

中国 WTO/TBT 国家通报咨询中心

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Subject: <p style="text-align: center;">Comments from China on USA Notification G/TBT/N/USA/214</p> Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs; Proposed Rule	

Comments from China on USA Notification

G/TBT/N/USA/214

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs,
Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs;
Proposed Rule

Dear Sir or Madam,

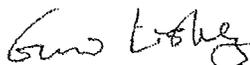
We appreciate the opportunity to submit comments on this regulation proposed by
Food and Drug Administration (FDA), USA.

Enclosed please find comments in English and Chinese.

Please acknowledge receipt of comments by e-mail to tbt@aqsic.gov.cn.

Thank you very much in advance for Food and Drug Administration (FDA) taking our
comments into consideration.

Best regards



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COMMENTS FROM CHINA ON USA NOTIFICATION

G/TBT/N/USA/214

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs,
Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs;
Proposed Rule

The government of China appreciates the opportunity to comment on this notification.

1. We suggest that FDA of the USA arrange a reasonable transitional period for drug enterprises in China.
2. It is proposed that FDA supply enquiry services to drugs enterprises in China after related regulations being promulgated.

Comments in Chinese are as below:

- 一、建议美国 FDA 在政策制定中能给中国制药企业一定的过渡期。
- 二、建议有关政策法规正式出台后，美国方面为中国制药企业提供咨询服务。