



Bristol-Myers Squibb Company

Worldwide Consumer Medicines

1350 Liberty Avenue Hillside, New Jersey 07205 908 851-2400

September 12, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Attention: Charles Ganley, MD, Director
Division of OTC Drug Products (HFD-560)
Food and Drug Administration

Re: Docket No. 77N-0094 / CP 15
Internal Analgesic, Antipyretic, and Antirheumatic
Drug Products for Over-the-Counter Use

Supplement to Citizen Petition

Dear Dr. Ganley:

Reference is made to the Citizen Petition (Docket No. 77N-0094 / CP 15) submitted on 7/30/01 by Bristol-Myers Squibb Company (BMS) requesting the Agency to Amend the Proposed Rule for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Use.

Due to inadvertent technical errors resulting from computer difficulties, BMS is providing correction pages to Volume 1 of the Citizen Petition. Please note that changes have been made only to the revised Figures being provided herein and that the information in the Citizen Petition, presented in the text and supporting tables, is correct. These revisions do not affect any of the summaries or conclusions. For ease of review, a listing of the changes is also provided herein. We apologize for any inconvenience this may have caused. If you have any questions or comments regarding this submission please contact me at (908) 851-6126.

Sincerely,

Rich Cuprys
Director, Regulatory Affairs
Worldwide Consumer Medicines
Bristol-Myers Squibb Company

CC: Walt Ellenberg, Ph.D. (HFD-560)

77N-0094

SUP 46

**Supplement to Citizen Petition
Listing of Changes to Original Pages**

Page 11

Figure A
Pain Intensity Difference
Tension Headache
(ITT)

New Page 11A

Revisions:

Graph for Study HPD-H203

- Deleted asterisk denoting statistical significance at 0.75 hour
- Deleted asterisk denoting statistical significance at 1.00 hour

Graph for Study 170-02-88

- Added asterisks denoting statistical significance at 0.5, 1.00, 2.00, 3.00 & 4.00 hours

Page 12

Figure B
Pain Relief
Tension Headache
(ITT)

New Page 12A

Revisions:

Graph for Study HPD-H203

- Deleted asterisk denoting statistical significance at 0.75 hour
- Deleted asterisk denoting statistical significance at 1.00 hour

Graph for Pooled Studies

- Repositioned asterisks to appear above APAP/CAF line at 0.50, 1.00, 1.25, 1.50, 2.00, & 3.00 hours
- Added asterisk denoting statistical significance at 4.00 hours

Page 14

Figure D
Pain Relief
Dental Pain (ITT)

New Page 14A

Revisions:

Graph for Pooled Studies

- Deleted asterisk denoting statistical significance at 4.00 hour

Page 38

Figure A
Pain Intensity Difference
Tension Headache
(ITT)

New Page 38A

Revisions:

Graph for Study HPD-H203

- Deleted asterisk denoting statistical significance at 0.75 hour
- Deleted asterisk denoting statistical significance at 1.00 hour

Page 39

Figure B
Pain Relief
Tension Headache
(ITT)

New Page 39A

Revisions:

Graph for Study HPD-H203

- Deleted asterisk denoting statistical significance at 0.75 hour
- Deleted asterisk denoting statistical significance at 1.00 hour

Graph for Pooled Studies

- Added asterisk denoting statistical significance at 4.00 hours

Page 41

Figure D
Pain Relief
Dental Pain (ITT)

New Page 41A

Revisions:

Graph for Pooled Studies

- Deleted asterisk denoting statistical significance at 4.00 hour

Page 59

Figure 4.1.1
Pain Intensity Difference
Tension Headache (ITT)

New Page 59A

Revisions:

Graph for Study HPD-H203

- Deleted asterisk denoting statistical significance at 0.75 hour
- Deleted asterisk denoting statistical significance at 1.00 hour

Page 65

Figure 4.1.2
Pain Relief
Tension Headache
(ITT)

New Page 65A

Revisions:

Graph for Study HPD-H203

- Deleted asterisk denoting statistical significance at 0.75 hour
- Deleted asterisk denoting statistical significance at 1.00 hour

Page 72

Figure 4.2.1
Pain Intensity Difference
Dental Pain (ITT)

New Page 72A

Revisions:

Graph for Study HPD-D105

- Added asterisk denoting statistical significance at 1.25

Page 78

Figure 4.2.2
Pain Relief
Dental Pain (ITT)

New Page 78A

Revisions:

Graph for Pooled Studies

- Deleted asterisk denoting statistical significance at 4.00 hour

Page 90

Figure A
Pain Intensity Difference
Tension Headache
(ITT)

New Page 90A

Revisions:

Graph for Study HPD-H203

- Added asterisk denoting statistical significance at 1.25 hour

Graph for Pooled Studies

- Moved asterisk denoting statistical significance from 0.75 hour to 1.25 hour

Page 93

Figure D
Pain Relief
Dental Pain (ITT)

