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*APPLICATION NUMBER:*  
**20-538/S-015**

**PHARMACOLOGY REVIEW**

**REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA:**

**KEY WORDS:**

Reviewer Name: Krishan L. Raheja, D.V.M., Ph.D.

Division Name: DRUDP

HFD#: 580

Review Completion Date: 8-1-2001

IND/NDA number: NDA 20-538

Serial number/date/type of submission: supplements 14 and 15 dated 1-18-2001 and 1-22-2001

Sponsor (or agent): Novartis

Drug: Vivelle-Dot

Recommendations: Since vivelle is approved at doses higher than proposed under supplements 14 and 15, Pharmacology recommends approval of these supplements.

Krishan L. Raheja

Original NDA- 20-538, supplements 14 & 15

HFD-580

HFD-580/A.Jordan/K.Raheja/D.Moore

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/s/

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8/1/01 10:50:28 AM  
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