



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by
Mylan Health Pty Ltd

I, Leanne McCauley, Delegate of the Secretary to the Department of Health, on receipt of an application from Mylan Health Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989* (the Act) the restricted representations described in paragraph (A) below for use in advertisements directed to consumers, for the product identified in paragraph (B):

A)

Indications Statements

- i. *“Iron for the prevention & treatment of tiredness & fatigue, associated with iron deficiency”*
- ii. *“for the prevention & treatment of tiredness & fatigue, associated with iron deficiency”*

Diagnosis Statement

- iii *“For use when iron deficiency has been diagnosed by your doctor and a therapeutic oral iron supplement is recommended.”* or words to that effect on the basis that when either or both of the Indication Statements in *i* and *ii* above are used in advertisements, other than the label, then:
 - the Diagnosis Statement in *iii* is also used; and
 - that Diagnosis Statement is displayed with equal or greater prominence to the Indication Statements in *i* and *ii*.

B)

- FERRO-GRAD – ferrous sulfate 325mg tablet bottle (AUST R 59522)
- FERRO GRAD C tablet bottle (AUST R 66841)

Dated this 13th day of May 2019

Signed electronically

Leanne McCauley
Delegate of the Secretary to the Department of Health
Advertising Compliance Unit
Regulatory Education and Compliance Branch