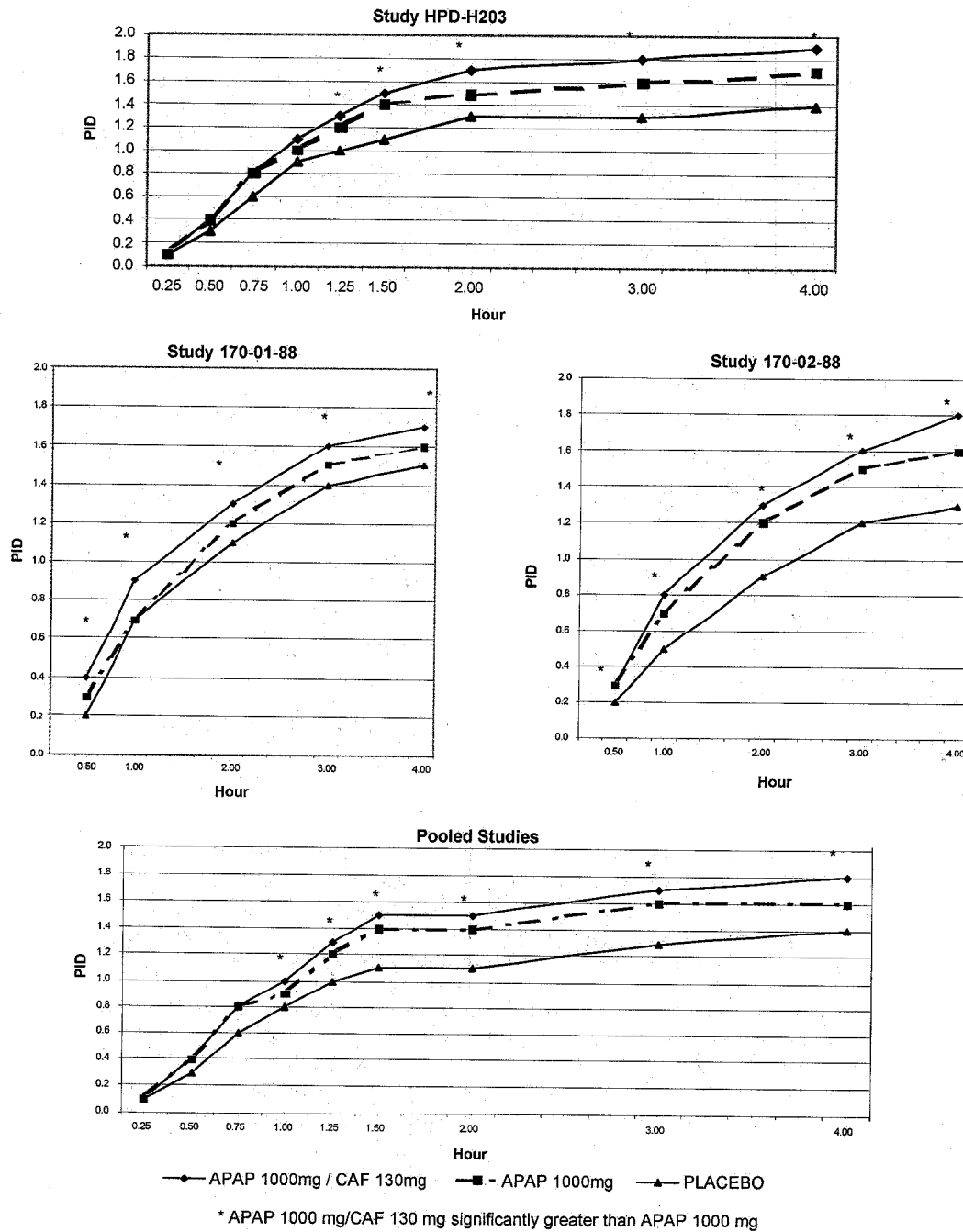
New Page 93A

Revisions:

Graph for Pooled Studies

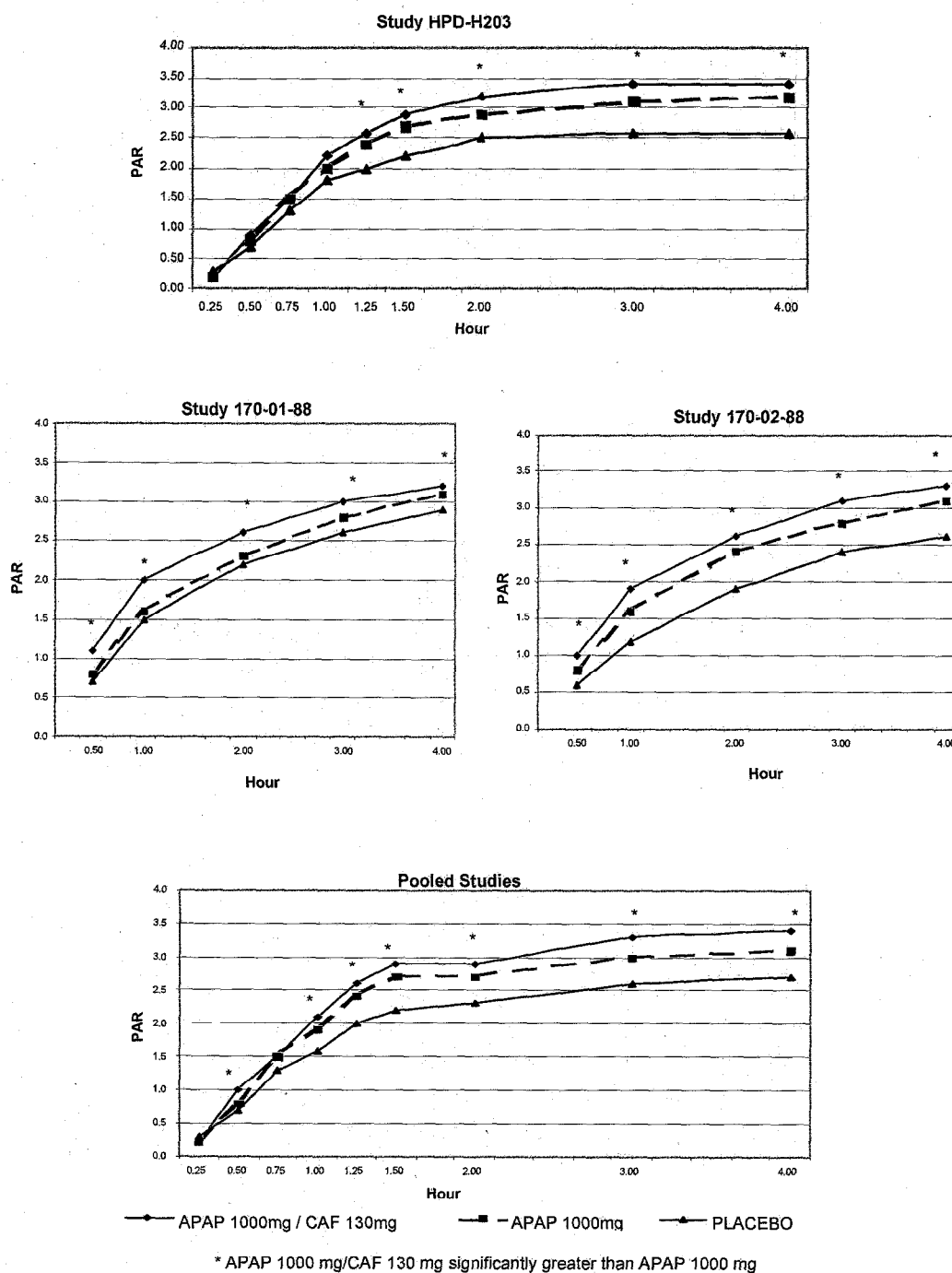
- Deleted asterisk denoting statistical significance at 4.00 hour

Figure A
Pain Intensity Difference
Tension Headache (ITT)



