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RESEARCH**

*APPLICATION NUMBER:*

**11-522/S-030**

**ADMINISTRATIVE DOCUMENTS**

**MEMORANDUM OF TELECON**

**NDA:** 11-522/S-030

**DRUG:** Adderall® Tablets

**SPONSOR:** Shire Pharmaceuticals Inc.

**DATE:** November 8, 2002

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**TELEPHONE NUMBER:** (240) 453-6642

**CONVERSATION WITH:** Ms. Catherine Symington, Regulatory Affairs Department

**BACKGROUND:** The purpose of the call was to obtain agreement from Shire on the wording of the approved labeling for this supplement.

**CONVERSATION:**

Ms. Symington informed me at 2:30 PM EST that Shire would agree to approved labeling which would include the addition of the information about the PK studies that were conducted in support of the new formulation and a statement about food to the 'Pharmacokinetics' section of the labeling dated November 20, 2001.

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Anna Marie H. Weikel, R.Ph.  
Regulatory Affairs Manager