMYCIN ARE APPROVED HAVE NOT BEEN ESTABLISHED.

### 1. What age ranges are included in your waiver request?

Pediatric Population, all age groups

### 2. Reasons for waiving pediatric studies:

- (a) No meaningful therapeutic benefit over existing treatments **and** is unlikely to be used in a substantial number of **pediatric** patients
- (b) Studies are impossible or highly impractical because the number of patients is so small or geographically dispersed
- (c) The product would be ineffective or unsafe in all **pediatric** age groups
- (d) Attempts to develop a **pediatric** formulation for a specific age group have failed
- (e) Disease-specific waiver indicated for the treatment of the condition in adults (please check)



Alzheimer's disease  
Age-related macular degeneration  
Prostate Cancer  
Breast cancer  
Renal cell cancer  
Non-germ cell ovarian cancer  
Hairy cell cancer  
Pancreatic cancer, colorectal cancer  
Osteoarthritis  
Squamous cell cancers of the oropharynx  
Uterine cancer  
Basal cell and squamous cell cancer  
Endometrial cancer  
Small cell and non-small cell lung cancer  
Parkinson's disease  
Amyotrophic lateral sclerosis  
Arteriosclerosis  
Symptoms of menopause  
Infertility  
Other (please state and justify)

**3. Justification for waiver (not necessary if category 2(e) is checked):**

Please see attached the letter providing the justification for the waiver.