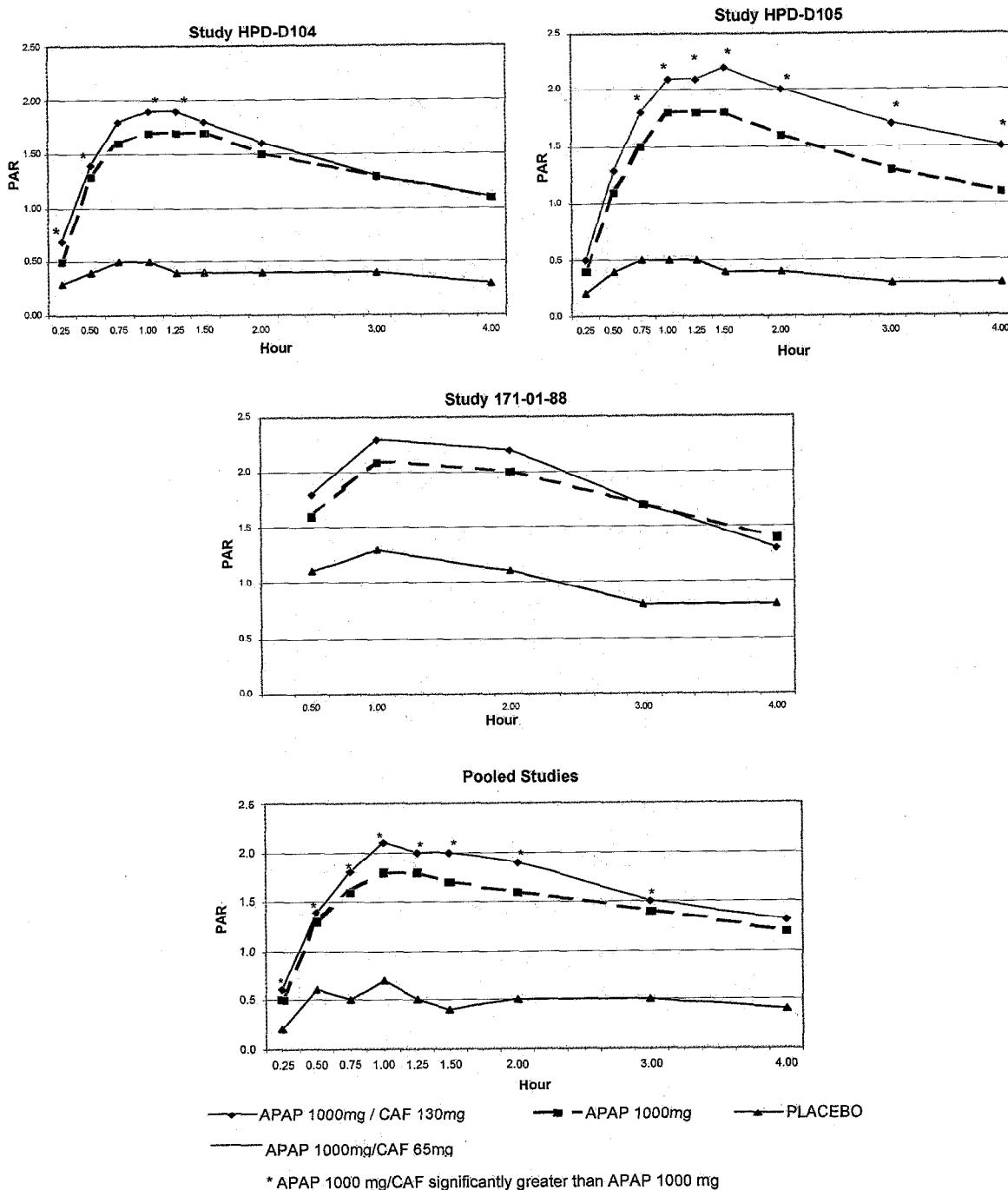
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Figure B
Pain Relief
Tension Headache (ITT)



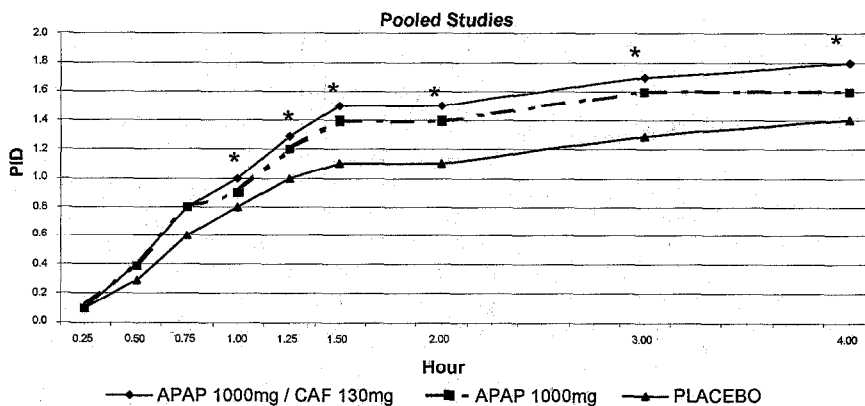
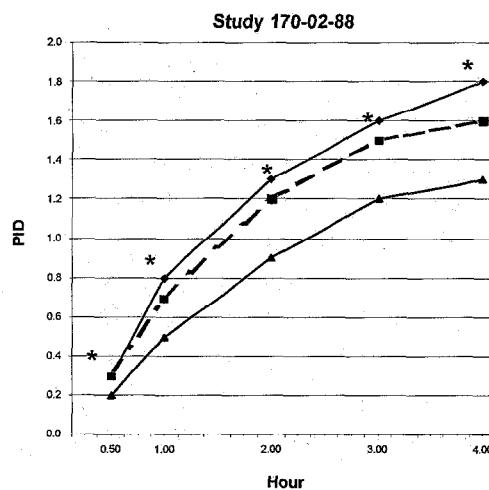
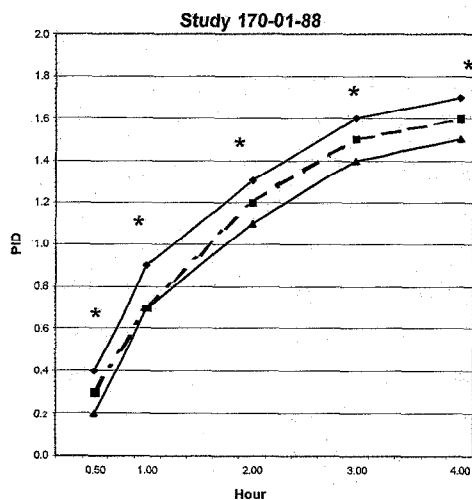
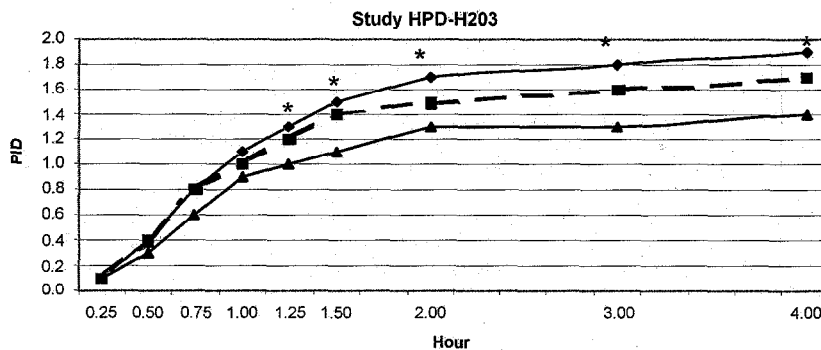
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Figure D
Pain Relief
Dental Pain (ITT)



