Reviewer's report

Title: In vitro and in vivo safety evaluation of Dipteryx alata Vogel extract

Version: 1 Date: 17 September 2011

Reviewer: Iwonna Rahden-Staron

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Re: Manuscript The article “In vitro and in vivo safety evaluation of dipteryx alata vogel extract” by Mencacci Esteves-et al. describes lack of mutagenic activity and lack of effects on the pregnancy of rats.

The reviewed manuscript is original, well presented, and a great amount of work done.

Since in Brazil, medicinal plants are widely used by the people, which leads to a constant requirement for toxicity tests to be performed on the plant extracts, these findings are potentially of interest. The study is well conducted and the results are important in view of the level of human exposure, especially in Brasil, and the limited results regards the mutagenicity and toxicity of tested plant extract on mammal organism.

The objective of presented study was to evaluate the safety of D. alata barks extract. The authors used two approaches. Vegetal drugs of D. alata barks were submitted to quality control assays and further to the safety assays under 1) in vitro parameter by Salmonella (Ames) mutagenicity, and 2) in vivo parameter on the pregnancy of rats.

The authors show that the extract was non-mutagenic to any of the assessed strains TA97a, TA98, TA100 and TA102 even after metabolic activation (+S9). All in vivo parameters (reproductive ability evaluation, physical development of rat offsprings, and neurobehavioral development assays) showed no changes related to control group.

While the paper contains some useful information, I have the concern that need to be addressed before it is accepted for publication.

I have the following specific comment: the recommended set of bacteria strains (OECD) according to Guideline for industry. Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals, April 1996, ICH S2A (see: OECD Guidelines for the testing of Chemicals, Bacterial Reverse Mutation Test 471, 1997) needs additional Salmonells typhimurium TA1535 strain. So, the authors should complete their study with that strain.

(Major Compulsory Revisions)

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests' below