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(12) **United States Patent**  
**Oppenheimer et al.**

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(54) **METHODS OF ADMINISTERING  
TETRAHYDROBIOPTERIN, ASSOCIATED  
COMPOSITIONS, AND METHODS OF  
MEASURING**

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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This patent is subject to a terminal disclaimer.

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(65) **Prior Publication Data**

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**Related U.S. Application Data**

(63) Continuation of application No. PCT/US2008/060041, filed on Apr. 11, 2008.

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(51) **Int. Cl.**

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**A01N 43/60** (2006.01)  
**A61K 31/495** (2006.01)

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(52) **U.S. Cl.** ..... **514/249**

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(58) **Field of Classification Search** ..... **514/249**  
See application file for complete search history.

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(57) **ABSTRACT**

The present invention is directed to treatment methods of administering tetrahydrobiopterin, including in oral dosage forms, in intravenous formulations, and with food. Also disclosed herein are biopterin assays for measuring the amount of biopterin and metabolites of biopterin in a sample.