SFDA 国家食品药品监督管理局
State Food and Drug Administration

组合产品法规介绍

Combination Product Regulation & Supervision In China

国家食品药品监督管理局 医疗器械监督管理司

State Food and Drug Administration Medical Device Dept.

组合产品监管的法规要求

Combination Products' Supervision Requirements

- 《关于药械组合产品注册有关事宜的通告》（国家食品药品监督管理局通告，2009年 第16号）
- **<Notification on Matters Concerning Registration of Drug and Medical Device Combination Products >（ SFDA， No. 16, 2009 ）**

URL：http://www.sfda.gov.cn/WS01/CL0087/43215.html

- ❑药械组合产品的定义
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组合产品定义

Definition of Combination Products

药品 + 医疗器械 = 组合产品（单一实体）

Drug + Medical Device = Combination Products (one entity)

申报途径

Registration Application Pathway

- 以药品作用为主，申报药品注册
- If drug plays the leading role，apply for drug registration

- 以医疗器械作用为主，申报医疗器械注册
- If medical device plays the leading role，apply for medical device registration

申请组合产品的属性界定

Combination Product Categorical Application

- **申请资料受理单位：**国家食品药品监督管理局行政受理服务中心
- **Application Acceptance Authority:** Administrative Processing Service Center of the State Food and Drug Administration

- **申请材料：** 产品拟按照药品或医疗器械申报注册的说明及相关支持性资料
- **Application Supporting Documents:** explanation and relevant supporting materials for the product to facilitate decision making whether the product will be registered as a drug or medical device

组合产品属性界定的部门和时限
Combination Product Categorical Decision Making Authority and Timeline

属性界定主管部门：
Authorities:

- 国家食品药品监督管理局行政受理服务中心
- The Administrative Processing Service Center of the State Food and Drug Administration

- 药品审评中心
- The Center of Drug Evaluation

- 医疗器械技术审评中心
- The Center of Medical Device Evaluation

时限：**Timeline**
20个工作日内 Within 20 working days

依据组合产品属性界定意见申请注册

Application Based on the Category and Classification of the Combination Product

注册审评主体：国家食品药品监督管理局
Review Authority: State Food and Drug Administration

注册途径： 药品或医疗器械注册申请
Application Pathway: apply for drug registration or medical device registration

***注明“药械组合产品”**

*** Indicate “drug and medical device combination product”**

申请组合产品注册对原产国/地区上市许可的要求

Country of Origin Requirement for Combination Product Registration Application

未获出口国（地区）批准上市的，以及药械组合产品中所含药品未获我国注册或未获生产国（地区）批准上市的，均不予受理

If the combination products have not been approved for sale in the export country (region), and if the drug in a drug - device combination product has not been registered in China or has not been approved for sale in the country (region) of manufacturer , then the application will not be accepted.

药械协调机制和联合审评机制

Drug-Device Coordination and Joint Evaluation Mechanism

- 药品审评中心与医疗器械技术审评中心建立协调机制
- The Center of Drug Evaluation and the Center of Medical Device Evaluation will establish a coordinative mechanism

- 分别牵头，联合审评，同步进行
- Technical review lead by leading party; joint-effort review; simultaneous review.

- 国家食品药品监督管理局相应业务司进行行政审批
- Corresponding department of the State Food and Drug Administration for administrative evaluation and approval.

组合产品示例

Combination Product Examples

- 带药物涂层的支架 Drug-eluting Stent
- 带抗菌涂层的导管 Antibacterial-coated catheters
- 含药避孕套 Condoms with drug
- 含药节育环 Contraceptive rings with drug

- 含抗菌、消炎药品的创口贴 Wound dressings with antibacterial and anti-inflammatory drugs
- 中药外用贴敷类产品 Patches which contain traditional Chinese medicine for external

实施时限

Promulgation Timeline

自发布之日起实施（2009.11.12）

Come into force as of the date of promulgation （November 12, 2009 ）


谢谢
THANK YOU