

TGA eBusiness Services Clearance Application

Variation: Application Details

Applicant's Ref: ICN Polfa GMP clearance (solid dose products)
Status: Active
Original Tracking Number: MI-2017-CL-14316-1
Tracking Number: MI-2015-CL-06825-1
Variation Type: Renewals

Client Details

Variation Requests:
Select application type: MRA

Applicant Details

Applicant Name: iNova Pharmaceuticals (Australia) Pty Ltd
Client Id: 436
Address: PO Box 5033
Suburb: WEST CHATSWOOD
Postcode: 1515
State: NSW
Country: Australia

Sponsor

Sponsor Name: iNova Pharmaceuticals (Australia) Pty Ltd
Client Id: 436
Address: Level 10 12 Help Street
Suburb: CHATSWOOD
Postcode: 2067
State: NSW
Country: Australia

Contact Details

Contact Name: Brett Robinson
Phone: 02 9875 6246
Mobile:
Email: b.robinson@inovapharma.com
Fax: 02 9875 6477

Existing Manufacturer

Manufacturer Name: ICN Polfa Rzeszow SA
Manufacturer ID: 40909
Existing Manufacturing Site:
Manufacturer Site: 39-959 Rzeszow Ul Przemyslowa 2
Manufacturer Site ID: 54047
Suburb:
Postcode:
State:
Country: Poland

API/Product Details

| Product | Manufacturer Type | Sterility | Manufacturing Class | Dosage Form | Product Code | Manufacturing Steps |
|---------|----------------------|-------------|--|--|-----------------------------|------------------------------|
| | Medicine manufacture | Non Sterile | Multiple manufacturing steps/Multiple products | Solid Unit Dosage Forms - Hard Capsules | Registered Therapeutic Good | Finished Product Manufacture |
| | Medicine manufacture | Non Sterile | Multiple manufacturing steps/Multiple products | Solid Unit Dosage Forms - Tablets | Registered Therapeutic Good | Finished Product Manufacture |

Evidence

Is this GMP Clearance application related to a product listing/registration submission or variation of an Australian Register of Therapeutic Goods (ARTG) entry? N

Is this a Compliance Verification Assessment? N

In the Evidence to be provided are you using a Letter of Access to Clearance or Evidence? N

Supporting Documents

Mandatory Certificates or Letters

1 Current GMP Certificate

Upload Evidence
-File Name: 1 certificate - ICN polfa -GIF-IW-400-0098_01_05-04-218-17.pdf
-Last Inspection Date: 30/06/2017

Optional Evidence

| | |
|--|------------------------|
| <input type="checkbox"/> 12 Manufacturer's declaration for Active Pharmaceutical Ingredients (APIs) | Select delivery method |
| <input type="checkbox"/> 13 Certified translation statement | Select delivery method |
| <input type="checkbox"/> 14 Copy of the certificate of registration or a letter from the registrar in the manufacturer's country confirming the change of name | Select delivery method |
| <input type="checkbox"/> 15 Cover letter detailing extension request & reason | Select delivery method |
| <input type="checkbox"/> 16 Cover letter requesting change | Select delivery method |
| <input type="checkbox"/> 17 Botanical ingredients evidence for authenticated standard reference materials | Select delivery method |
| <input type="checkbox"/> Other | Select delivery method |

Conditions

Expiry Date: 30/12/2020

Conditions:

Declaration

In submitting this application on behalf of iNova Pharmaceuticals (Australia) Pty Ltd, I **DECLARE** that:

- I am a person authorised to make this application; and
- this application, and any supporting material provided with this application, does not contain any information that is inaccurate, false or misleading.

Further, I **UNDERSTAND** that:

- giving inaccurate, false or misleading information, or omitting to give information in relation to a material particular, is a serious offence under the Criminal Code Act 1995.


By clicking on the Agree button below, I **AGREE** with all of the above statements.

Agree

We encourage applicants to save a copy of their application prior to submitting their application.

Just to let you know that TGA have approved the GMP clearance MI-2015-CL-06825-1 for the solid dosage plant. Please find below screen shots with the details. Any questions please let me know.

Thanks



Australian Government
Department of Health
Therapeutic Goods Administration

Portal - Brett Robinson

- View Drafts
- View Lodged Submissions

Create Applications & Submissions

- Annual Charge Exemption
- Biologicals
- Adverse Event Reporting
- Regulatory Compliance

Listed Medicine

- General Listed
- Assessed Listed

Manufacturer Information

Approval Area: All Approval Areas

Manufacturer: ICN Polfa Rzeszow SA

Filter on: Identifier for

| Approved | Identifier | Site Address | Received |
|----------------------------|-------------------------------|---------------------------------|-----------------------|
| <input type="checkbox"/> ⓘ | 2021-04-28 MI-2015-CL-06825-1 | 39-959 Rzeszow UI Przemysłowa 2 | 2021-03-31 2022-09-21 |
| <input type="checkbox"/> ⓘ | 2019-09-25 MI-2017-CL-01071-1 | 39-959 Rzeszow UI Przemysłowa 2 | 2019-09-06 2022-10-11 |
| <input type="checkbox"/> ⓘ | 2015-06-12 MI-2014-CL-09376-1 | 39-959 Rzeszow UI Przemysłowa 2 | 2014-10-20 2017-04-24 |
| <input type="checkbox"/> ⓘ | 2014-10-27 MI-2012-CL-08388-1 | 39-959 Rzeszow UI Przemysłowa 2 | 2014-10-27 2015-05-12 |
| <input type="checkbox"/> ⓘ | 2013-06-05 MI-2012-CL-07761-1 | 39-959 Rzeszow UI Przemysłowa 2 | 2013-05-31 2015-07-12 |