Latest Updates of CFDA Regulations on Cosmetics and New Cosmetic Ingredients in China

Date: 18 March 2014
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Summary of Main Changes - 2013-2014

- Imported non special use cosmetics will be registered with FDA at provincial level;
- Toothpaste is regarded as cosmetics;
- Online record-keeping will be available to domestic non special use cosmetics on 30th Jun 2014;
- Whitening product is considered as special use cosmetics;
- Animal tests no longer mandatory for non-special use cosmetics produced in China;
- IECIC 2014 draft version issued;
- New rules proposed for the management of new cosmetic ingredient registrations.
**Registration of imported non special use cosmetics**

**Authority Change: CFDA -> Provincial FDA**

<table>
<thead>
<tr>
<th>Effective date</th>
<th>Authority</th>
<th>Dossier</th>
<th>Testing</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Jun 2014*</td>
<td>CFDA -&gt; Provincial FDA</td>
<td>No change</td>
<td>No change</td>
<td>Might be shortened</td>
</tr>
</tbody>
</table>

* Will be delayed as CFDA will take more time to assess if the provincial FDA is qualified to manage imported non special use cosmetics;

** Not all provincial FDAs are qualified at the moment.
# How to manage toothpaste in China?

<table>
<thead>
<tr>
<th>Before</th>
<th>Now</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Not regarded as cosmetics;</td>
<td>• Regarded as cosmetics since Oct 2013.</td>
</tr>
<tr>
<td>• CFDA registration not required;</td>
<td>• CFDA registration may be required in the future;</td>
</tr>
<tr>
<td>• Only customs clearance required.</td>
<td>• CFDA is drafting detailed guidance.</td>
</tr>
</tbody>
</table>
# New record-keeping requirements for domestic non special use cosmetics

<table>
<thead>
<tr>
<th>New system</th>
<th>Old system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both pre-market record-keeping and post-market inspection;</td>
<td>Post-market record-keeping.</td>
</tr>
<tr>
<td>Online record-keeping of formula and packaging only;</td>
<td>All materials are submitted to provincial FDA in hard copies;</td>
</tr>
<tr>
<td>Other documents kept by manufacturer for future reference/inspections;</td>
<td>Record-keeping certificate issued;</td>
</tr>
<tr>
<td>No record-keeping certificate</td>
<td>Not available online.</td>
</tr>
<tr>
<td>Available for search on CFDA’s website</td>
<td></td>
</tr>
</tbody>
</table>
Latest IECIC list

- **IECIC 2014 draft**
  - 8641 ingredients
  - Extracted from IECIC 2003 and finalized two batches of IECIC 2012

- **IECIC 2014 final**
  - Time: no available
  - Composition: IECIC 2003, IECIC 2012(final) and part of new cosmetic ingredients listed in domestic non special use cosmetics
  - Quantity: More that 8641
  - Regarded as the sole list to identify new cosmetic ingredient.
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  - Quantity: More than 8641
  - Regarded as the sole list to identify new cosmetic ingredient.
Management of Whitening Products

Non special use cosmetics  16 Dec 2013  Special use cosmetics (anti-freckle type)

Implications

- Previously approved whitening products

- Sale or import after 30th Jun 2015

- Imported cosmetics: Application of changing product types;

- Domestic cosmetics: New product registrations;
## Registration Requirements for Whitening Products with Different Claims

<table>
<thead>
<tr>
<th>Item</th>
<th>CFDA license</th>
<th>Testing items</th>
<th>Review process</th>
<th>Labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type I</strong></td>
<td><strong>Hygiene license for anti-freckle</strong></td>
<td>As special use cosmetics for anti-freckle</td>
<td>As special use cosmetics for anti-freckle</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type II</strong></td>
<td><strong>Hygiene license for anti-freckle marked with ”Only for physical covering”</strong></td>
<td>As non special use cosmetics</td>
<td>As non special use cosmetics</td>
<td>Marking with ”Only for physical covering”</td>
</tr>
</tbody>
</table>

* Having the claims of whitening skin or reducing skin pigment

** Achieving the whitening effect via physical covering.
Animal Testing Requirements for Cosmetics in China – Current System

- **Imported and domestic non special use cosmetics***
  - Eye irritation
  - Acute skin irritation
  - Repeat skin irritation

- **Special use cosmetics**
  - Eye irritation
  - Acute skin irritation
  - Repeat skin irritation
  - Skin sensitization
  - Skin phototoxicity
  - Reverse mutation assay
  - In vitro mammalian cell chromosome aberration

- **Domestic non special use cosmetics for export only**
  - Testing is not required

* Domestic non special use cosmetics consist of products manufactured in mainland China or products packed in mainland China.
Animal Testing Requirements for Cosmetics in China – New System from 30 June 2014

- Imported non special use cosmetics
  - Eye irritation
  - Acute skin irritation
  - Repeat skin irritation

- Special use cosmetics
  - Eye irritation
  - Acute skin irritation
  - Repeat skin irritation
  - Skin sensitization
  - Skin phototoxicity
  - Reverse mutation assay
  - In vitro mammalian cell chromosome aberration

- Domestic non special use cosmetics for export only
  - Testing is not required

- Domestic non special use cosmetics
  - Testing can be waived based on the safety assessment result of ingredients.
### How to manage the registration of new cosmetic ingredient in the future?

<table>
<thead>
<tr>
<th>Current system</th>
<th>Future system</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Existing cosmetic ingredient list for reference to determine new ingredient:</td>
<td>• Existing cosmetic ingredient list to determine new ingredient:</td>
</tr>
<tr>
<td>- IECIC 2003</td>
<td>- IECIC 2014</td>
</tr>
<tr>
<td>- IECIC 2012 (Two final versions plus one draft version)</td>
<td>• 4 Years of Protection Period for New Cosmetic Ingredient Registrants</td>
</tr>
<tr>
<td>• Each user or producer can use a new ingredient once it has been approved;</td>
<td>• More Post-registration Obligations on Registrant;</td>
</tr>
<tr>
<td>• No post-registration obligations on registrant.</td>
<td>• New cosmetic ingredients may no longer be allowed in domestic non-special use cosmetics.</td>
</tr>
</tbody>
</table>
Summary of Main Changes - 2013-2014

- **Imported non special use cosmetics** will be registered with provincial FDA;
- **Toothpaste** is regarded as cosmetics;
- Online record-keeping will be available to **domestic non special use cosmetics** on 30th Jun 2014;
- **Whitening product** is considered as special use cosmetics;
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- IECIC 2014 draft version issued;
- New rules proposed for the management of **new cosmetic ingredients**.
## Special Use vs Non Special Cosmetics

<table>
<thead>
<tr>
<th>Special use cosmetics</th>
<th>Non special use cosmetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hair growth</td>
<td>Hair care</td>
</tr>
<tr>
<td>Hair dye</td>
<td>Skin care</td>
</tr>
<tr>
<td>Hair perm</td>
<td>Make-up</td>
</tr>
<tr>
<td>Depilation</td>
<td>Nail care</td>
</tr>
<tr>
<td>Breast shaping</td>
<td>Perfume</td>
</tr>
<tr>
<td>Fitness</td>
<td></td>
</tr>
<tr>
<td>Deodorization</td>
<td></td>
</tr>
<tr>
<td>Anti-freckle</td>
<td></td>
</tr>
<tr>
<td>Sun block</td>
<td></td>
</tr>
</tbody>
</table>
Thank You!

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