**Sponsor Declaration for a dietary supplement with a maximum daily dose of more than 300 mcg of folic acid**

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| --- | --- | --- |
| Sponsor name and address:  (the company or business details of the NZ sponsor) | | |
| Product trade name:  (as it appears on the product label) | | |
| Dose form:  (e.g. tablet, capsule) | **M**aximum daily dose (folic acid):  (being greater than 300 mcg but not greater than 500 mcg) | Overage: |
| Manufacturer name and street address:  (details relating to the site of manufacture) | | |

SPONSOR’S DECLARATION[To be completed by a nominated representative of the sponsor]

I declare that the information provided in this form is correct **AND**

The product complies with the Dietary Supplements Regulations 1985 (DSR) **AND**

Good manufacturing practice certification for the manufacturer is provided that meets the requirements of *Guidelines on the Regulation of Therapeutic Products in New Zealand: Manufacture Medicine* **AND**

The product is manufactured according to the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods* **AND**

The product is a chewable, effervescent, dispersible or modified release tablet; or a soft or modified release capsule; or a powder **OR**

The finished product specification includes a test for dissolution that meets TGO101 / USP requirements for products containing folic acid and only batches of product which have passed the test will be supplied in New Zealand.

A copy of the product formulation is provided with this application, with a justification for any overage.

A copy of the finished product specification is provided with this application.

A copy of the finished product labelling is provided with this application.

**Signed:**   **on:**  (date)

Name:

Position title:

Postal or email address:

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| --- |
| **For Medsafe use only:** Sponsor declaration of compliance with DSR accepted: **Yes / No** (delete one)  Signed: on: (date)    Medsafe reference number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

November 2023