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| **Medsafe consultation submission**  |

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| **Changes to warning statement for products containing sedating antihistamines** |

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| Name and designation |       |
| Company/organisation name and address |       |
| Contact phone number and email address |       |
| I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*     (Reasons for requesting confidentiality must meet [Official Information Act](http://www.legislation.govt.nz/act/public/1982/0156/latest/DLM64785.html?search=qs_act_official+information+act_resel_25_h&p=3&sr=1) 1982 criteria) | [ ]  Yes [ ]  No |
| I would like my name to be removed from all documents prior to publication on the Medsafe website. | [ ]  Yes [ ]  No |
| I would like for my name not to be included within the list of submissions published on the Medsafe website. | [ ]  Yes [ ]  No |

**It would help in the analysis of stakeholder comments if you provide the information requested below.**

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| **I am, or I represent, an organisation that is based in:** |
| [ ]  New Zealand [ ]  Australia [ ]  Other (*please specify*):       |

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| I am, or I represent, a: *(tick all that apply)* |
| [ ]  Importer | [ ]  Manufacturer | [ ]  Supplier | [ ]  Sponsor |
| [ ]  Government | [ ]  Researcher | [ ]  Professional body | [ ]  Industry organisation |
| [ ]  Consumer organisation | [ ]  Member of the public | [ ]  Institution (e.g. university, hospital) |
| [ ]  Regulatory affairs consultant | [ ]  Laboratory professional |  |  |
| [ ]  Health professional – *please indicate type of practice*:       |
| [ ]  Other - *please specify*:       |

**Please return this form to:**

**Email:** **medsafeapplications@moh.govt.nz**including ‘Sedating antihistamine warning statements’ in the subject line

**Or Post:** Product Regulation

 Medsafe

 PO Box 5013

 Wellington 6145

**Medsafe is seeking comments on:**

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| *Whether the following statement should be added to the Label Statements Database for all sedating antihistamine products (unless other age restrictions apply):***For oral use: Do not use in children under 2 years old.**- Please provide your reasoning - Is the statement acceptable or should it be reworded? |
| *Whether the following statement in the Label Statements Database for sedating antihistamines is amended (when appropriate) to:* **For the treatment of insomnia ~~or anxiety~~: Consult a doctor if sleeplessness ~~(or anxiety)~~ persists**- Please provide your reasoning - Are the statements acceptable or should they be reworded? |
| *What is a suitable target date for implementation?*- Please provide justification  |