

Choon Mei Lai

From: Choon Mei Lai
Sent: Wednesday, September 8, 2021 8:59 AM
To: Syazreen Arshad
Subject: RE: B. Braun 0.9% Sodium Chloride Injection BP | MAL 19920250AZ | MiV-PA2 and MiV-N7-Correspondence 5

Dear Puan Syazreen,

We have submitted the justification letter as per request. Should you need further clarification, please let us know.

Thank you very much for the kind consideration.

Best regards
Choon Mei

From: Syazreen Arshad [mailto:syazreen.arshad@npra.gov.my]
Sent: Thursday, September 2, 2021 3:05 PM
To: Choon Mei Lai <choon_mei.lai@bbraun.com>
Subject: Re: B. Braun 0.9% Sodium Chloride Injection BP | MAL 19920250AZ | MiV-PA2 and MiV-N7-Correspondence 5

Dear Ms Choon Mei,

Kindly submit a justification letter for not printing the manufacturing date in immediate labels with the stated reasons and reply in correspondence in Quest 3+ system.

Thank you.

Regards,
Syazreen Bt Arshad
Principal Assistant Director
Prescription Unit, Generic Section
Centre of Product and Cosmetic Evaluation
National Pharmaceutical Regulatory Agency
Ministry of Health
Tel: 03-7883 5533
http: www.npra.gov.my

Disclaimer: The National Pharmaceutical Regulatory Agency (NPRA) accepts no liability for the content of this email, or for the consequences of any actions taken on the basis of the information provided, unless that information is subsequently confirmed in writing.

From: Syazreen Arshad <syazreen.arshad@npra.gov.my>
Date: Friday, 27 August 2021 at 3:48 PM
To: Choon Mei Lai <choon_mei.lai@bbraun.com>
Subject: Re: B. Braun 0.9% Sodium Chloride Injection BP | MAL 19920250AZ | MiV-PA2 and MiV-N7-Correspondence 5

Dear Ms Choon Mei,

I will discuss internally before get back to you. Once we have a conclusion, I will get back to you.

Thank you.

Regards,

Syazreen Bt Arshad

Principal Assistant Director

Prescription Unit, Generic Section

Centre of Product and Cosmetic Evaluation

National Pharmaceutical Regulatory Agency

Ministry of Health

Tel: 03-7883 5533

http: www.npra.gov.my

Disclaimer: The National Pharmaceutical Regulatory Agency (NPRA) accepts no liability for the content of this email, or for the consequences of any actions taken on the basis of the information provided, unless that information is subsequently confirmed in writing.

From: Choon Mei Lai <choon_mei.lai@bbraun.com>

Date: Friday, 27 August 2021 at 3:36 PM

To: "syazreen.arshad@npra.gov.my" <syazreen.arshad@npra.gov.my>

Subject: B. Braun 0.9% Sodium Chloride Injection BP | MAL 19920250AZ | MiV-PA2 and MiV-N7-
Correspondence 5

Dear Puan Syazreen Arshad,

Greetings from B. Braun Medical Industries Sdn. Bhd.

Regarding the correspondence 5 received, I would like to clarify that B. Braun 0.9% Sodium Chloride Injection BP 10ml (MAL20001035AZ) and B. Braun Water for Injections BP 10ml (MAL 20001037XCZ) can have the manufacturing date printed on the Miniplasco label. This is because both products are manufactured in Berlin site with new machines that can cater front and back labels. The manufacturing date can then be printed on the back labels to meet the MY labeling requirement.

However, for B. Braun 0.9% Sodium Chloride Injection B.P. 10ml and 20ml (MAL19920250AZ), it is manufactured in BMI site with an old machine installed that can only cater for front label with dimension 2 x 3.1 cm. Therefore, the printing of manufacturing date on the Miniplasco label is not possible. The embossment of manufacturing date on the ampoule is also not possible as the space has been catered for the embossment of batch number and expiry date.

Would it be possible for Puan to discuss with the Head of Variation to provide an exemption for the printing of manufacturing date on the Miniplasco label based on the following reasons?

- The smallest selling unit is by the duplex box, and not by the ampoule.
- The Miniplasco ampoule will be phase out and replaced by Miniplasco Connect ampoule in the near future once the Miniplasco Connect production line is loaded with the maximum capacity.

If required, B. Braun can provide a letter to justify our stance for the requested exemption. We sincerely hope that NPRA could consider our request in order to ensure continuous supply of this product for the local and export (Brunei) markets.

Upon checking in Quest 3+ system, there are two products; B. BRAUN 0.9% SODIUM CHLORIDE INJ BP (10ML) (MAL20001035AZ) and B. BRAUN WATER FOR INJECTIONS BP (10ML) (MAL20001037XCZ) with the same packaging material Miniplasco (10ml) and Miniplasco Connect (10ml) but the manufacturing date can be printed on the Miniplasco. Please clarify why it can't be implemented to this product?

Referring to DRGD Appendix 19; page 2/5 & 3/5, it is stated that manufacturing date, storage condition, registration number and words "keep medicine out of reach of children" in both bahasa Malaysia & English are required to be included in immediate labels. Exempted only given for small labels (i.e. 5ml and less) used for ampoules/ cartridge, vials, eye drops, ear drops, and nose drops. Kindly add in the manufacturing date as per requirement in DRGD

— Syazreen Arsad @ Arshad / Product Department / 2021-08-24 10:35:24

Should you need further clarification, please let me know.

Thank you.

Best regards,

CHOON MEI

B. Braun Medical Industries Sdn. Bhd.

Regulatory Affairs

Tel: +604-6323 490

Fax: +604-6433 750

Choon Mei Lai

Regulatory Affairs Manager

Tel: ++60-4-6323 490 Fax: ++60-4-6433 750

B. Braun Medical Industries Sdn. Bhd. (Company Reg: 197401001922 (19051-M))

Registered Office:

B. Braun 8,
No 140 Lebuhr Sungai Tiram 1,
Taman Perindustrian Bebas Bayan Lepas Fasa 2,
11900 Bayan Lepas,
Pulau Pinang,
Malaysia.

Correspondence Address:

P.O Box 880,
10810 Pulau Pinang,
Malaysia.

<http://www.bbraun.com>

The information contained in this communication is confidential, may be attorney-client privileged, may constitute inside information, and is intended only for the use of the addressee. It is the property of the company of the sender of this e-mail. Unauthorized use, disclosure, or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify us immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.