Pfizer Europe MA EEIG
Boulevard de la Plaine 17,
1050 Brussels,
Belgium
[redacted]

[redacted]

05 December 2018

Dr Harald Enzmann
Chairman of the Committee for Medicinal Products for Human Use
European Medicines Agency
30 Churchill Place
Canary Wharf
London
E14 5EU
United Kingdom

Subject: Withdrawal of FYZOCLAD (adalimumab) Solution for Injection, EMEA/H/0005253

Dear Dr Harald Enzmann,

I would like to inform you that, at this point of time, Pfizer Europe MA EEIG has taken the decision to withdraw the application for Marketing Authorisation of FYZOCLAD (adalimumab), Solution for Injection, which was intended to be used for the following indications:

- Rheumatoid arthritis
- Juvenile idiopathic arthritis
- Axial spondyloarthritis
- Psoriatic arthritis
- Psoriasis and paediatric plaque psoriasis

Enregistré en Belgique : Numéro d'entreprise: 0696.658.156
RPM Bruxelles – division francophone
Boulevard de la Plaine 17, 1050 Bruxelles, Belgique

Registered in Belgium: Enterprise Number: 0696.658.156
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- Uveitis and paediatric uveitis

This withdrawal is based on the following reason: a change in Pfizer's strategy. This is unrelated to product quality or safety.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Sincerely,

[redacted]

Senior Manager, Regulatory Affairs
EU Regulatory Affairs – Biosimilars