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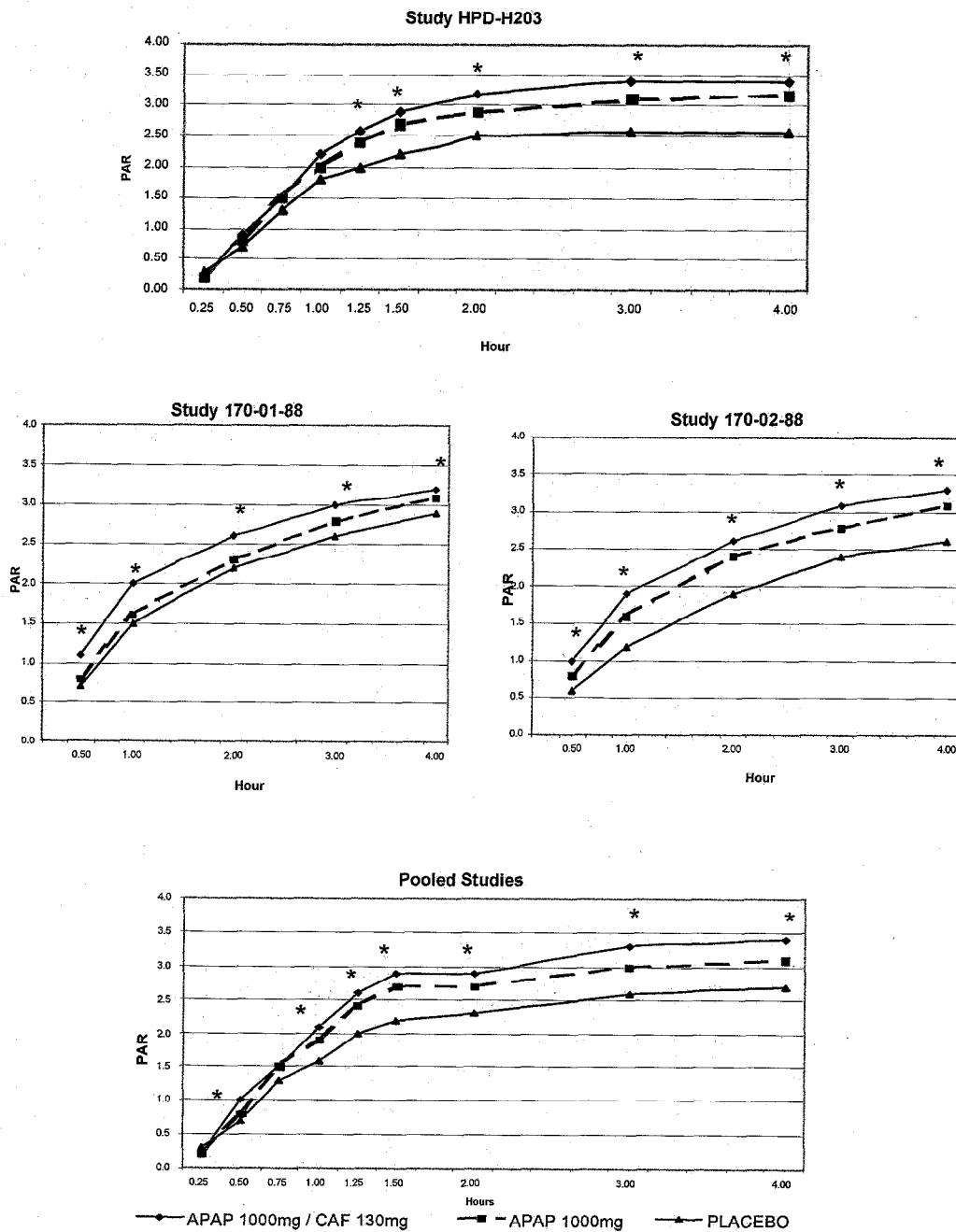
Figure A
Pain Intensity Difference
Tension Headache (ITT)



