



Australian Government
Department of Health
Therapeutic Goods Administration

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

I, Leanne McCauley, Delegate of the Secretary to the Department of Health, on receipt of an application from Apotex 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 Statement

(i) *“for the prevention & treatment of iron deficiency anaemia”*

Diagnosis Statement

- (ii) *“For the prevention and treatment of medically diagnosed iron deficiency anaemia which can result from inadequate dietary iron (and sometimes also vitamin C) intake”*
- (iii) *“For use when iron deficiency anaemia has been diagnosed by your doctor and a therapeutic oral iron supplement is recommended as treatment or for ongoing prevention.”*

On the basis that when the Indication Statement in (i) above is used in advertisements, other than the label, then:

- Either or both of the Diagnosis Statements in (ii) and (iii) are also used; and
- Either or both of the Diagnosis Statements in (ii) and (iii) are displayed with equal or greater prominence than the Indication Statement in (i).

B)

- FERROVANCE IRON SUSTAINED RELEASE (AUST R 305023)
- FERROVANCE C IRON SUSTAINED RELEASE +C (AUST R 303806)

Dated this 14th 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