

# COVER LETTER TEMPLATE

[DATE]

National Pharmaceutical Regulatory Agency,  
Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz),  
46200 Petaling Jaya,  
Selangor, Malaysia.

Dear Sir/Madam,

## COVER LETTER FOR NEW **BIOLOGICS / DRUG PRODUCT** REGISTRATION APPLICATION

PRODUCT NAME : [FULL NAME]  
ACTIVE INGREDIENT : [LIST OF ACTIVE INGREDIENTS]

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The above matter is referred to.

This cover letter is appended as part of the registration application for [Product Name] to provide NPRA with a summary of important information to assist your review:

List of pertinent information to share with NPRA. A brief summary should be included where relevant. Some examples are shown below:

- Registration pathway/category, e.g. Facilitated Registration Pathway, Orphan designation (must be granted before submission), Hybrid, etc.
- Data Exclusivity
- Outcome from Pre-Submission Meeting e.g. Conditional Registration, First wave
- Product development – e.g. reference product for hybrid/biosimilar, line extension of a registered product (e.g., comparison table between proposed and registered products for Part I-IV), product replacement
- Anticipated gaps in data package, e.g. early phase data, stability data, COAs
- Commitments to submit any additional documents during the evaluation
- Shared pack strategy

The details are provided in the screening checklist.