* APAP 1000 mg/CAF 130 mg significantly greater than APAP 1000 mg

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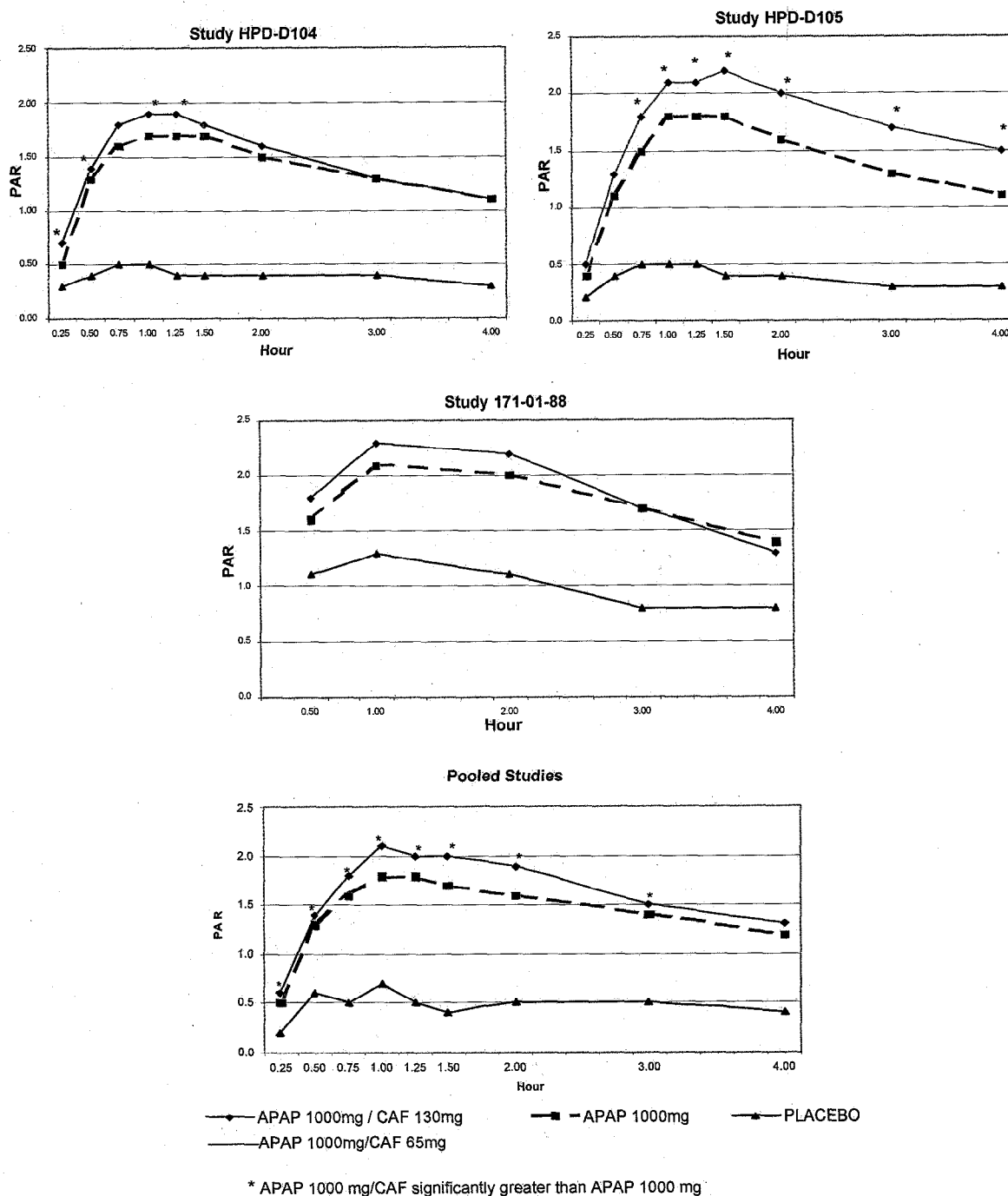
Figure B
Pain Relief
Tension Headache (ITT)



* APAP 1000 mg/CAF 130 mg significantly greater than APAP 1000 mg

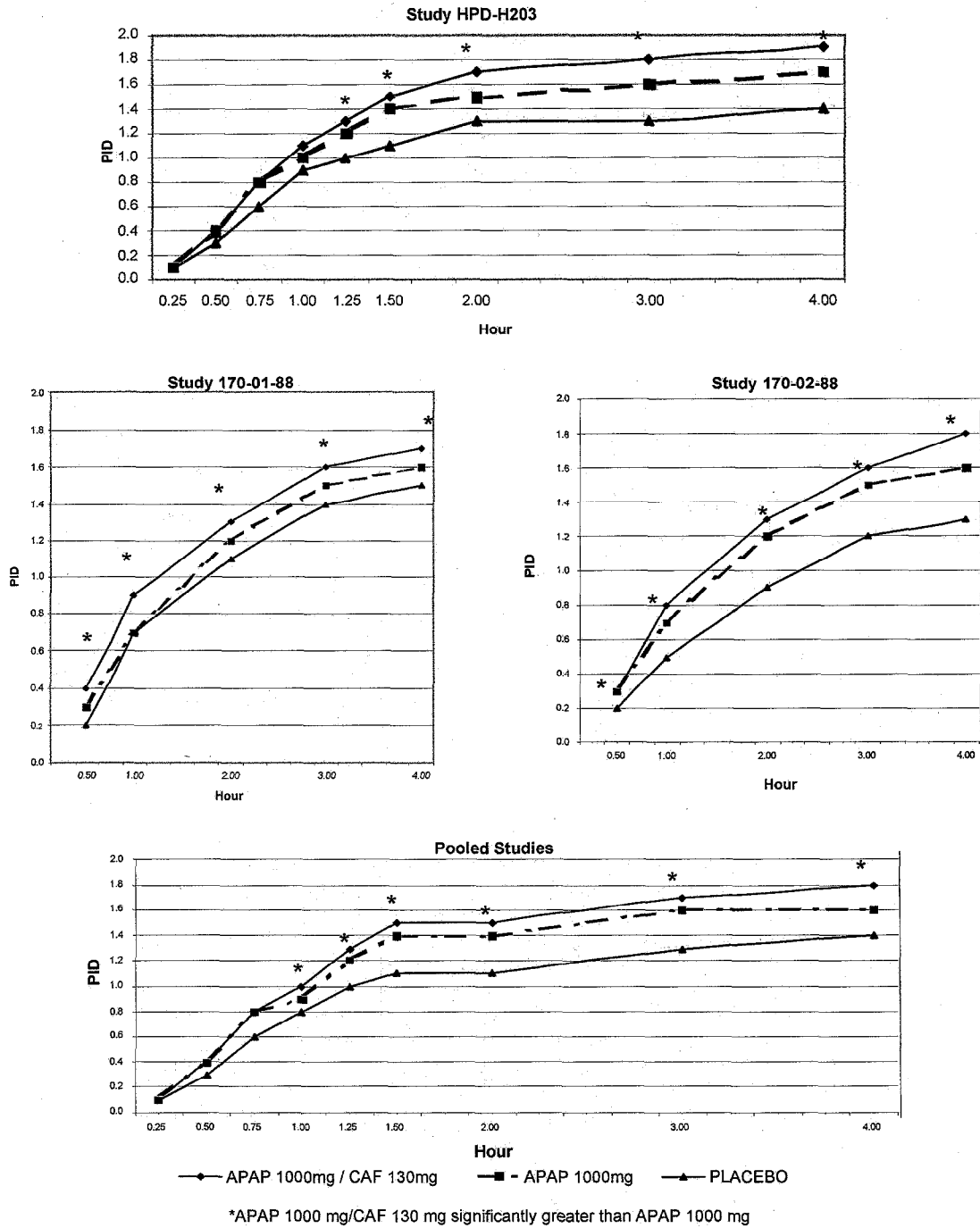
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Figure D
Pain Relief
Dental Pain (ITT)



