U.S. – China HPA Health Products Association 美中健康产品协会

Regulatory Insights

Industry Report

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Report on 2016 China Special Food International Conference

有关 **2016** 中国特殊食品合作发展国际会议的报告

Report on 2016 China Special Food International Conference

The association attended the 2016 China Special Food International Conference which was hosted by China Food and Drug Administration (CFDA) on December 12-13th. During the conference, CFDA officers gave several speeches about regulatory perspectives on Health Food. Here is a summary for your references.

- **Electronic Declaration**
  CFDA is launching a brand new Health Food Registration electronic declaration system. In the near future, the entire application process will be paperless.

- **Contact Information of the Applicant**
  CFDA will either call or send a text message to the applicant's contact number to notify some issues related with the health food registration application such as grant technical review notice letter or health food registration certificate etc. If any changes happen to the contact information, the applicant shall provide change request to the acceptance institute for immediately update.

- **Review Center & Expert Panel**
  According to the new health food registration review rules, the review center has the power to ignore the review suggestions from the expert panel and then request Expert Demonstration Panel to provide another review suggestion. The previous single expert panel has been divided into four categories, which are safety expert review panel, health function expert review panel, technology expert review panel and technical requirements expert review panel.

- **On-site Inspection**
  The inspection center rarely conducts on-site inspection for overseas companies who apply for health food registration. However, CFDA officers mentioned about the on-site inspection for oversea companies will be established and stricter in the future, so the law does allow for them to request an on-site inspection.

- **Testing Segment**
  If there is no applicable national standard, local standard or industry standard can be referred for testing method or if any reagents are not able to be purchased, the testing center can ask the applicant to provide those outside resources for testing purposes.

- **Clarify Definition of Overseas Applicant**
  Overseas applicant refers to any legal overseas health food manufacturer or trader. The name on the one-year free sales certificate shall be the name of the overseas applicant. New health food products to China applying for registration or recording must have a minimum of one-year sales data in the home country prior to applying for CFDA approval. A special Free Sale Certificate that guarantees "one-year sales" is required by CFDA as part of the overall application process.

- **Checklist of Imported Health Food Registration Application Materials**
  1) Imported Health Food Registration Application Form;
  2) Copy of applicant's ID, business license or other legal registered demonstration documents;
  3) Retrieval data to show the health food name is not the same as the name of any approved registered drug on CFDA's database;
  4) Guarantee letter of the applicant will not constitute infringement for any patents which are obtained by others;
  5) Documents proving brand is trade marked;
  6) Product R&D report (Include R&D plan, function selection process, expected effect etc.);
  7) Product formula (ingredients and excipients) and basis for formula;
  8) Name, content and testing method of functional components;
  9) Production process sketch and its explanation, related research materials;
  10) Product quality standard and its explanation (Include quality standard of ingredients and excipients);
  11) Type, name, quality standard and selection basis of direct-contact product package materials;
  12) Testing report and related materials issued by test agency;
  13) Samples of product label and instruction book;
  14) Product technical requirements and upload succeed confirmation letter of product technical requirements.
  15) Other materials benefit product review process;
  16) 3 unopened smallest sales package samples;
  17) Provide related materials if function claim is not listed on the functional claim list;
  18) Demonstration documents issued by manufacturer country (region) to show the product manufacturer compliance to the local GMP;

19) If overseas company's representative office in china handles the registration process, the company shall provide a copy of <Oversea Resident China Representative Office Registration Form>. If the overseas company authorized domestic agency handles the registration process, they shall provide the original copy of notarized authorization letter and copy of business license of the authorized agency;
20) Proof documents notarized by country of origin (region) officials and confirmed by China Embassy to show the product has been manufactured and sold in that country (region) for at least one year;
21) Product related standards of country of origin (region) or international organization;
22) Product package, label, instruction book samples from country of origin;
23) Three times the sample amount requested by the testing agency from three consecutive batches.

- Here is an updated list of current core legislations regarding health food regulatory reform process:

Legislation	Chinese Name	Issue Authority	Status
New Food Safety Law	《新食品安全法》	President of China	Effective on October 1st, 2015
Implementation Rules of Food Safety Law	《食品安全法实施条例》	CFDA	Asked for comments on December 9th, 2015
Measures for Health Food Registration and Recording	《保健食品注册与备案管理办法》	CFDA	Effective on July 1st, 2016
Measures for Health Food Raw Material Category & Function Category	《保健食品原料目录与功能目录管理办法》	CFDA	Asked for comments on July 28th, 2015
Health Food Raw Material Category (Part 1)	《保健食品原料目录（第一批）》	CFDA	Asked for comments twice on February 17th, 2016 and June 2nd, 2016.
Excipients List for Health Food Recording (Part 1)	《保健食品备案辅料名单（第一批）》	CFDA	Asked for comments twice on May 30th, 2016 and July 16th, 2016.
Health Food Registration Review Rules	《保健食品注册审评细则》	CFDA	Issued and effective on November 14th, 2016.
Health Food Function Category	《保健食品功能目录》	CFDA	Still processing
Health Food Production Permit Review Rules	《保健食品生产许可审查细则》	CFDA	Effective on January 1st, 2016