CFDA to Simplify Record-keeping Requirements and are to Remove Compulsory Animal Test requirement for Non-special Use Cosmetics Produced in China

5 Nov 2013, CFDA issued a public notice inviting public comments on the adjustment of record-keeping management of non-special use cosmetics in China. The notice intends to simplify record-keeping requirements and remove compulsory animal test requirements for non-special use cosmetics made in China.

There are three major changes:

- For domestic non-special use cosmetics, companies need to conduct online record-keeping from 1st Jun 2014. The provincial food and drug authority will no longer issue record-keeping certificates for approved domestic non-special use cosmetics. The record-keeping requirements will be reduced while post-market supervision will be strengthened.

- Cosmetics with skin-whitening and skin pigmentation reduction claims will be classified as special use cosmetics (anti-freckle category) from 1st Jan 2015. The whitening cosmetics produced before 1st Jan 2015 can be sold until the end of their shelf life;

- For imported non-special use cosmetics, provincial food and drug authorities can undertake responsibilities of the administrative approval of imported cosmetics from 30 June 2014 after receiving confirmations and unified training from the State Food and Drug Administration in Beijing.

CIRS' Comments

The most dramatic change is that there is one provision in the notice stating that if manufacturers have the capabilities to conduct their own safety assessment of ingredients to ensure the safety of finished cosmetic products, toxicology tests on finished products can be waived. This provision is applicable to non-special use cosmetics produced in China. It is not clear if it is also going to be applicable to imported non-special use cosmetics in the future.

For many foreign cosmetic brands who wish to enter the Chinese market while avoiding animal test during CFDA approval process, there may be a way forward for them to achieve both: finding a toll manufacturer to manufacture their cosmetic products locally in China.

For many local cosmetic companies that do not have sufficient safety assessment capabilities, carrying out toxicology test is easier to do.

Source

http://www.sda.gov.cn/WS01/CL0781/93896.html

Background Info

In China, cosmetics are divided into two classes: non-special use cosmetics and special use cosmetics. Each class requires different type of license from CFDA. Companies who plan to place cosmetics on Chinese market must apply for and obtain hygiene license or record-keeping certificate from the China Food & Drug Administration (CFDA). Due to governmental reform, imported ordinary use cosmetics are approved by food & drug administration authorities at provincial level while imported special use cosmetics are approved by CFDA in Beijing.

Type of Product	*Required License*
Ordinary cosmetics hair care, nail care, skin care, perfumes and make-up	Record-keeping Certificate
Special use cosmetics products for hair growth, hair dye, hair perm, hair removal, breast shaping, fitness, deodorizing, spots removal and sun block	Hygiene License (More expensive and time-consuming)

Chemical Inspection and Regulation Service Limited(CIRS China)

■Address: 288 Qiuyi Road, Hangzhou City, China

■Contact: Ms April Guo ■ Tel：+86 571 8720 6555 ■ +86 571 8720 6533

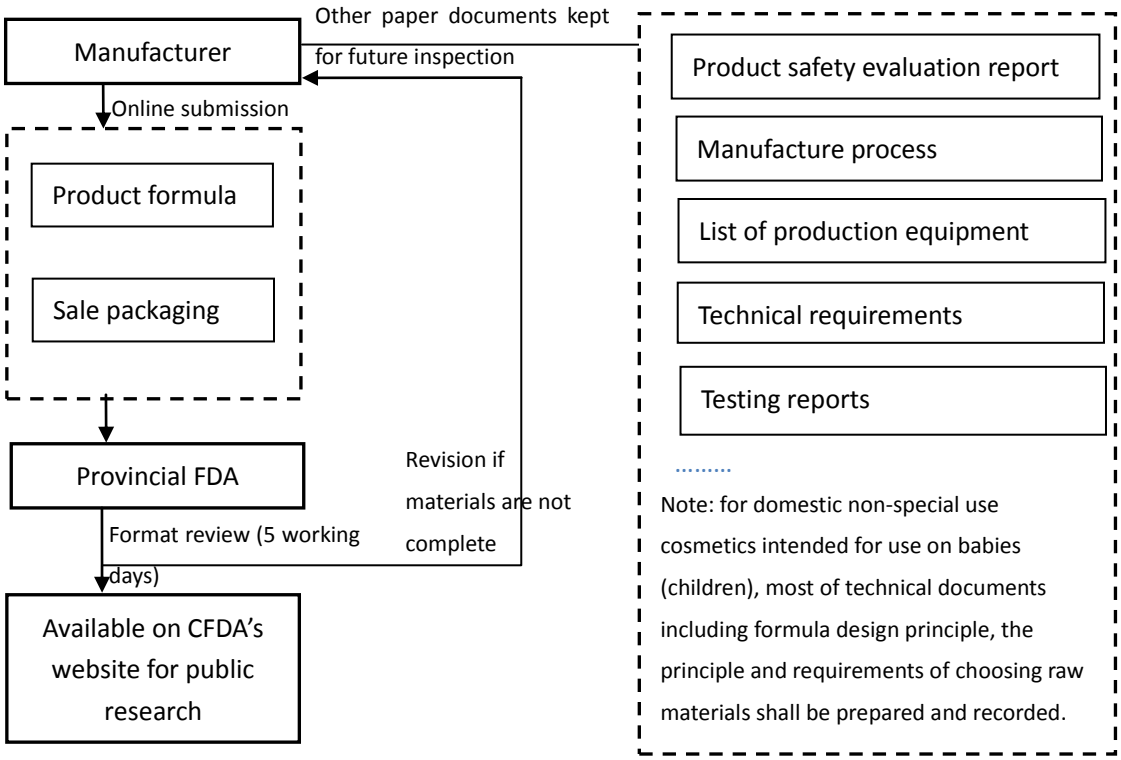
■Email: april.guo@cirs-reach.com ■ http://www.cirs-reach.com

Attachment:

The flow charts below compare the new and the old record-keeping system.

New Record-keeping System for Domestic Non-special Use Cosmetics

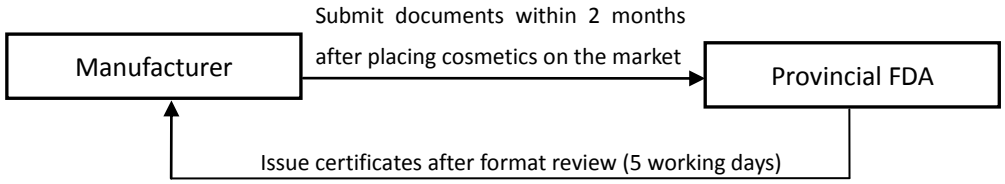
Step 1: Pre-market Record-keeping



Step 2: Post-Market Supervision by Authority.

- Authorities may conduct on-site inspection of other files not submitted in the record-keeping process.

Old Record-keeping System for Domestic Non-special Use Cosmetics



Comparison

New system	Old system
Both pre-market record-keeping and post-market inspection	Post-market record-keeping
Online record-keeping of formula and packaging; Other documents are kept by manufacturer for future reference/inspections	All paper materials are submitted to provincial FDA
No record-keeping certificate issued	Record-keeping certificate issued after format review
Available for search on CFDA's website	Not available online.