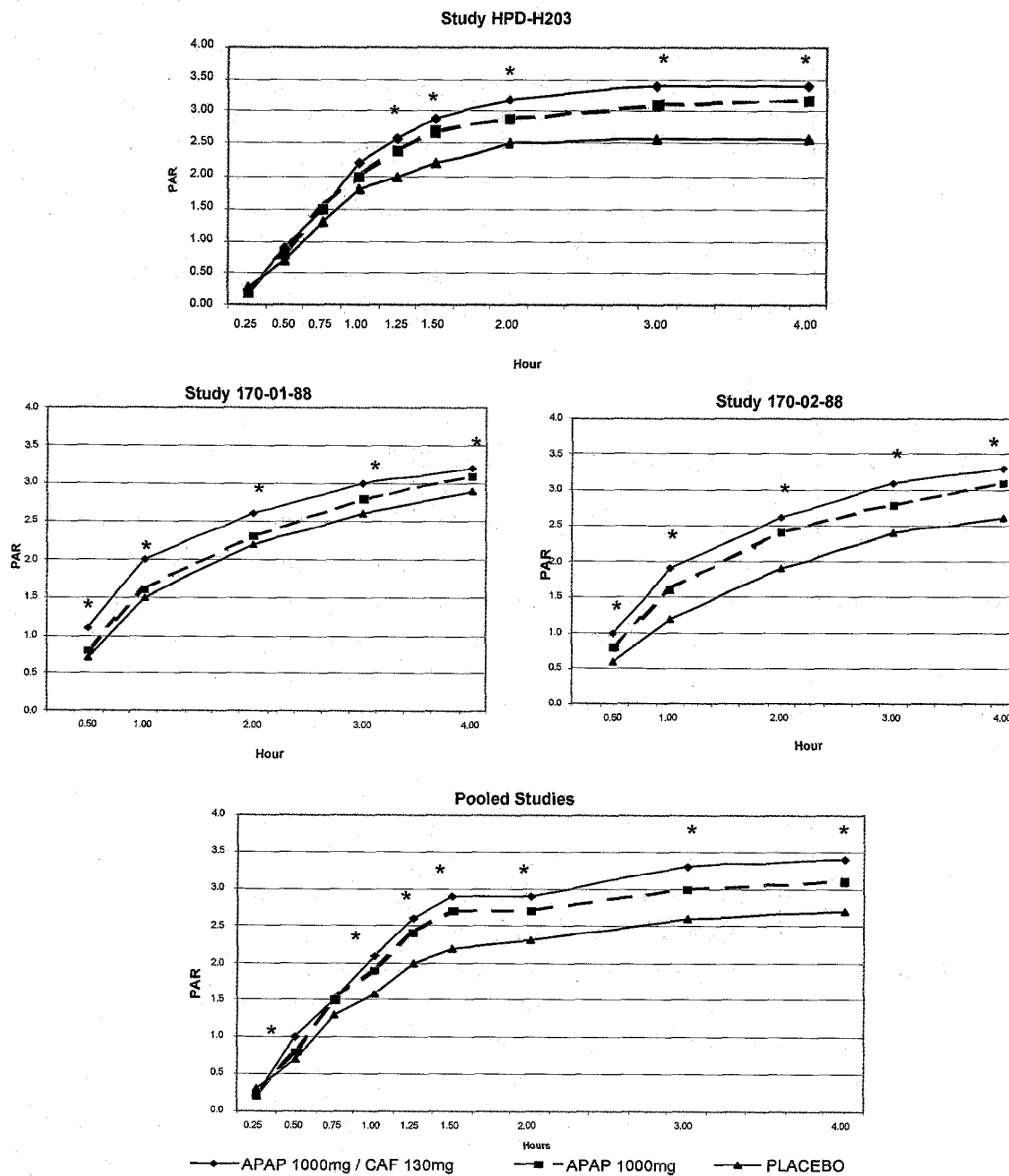
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Figure 4.1.1
Pain Intensity Difference
Tension Headache (ITT)



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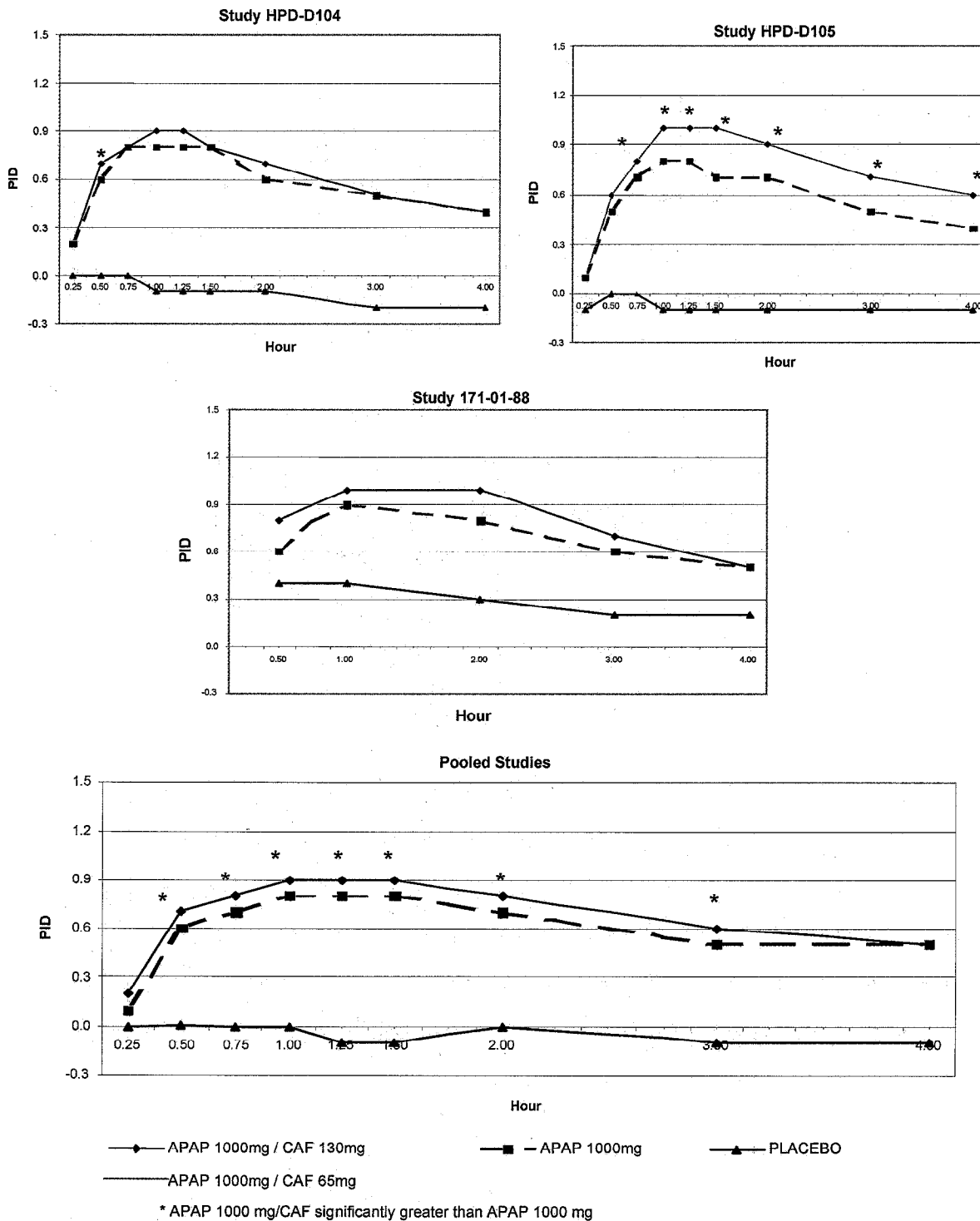
Figure 4.1.2 Pain Relief Tension Headache (ITT)



