



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF REGORAFENIB (STIVARGA) AS AN ORPHAN DRUG

I, Dr Anthony Gill, Delegate of the Secretary for the purposes of 16J of the Therapeutic Goods Regulations 1990 ("the Regulations"), acting under subregulation 16J(2) of the Regulations, designate for regorafenib (STIVARGA) as an orphan drug on 13 July 2016 for the treatment of hepatocellular carcinoma .

The dose form of regorafenib (STIVARGA) for this indication is tablet.

The sponsor of regorafenib (STIVARGA) is Bayer Australia Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

13 July 2016