



13 August 2010

FDA CIRCULAR
No. 2010 - 014

SUBJECT: **Updates and Amendments of ASEAN Cosmetic Directive (ACD)**

In the interest of service, and for the information of all, the Food and Drug Administration (FDA) hereby provides the list of approved/agreed upon recommendation/proposals presented during the 13th ASEAN Cosmetic Committee (ACC) Meeting and 12th ASEAN Cosmetic Scientific Body (ACSB), 14th ASEAN Cosmetic Committee (ACC) Meeting and 13th ASEAN Cosmetic Scientific Body (ACSB) respectively.

FDA reiterates that company/s or person/s responsible for placing the cosmetic product/s in the market are responsible for continually checking any **updates and amendments** to the ACD for proper guidance.

Further, all concerned must comply with the cited grace period as noted in the updates.

For updates and amendments, please visit the following websites:

www.bfad.gov.ph (under ASEAN Cosmetic Harmonization)

www.aseancosmetic.org

www.asean.org

This order shall take effect immediately.


NAZARITA T. TACANDONG, RPh., MPA
Acting Director IV

Subject / Topic	Recommendation Date of Discussion / Meeting Place 12/02/09 – Chiang Mai, Thailand	Recommendation Date of Discussion / Meeting Place 06/09/10 – Jakarta, Indonesia
Annex III – Part 1 Adoption of 2009/129/EC	Mandatory Fluoride labeling provision already adopted. Adoption Period: <u>26/06/08 (Bali)</u> Grace Period: <u>24 Months (26/06/10)</u>	
Annex III – Part 1 Adoption of 2009/134/EC	Adopt all mandatory warning statements with the exception of “read and follow instructions” and “temporary black henna tattoos may increase your risk of allergies”.	
Preamble to preservatives Annex VI	Maintain (+) symbol for entries 18, 25, 32, 35, 42, 44 and 47 and continue to be allowed to be used for purposes other than preservation at other concentrations until the EU Directive is amended.	
Annex III, Part 2 deadlines	Extend to 31/12/2010 those hair dye entries in annexe III, part 2 with <u>“allowed until” dates of 31/12/09.</u>	

Annex III Adoption of 2009/159/EC		<p>Extension of dates 3,4,5,6,10,11,12,16,19,20,21,22, 25,26,27,29,31,32,33,34,35,36, 37,38,39,44,48,49,50,55 and 56 of column g in Part 2 Annex III to Directive 76/768/EEC, <u>the date “31/12/2009” is replaced by “31/12/2010” – already adopted.</u></p>
Annex III – Part 1 Adoption of 2009/164/EC		<p>Annex II, entry 450 replace "Verbena oil (<i>Lippia citriodora</i> Kunth) when used as a fragrance ingredient" with "Verbena essential oils (<i>Lippia citriodora</i> Kunth.) and derivatives other than absolute (CAS No 8024-12-2), when used as a “fragrance ingredient” and add to Annex III Part 1 entry 206 "Verbena absolute (<i>Lippia citriodora</i> Kunth.) CAS No 8024-12-2 with a maximum authorised concentration in the finished cosmetic product of 0.2%".</p> <p>2009/164/EC - Allyl phenethyl ether</p> <p>Note that this is a proposed addition to a group of fragrance ingredients requiring specific labelling in the EU. ACC decided not to adopt this labelling for ASEAN (Decision number 11 14/06/2007 Vientane). It is proposed that this decision be reviewed against current knowledge by a technical working group of ACSB.</p>

<p>Annex III – Part 1 2010/3/EC – Propose adoption of changes</p>		<p>Ethyl Lauroyl Arginate HCl (INCI) (*) Ethyl-N α - dodecanoyl- L-arginate hydrochloride CAS No 60372- 77-2 EC No 434-630-6</p> <p>Add new entry number 207 to Annexe III Part 1 to permit use in soap, in anti-dandruff shampoo and in deodorants (not in spray form) at a maximum level of 0.8% for purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. Footnote (*) For use as a preservative, see Annex VI, Part 1, entry No 58. Add new entry number 58 to Annexe VI Part 1 to permit use as a preservative at a maximum level of 0.4%. Not to be used in lip products, oral products and spray products. Footnote (**) For other uses than preservatives, see Annex III, Part I, entry No 207.</p>
---	--	---

<p>Annex III – Part 1 2010/4/EC – Propose adoption of changes</p>		<p>Add Annex III Part 1 Entry 209 2-[(2-methoxy-4- nitrophenyl)amino]ethanol and its salts 2-Hydroxyethylamino- 5-nitroanisole CAS No 66095- 81-6 EINECS 266-138-0 for use as a Hair dye substance in non- oxidative hair dye products with a Maximum authorised concentration in the finished cosmetic product of 0.2% and associated limitations and conditions of use.</p> <p>Adoption of the labelling provisions of 2009/134/EC was also discussed. It was agreed to propose that the new mandatory labelling be adopted without modification (a change from proposal 54 02/12/2009 ACSB Chiang Mai). With regards to the Warning Triangle symbol size, there is no mandatory size, flexibility is permitted to take into account pack size difference.</p>
<p>Mesotherapy Products</p>		<p>These products cannot be classified as Cosmetics.</p>

Annex III Part 1 Adoption of 2009/130/EC		<p>The meeting agreed to adopt the amendments to 2009/130/EC on PPD and PTD concentrations (to decrease) and noted that the timeline for its effective implementation in the EU is <u>15 July 2010</u>.</p> <p>In this regard, the existing products may be allowed to be in the market until <u>31 December 2010</u>, while new products shall comply with these requirements with effect from <u>15 July 2010</u>.</p>
---	--	---