2. SYNOPSIS

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<tr>
<th>Name of Sponsor/Company</th>
<th>Individual Study Table Referring to Part of the Dossier</th>
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<tr>
<td>McNeil Consumer Products Company</td>
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**Name of Finished Product:**

**Name of Active Ingredient:** acetaminophen, pseudoephedrine HCl, chlorpheniramine maleate

**Title of Study:** Phase IV Efficacy and Safety Study of Reformulated CoTylenol Tablets. Unpublished Report TA5.

**Investigators:**

**Study Centers:**

**Publication (reference):**

**Study Period:**

**Date of first enrollment:**

**Date of last completed:**

**Objective:**

**Methodology:** Multicenter, Open-label

**Number of Subjects (planned and analyzed):** 92 subjects were included in the efficacy analysis.

**Diagnosis and Main Criteria for Inclusion:** Subjects at least 6 y old with symptomology of upper respiratory infection or allergic rhinitis.

**Test Product, Dose and Mode of Administration, Batch Number:**
- Acetaminophen 325 mg + Pseudoephedrine Hydrochloride 30 mg + Chlorpheniramine Maleate 2 mg, tablet oral
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Adults (12 y or older) were instructed to take 2 tablets three or four times daily. Children (6 to < 12 y) were instructed to take one tablet three or four times daily. Subjects were instructed to take study medication for a period of up to 4 days or until complete recovery, whichever came first.

Duration of Treatment: This was a multiple-dose study lasting up to four days.

Reference Therapy, Dose and Mode of Administration, Batch Number:

Criteria for Evaluation:
Efficacy:
Safety:

Statistical Methods:

SUMMARY - CONCLUSIONS

Efficacy Results: The mean age of the subjects was 33.76 years with a range of 9 years to 86 years.

As assessed by the investigators, 79% of subjects achieved good or excellent results. 16 symptoms were rated pre- and post-medication use on a 4-point scale as none (0), mild (1), moderate (2), and severe (3). Post-medication symptom severity levels were significantly lower than pre-medication levels, all p-values < 0.000007. Each of the 16 symptoms showed an average improvement in severity level of between 62% and 94%, for an overall average improvement of 78%.

Safety Results: 18 (20%) subjects reported AEs. Reported AEs included (number of AEs): drowsy (6), dry mouth (3), dizzy (2), insomnia (2), nervousness (1), slight jittery feeling (1), dryness of eyes and throat (1), nosebleed (1), chills (1), weakness (1), sleepy (1), severe headache (1), diarrhea (1), nausea/epigastric distress (1).
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**Conclusions:** Conclusions were not provided in the clinical study report.

**Date of the Report:** November 1978