

May 21, 2010

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-D-0133: Revised Draft Guidance for Industry on Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling; Availability

Dear Ladies and Gentlemen,

On behalf of the American Society of Nephrology, thank you for the opportunity to provide comment on the 'Revised Draft Guidance for Industry on Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling; Availability.' ASN was pleased to recently submit comments from the society on this document to FDA.

In addition, ASN has reviewed and is in full support of the comment letter on this topic prepared by Kidney Disease: Improving Global Outcomes (KDIGO). Please accept this letter of notification that ASN endorses the comments submitted by KDIGO.

Again, thank you for your time and consideration of comments from the renal community on this important issue. To discuss ASN's endorsement of the KDIGO letter, please contact ASN Director of Policy and Public Affairs Paul C. Smedberg at psmedberg@asn-online.org or at (202) 416-0646.

Sincerely,



Sharon Anderson, MD, FASN
President