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| **Medsafe consultation submission** |

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| |  | | --- | | **Changes to warning statement for products containing sedating antihistamines** | | | |
| 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**](mailto: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 |