

THE FINDINGS AND CONCLUSIONS IN THIS REPORT HAVE NOT BEEN FORMALLY DISSEMINATED BY FDA AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY.

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## **Review Criteria and Search Terms Used in ORNL Literature Review**

The FDA submitted a work assignment (WA 2008 – 31) through a standing Interagency Agreement with Oak Ridge National Laboratories (ORNL) to conduct a search of the literature for publications that addressed the possible involvement of food ingredients in neurobehavioral issues in children. The FDA also requested that an in-depth review and analysis of all selected publications be conducted. The work assignment requested that;

- ORNL conduct a thorough search of the literature from 1982 to the present for peer-reviewed publications dealing with consumption of additives in food and their possible correlation with hyperactivity and behavioral changes. The search should include both animal and human studies. TOXLINE and PUBMED were to be searched in combined searches for the years 1982-2008. The following terms were to be used:  
**Food additives hyperactivity, Food additives autistic, Food additives psychomotor, Food additives attention deficit, Food additives neurotoxic, Food additives behavior neurologic\*, Food coloring hyperactivity, Food coloring autistic, Food coloring psychomotor, Food dyes hyperactivity, Food dyes autistic, Food dyes psychomotor, Food dyes attention deficit, Food dyes neurotoxic, Food dyes neurologic\*, Food dyes behavior.**
- All recovered references and abstracts were to be submitted to the ORNL reviewer for his selection of publications for in-depth review. If the reviewer rejected any article as not appropriate for review, he was to write a brief statement giving reasons for this rejection. The reviewer was to summarize studies that demonstrated a causal relationship between food additives and behavioral and/or hyperkinetic changes, and give his assessment as to the overall quality of the study and whether he felt that the study results supported a correlation. In addition, the reviewer was to note any deficiencies in the studies he reviewed and make recommendations as to how these deficiencies should be addressed in future studies. The reviewer was also to review any clinically-relevant publication that was included as part of the CSPI citizen petition.
- Once the reviewer completed his review he was to submit a completed report to FDA detailing his findings and giving an overall conclusion on his opinion regarding the key question. The FDA would conduct a secondary review of this report and submit its comments and requested changes to the reviewer for incorporation in the completed report.