COMMENTS ON THE PROPOSED AMENDMENTS TO ARGOM CHAPTER 10 AND OTHER IDENTIFIED ISSUES.

Johnson & Johnson Pacific (JJP) supports the consolidation of requirements for primary sunscreens into the one document and many of the additional explanations contained within the draft ARGOM Chapter 10.

SUGGESTED IMPROVEMENTS FOR THE DOCUMENT:

1. Section **X.3.2 Listing of Therapeutic Sunscreens, 3rd paragraph**

   (a) "The claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:1998, as in force from time to time"

   could be improved by the addition of "or equivalent" as follows:

   (a)"The claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:1998, or equivalent (see section X.5), as in force from time to time"

2. Section **X.5 SPF testing and reproducibility of results**

   In consideration of the low risk that sunscreens present and their cosmetic regulation in other significant markets we suggest that the last paragraph (para 9), line 2:

   "The TGA may request results of post-market testing which should be provided within 3 months from date of such a request:"

   should be amended to:

   "The TGA may request results of pre market SPF, broad spectrum or water resistant testing. If requested, it is expected that this information will be provided to the TGA within 3 months from the date of such a request."

   Post market SPF testing is inappropriate and unnecessary. This is further discussed under proposal impacts.

3. Section **X.9 Manufacturers of therapeutic sunscreens**

   Similar to the above section the last paragraph of this section (para 3, line 3):

   "If a British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopoeia/National Formulary monograph exists for an ingredient ingredient in the sunscreening product, it should comply with that monograph or one of those monographs".

   would be more appropriately worded:

   "If a British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopoeia/National Formulary monograph exists for an *active* ingredient in the sunscreen product, that active ingredient should comply with that monograph or one of those monographs".

Reference to excipients in relation to pharmacopoeias should be deleted in the interests of increasing harmonization with other markets and reducing regulatory burden in Australia for these low risk products.

4. Section **X.10 Sunscreening agents permitted as active ingredients**

We request amendment of the footnote to the table "*Note: The AANs of the 7 substances marked with an asterisk have changed. Sponsors should amend their labels accordingly at the next print run or by 1 July 2013 (whichever date comes sooner)."

,
To:

"*Note: The AANs of the 7 substances marked with an asterisk have changed. Sponsors should amend their labels accordingly by 1 July 2014."

This is further discussed under proposal impacts.

5. Section **X.12 Glossary of terms**

1. The definition of Measured or tested SPF is superfluous and should be removed. The definition for Sun Protection Factor (SPF) should refer also to the FDA method as well as the AS/NZS, or neither.

PROPOSED IMPACTS

Assessment of how the revisions 2 and 4 above will impact JJP.

Change	Impact
Sponsor should ensure that product is compliant with label SPF throughout shelf life. TGA may request results of post-marketing testing (3 months to comply with a request).	No other market requires end of shelf life SPF testing. Such testing done on human volunteers is expensive and unnecessary. Sunscreen UV Filters are very chemically stable and as long as they are intact will retain their SPF efficacy. Stability data is the appropriate and current means of supporting the shelf life efficacy of a sunscreen. To require end of shelf life SPF testing would add significant cost to the marketing of sunscreens, which will ultimately reduce the choice of available sunscreens in the Australian market.
Change in name of sunscreen actives	JJP agrees with the proposed changes as this increases harmonization with other significant markets even though other labeling requirements reduce opportunities for joint labels with other markets. JJP currently has 12 sunscreen products that are affected by the proposed change in name of ingredients. Many of these products are packaged in a container label and a carton label. An estimate of the costs involved in this change include the following per label component/product: Raise artwork change and routing of artwork involving 3 departments to approve and implement the change $200 Artwork change (simple) $400 Production of artwork proofs $100-$300 depending on manufacturer Approval of proofs $80 New printing plates $1000 - $2000 depending on manufacturer

	Estimated total cost will be approximately $2500 per product packaging component and up to $60,000 for JJP based on current products and packaging components. Additional variable costs of stock write offs and packaging write offs will also be incurred however these can be minimised with planned implementation over an appropriate transition period. The current proposal is "Sponsors should amend their labels accordingly at the next print run or by 1 July 2013 (whichever date comes sooner)". This does not allow for products that will have been registered just prior to implementation and for which plates would have to be renewed only after one print run. We request that this statement be revised to remove the phrase,"(whichever date comes sooner)", so as sponsors can minimise write-offs before the final date of implementation. As the TGA is aware there are also changes proposed to the Australian/New Zealand standard that will impact labelling and are likely to be implemented end 2011- early 2012. Given the seasonality aspects of supply of sunscreens, the proximity of proposed revised ARGOM implementation and Australian/NZ Standard 2604 changes it is highly desirable for companies and consumers that these changes are combined. We therefore request that consideration be given to extending the final date of implementation to at least 1 July 2014 to allow sponsors 3 seasons to implement all changes resulting from the updated Standard and ARGOM simultaneously and to quit stock of labelling components. A consumer education communication should also be provided by TGA to consumers to help them understand the changes. .

We are pleased the TGA has undertaken the review of the Australian Regulatory Guidelines for OTC Medicines (ARGOM) and thank you for the opportunity to comment on the proposed ARGOM Chapter 10: Sunscreens.