



Mr [REDACTED]
Helios Homeopathics Ltd
89-97 Camden Road
Tunbridge Wells
Kent
TN1 2QR

3rd January 2012

Dear [REDACTED]

I refer to your letter dated 27th September 2011 and the marketing of non registered homeopathic remedy kits.

As discussed in my previous letter dated 5th September 2011, in accordance with the Medicines Regulations, a homeopathic remedy must either be registered under the Simplified Registration Scheme or be authorised under the National Rules Scheme or be the subject of a Product Licence of Right, in order to be sold or supplied in the UK.

We are unable to deviate from this legal requirement and therefore only the 18 homeopathic remedies registered under the Simplified Scheme can be currently marketed in the UK. As agreed at the time of granting the registration certificates, the remedies may be included in a kit named 'Helios Basic 18 Kit.'

According to our records, we have 10 pending applications from you for homeopathic registration certificates:

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

We have reviewed the status of these applications and assure you that we will give them high priority and aim to grant (pending any outstanding information from you) by the end of January 2012. In order to help speed up the process, you may wish to submit updated labelling mock ups to me for these applications as soon as possible. In your letter, you mentioned that you have a further 6 applications that are almost ready for submission and when they are submitted, we assure you that we will give them priority also.

Action required:

Discontinue the sale and supply of Basic Plus 36 Kit, Accident & Emergency Kit, Child Birth Kit and Travellers Kit because:

- a. the kit names have not been agreed by the MHRA and are not in accordance with the registration certificates granted.
- b. the kits contain remedies that are not registered or authorised.

If you wish to vary the current approved kit name, Helios Basic 18 Kit, a variation may be submitted and bulk discounts applied.

You should confirm in writing **within seven days** of the date of this letter that you have received it and understood the contents. You should provide a timeframe for discontinuing the sale, supply and advertising of the remedy kits listed above until such time the remedies are registered for use in the UK by this Agency.

If you are not able to provide in writing, confirmation that you will act in accordance with the requirements of this letter, the matter will be referred to our Enforcement Group.

If you would like to discuss the contents of this letter, please do not hesitate to contact me or one of the Homeopathic Unit's team.

Regards,



Scientific assessor
Homeopathics Team - PLAT 5