*APAP 1000 mg/CAF 130 mg significantly greater than APAP 1000 mg

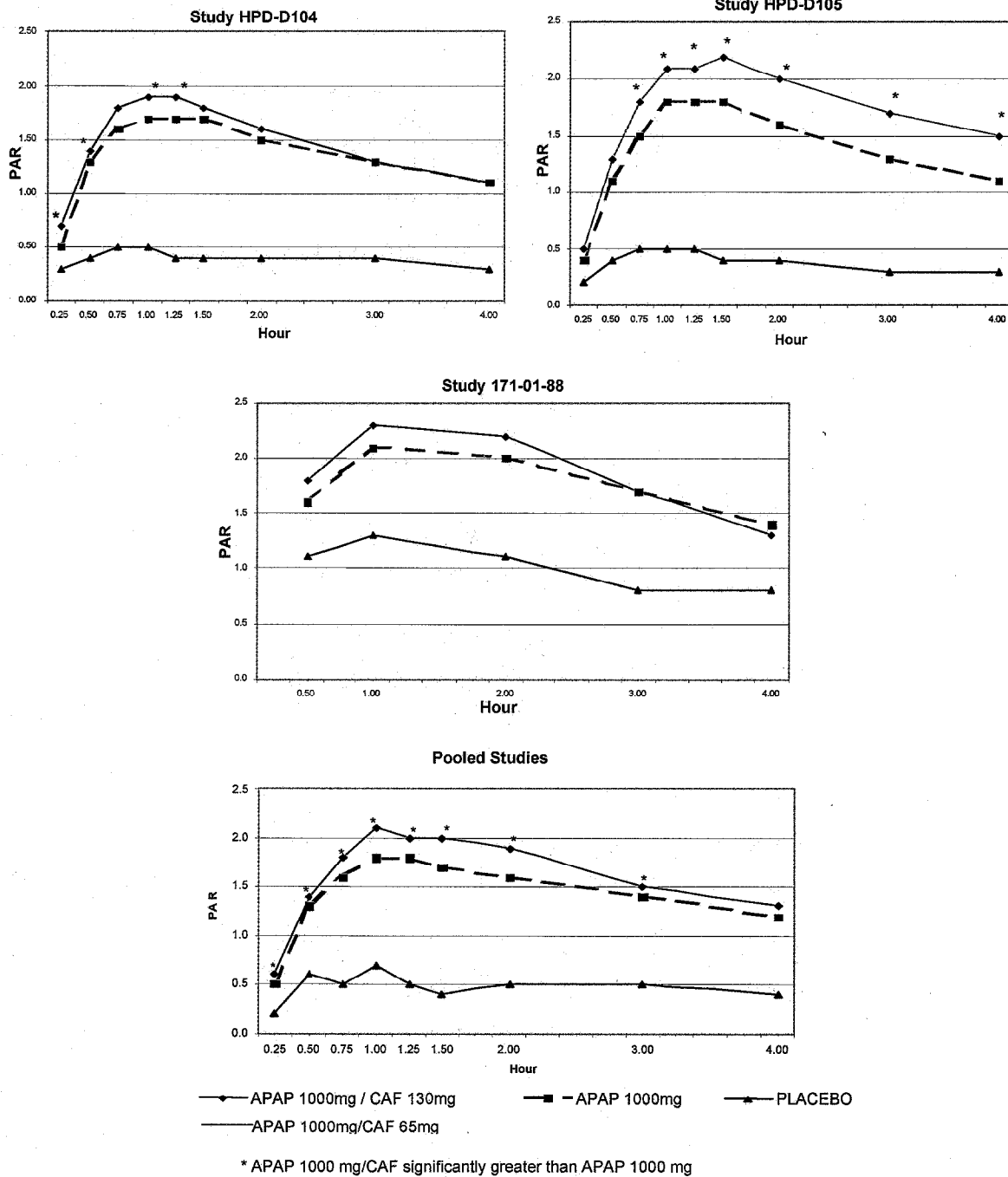
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Figure 4.2.1
Pain Intensity Difference
Dental Pain (ITT)



