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国家食品药品监督管理总局关于调整部分药品行政审批事项审批程序的决定

为贯彻落实《国务院关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号）以及国务院有关行政审批制度改革精神，进一步加强药品注册管理，切实提高审评审批效率，经国家食品药品监督管理总局局务会议研究决定，将下列由国家食品药品监督管理总局作出的药品行政审批决定，调整为由国家食品药品监督管理总局药品审评中心以国家食品药品监督管理总局名义作出：

一、药物临床试验审批决定（含国产和进口）；

二、药品补充申请审批决定（含国产和进口）；

三、进口药品再注册审批决定。

其他药品注册申请的审批决定，按现程序，由国家食品药品监督管理总局作出。

调整后的审批决定由国家食品药品监督管理总局药品审评中心负责人签发。申请人对审批结论不服的，可以向国家食品药品监督管理总局提起行政复议或者依法提起行政诉讼。

药品监管相关规章中审批程序与本决定不一致的，按照本决定执行。

本决定自2017年5月1日起施行。

（来自：国家食品药品监督管理总局）