

Date

Director

National Pharmaceutical Control Bureau
Lot 36, Jalan Universiti
46200 Petaling Jaya
Selangor.

Dear Sir / Madam,

Application for Data Exclusivity (DE)

With regards to the above, and as described and stipulated in “*Direktif Penguatkuasaan Keperluan Melaksanakan Data Eksklusiviti di Malaysia*” Bil. (11) BPFK/PPP/01/03 Jilid 1, we hereby request for DE for the following:

- New drug product containing a New Chemical Entity
- Second indication of a registered drug product

- i) Product name: _____
- ii) Reference no.: _____
- iii) Registration no.: _____
- iv) Country of manufacture: _____
- v) Country of product owner: _____
- vi) DCA reference country (where registration has been granted): _____

2. We declare that DE has been granted in the following country(s):

- i) Country: _____
Approval date: _____
Grant period: _____
- ii) Country: _____
Approval date: _____
Grant period: _____

3. Additional information:

- i) Marketing authorisation date (if not the same as the approval date):
- ii) Legislation of reference country (where the DE period is not specified in the public domain or in the approval letter):
- iii) Contact person of approving authority (phone number, email, etc.):

Thank you.

Yours Sincerely,

Name & Designation
(Note: To be endorsed by the legal department)