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On page four, paragraph 1 and 4, since many of the adverse reactions are needlessly repeated we suggest combining these paragraphs as follows. "Central nervous system: Overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, torpor, headache, hangover, fatigue, anxiety, transient paresthesias of the extremities; rarely, psychotic episodes at recommended doses."

On page four, paragraph 2, for better word flow we suggest the following. "Gastrointestinal: Dryness of the mouth, unpleasant taste, diarrhea, anorexia, nausea, emesis, epigastric discomfort and other gastrointestinal disturbances."

Our most serious concern is in the section under OVERDOSAGE appearing on pages four and five. The first two paragraphs in this section represent regulatory copy applicable to amphetamines. The remaining paragraphs appear to be a direct lift from methaqualone labeling as applied to a single entity drug. We believe this may be confusing and misleading. It would be possible to include the subheading "Amphetamine Overdosage" prior to the first two paragraphs and the subheading "Methaqualone Overdosage" at the beginning of the third paragraph. In our opinion, this is not satisfactory since the major section, OVERDOSAGE, should relate to a specific product, namely Biphentamine-T. We request that you reconsider the entire section under OVERDOSAGE with regard to acute overdosage with methaqualone. We do not question the basic accuracy of the information but rather its applicability in the labeling for this specific product.

An example of the resulting inconsistency is seen in the second paragraph recommending sedation with a barbiturate and in the fifth paragraph recommending supportive measures for the unconscious patient.

We offer the following suggested copy for OVERDOSAGE which covers the significant points in relationship to Biphentamine-T.

OVERDOSAGE:

Manifestations of acute overdosage with amphetamines include restlessness, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea and abdominal cramps. Fatal poisoning usually terminates in convulsions and coma. The symptomatology listed above may be aggravated by the methaqualone component of Biphentamine-T.