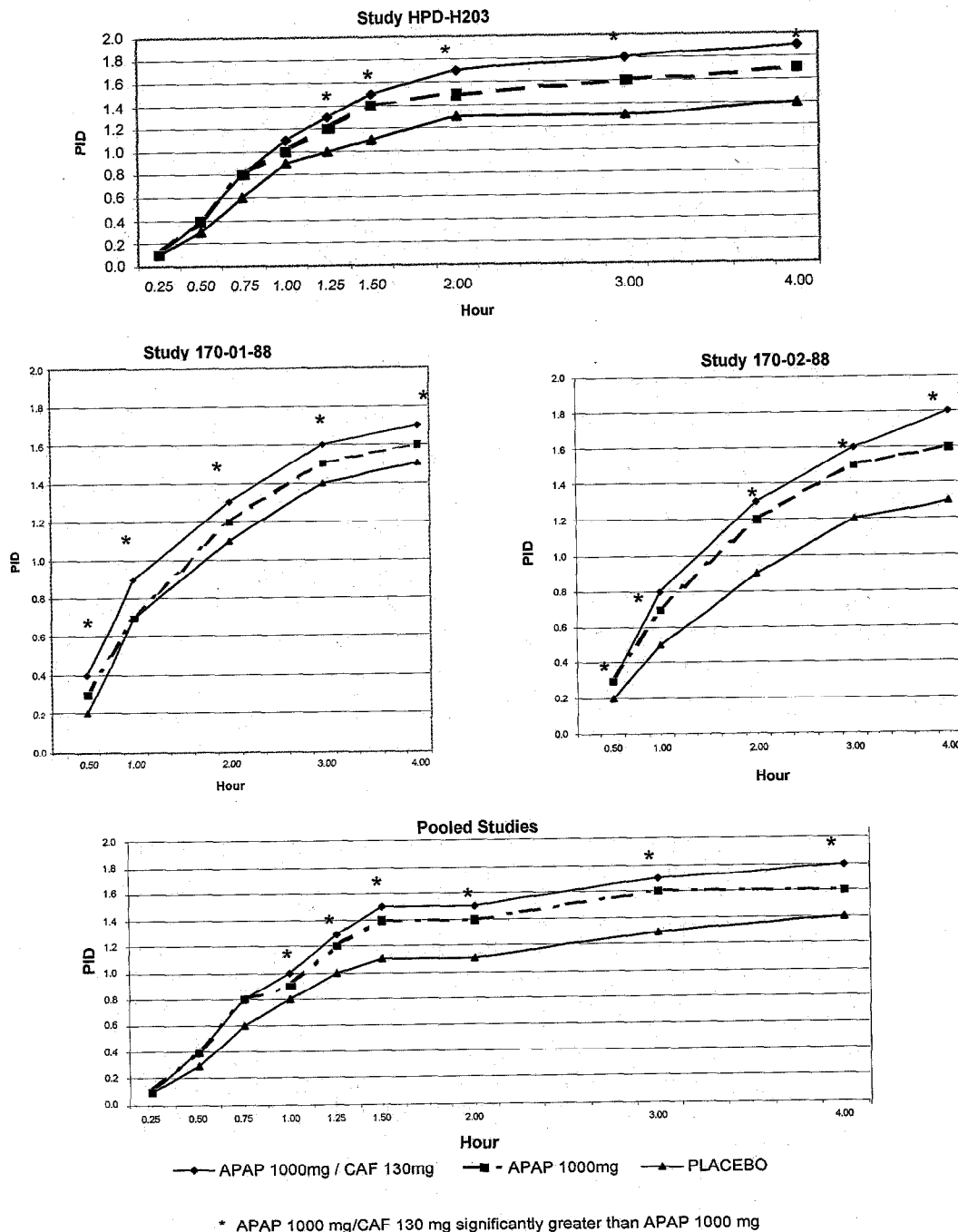
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Figure 4.2.2
Pain Relief
Dental Pain (ITT)



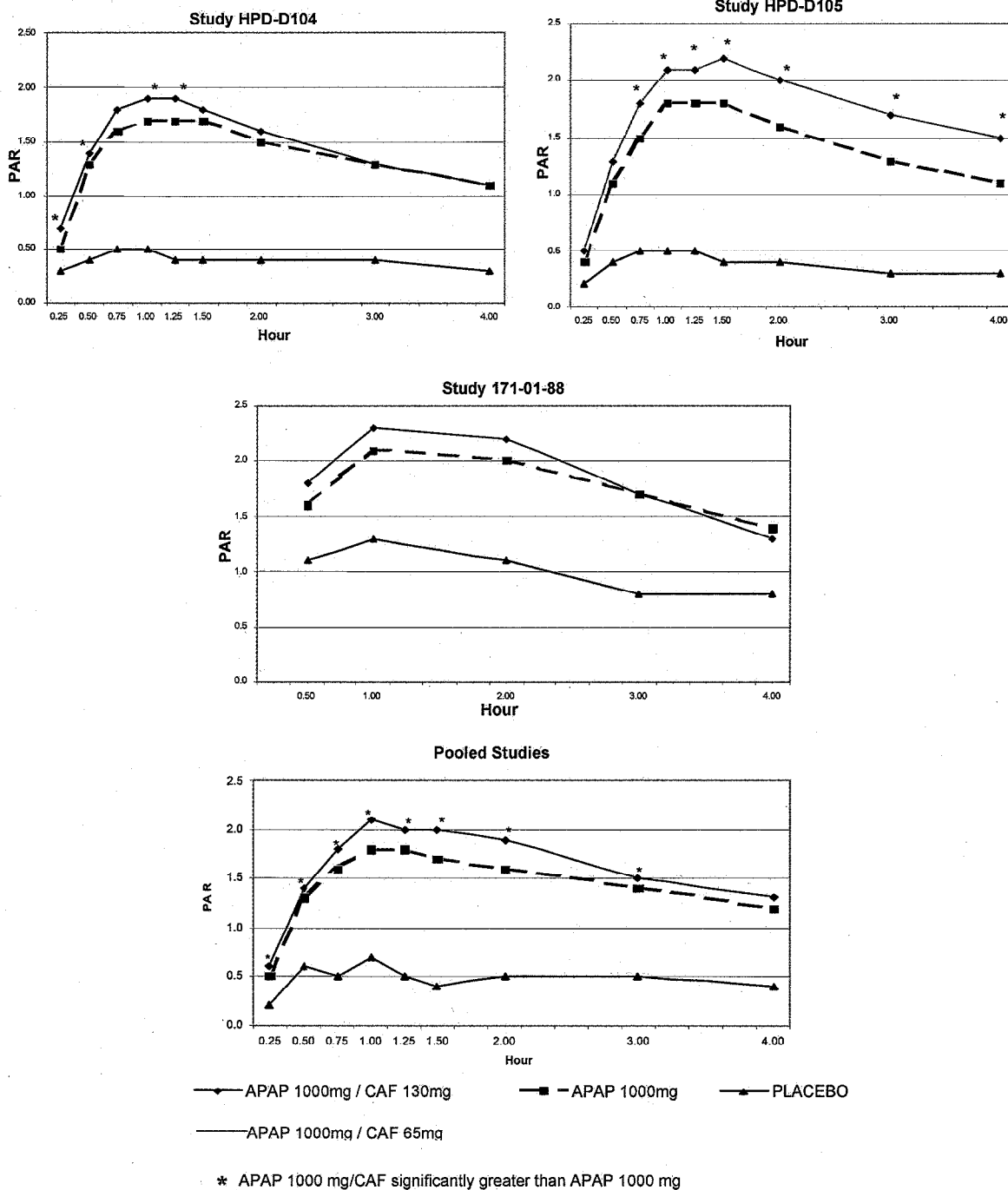
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Figure A
Pain Intensity Difference
Tension Headache (ITT)



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Figure D
Pain Relief
Dental Pain (ITT)



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