|  |
| --- |
| **Medsafe consultation submission**  |

|  |  |
| --- | --- |
|

|  |
| --- |
| **Proposed change to warning statements on labels of oral non-steroidal anti-inflammatory drugs (NSAIDs)**  |

 |
| 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 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.**

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

|  |
| --- |
| 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 by:**

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

**Or Post:** Product Regulation

 Medsafe

 PO Box 5013

 Wellington 6145

**Medsafe is seeking comments on:**

|  |
| --- |
| *Whether you support the proposed changes to warning statements regarding use in pregnancy.* - Is there a need to include this wording on the packaging? - Is the wording acceptable? If you do not support the wording of the statements please make suggestions for alternatives acceptable to you.      |
| *Do you agree with the proposed list of medicines this statements should apply to?*- If you do not support this, please provide your reasoning.       |
| *What is a suitable target date for implementation?*- Please provide justification       |
| *Are there any other comments you would like to make?*      |