

**FOOD AND DRUG ADMINISTRATION**  
**CENTER FOR DRUG EVALUATION AND RESEARCH**  
***Antiviral Drugs Advisory Committee***

The Great Room, White Oak Conference Center, Food and Drug Administration Campus  
April 28, 2011

**AGENDA**

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The committee will discuss a new drug application (NDA) 201-917, telaprevir (a hepatitis C virus protease inhibitor), manufactured by VERTEX Pharmaceuticals, Inc., with a proposed indication for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy. Compensated liver disease is a stage in which the liver is damaged but maintains ability to function.

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8:00 a.m. – 8:05 a.m.	Call to Order and Introductions	<b>Victoria A. Cargill, M.D., M.S.C.E.</b> <i>Committee Acting Chair</i> Antiviral Drugs Advisory Committee (AVDAC)
8:05 a.m. – 8:15 a.m.	Conflict of Interest Statement	<b>Paul Tran, R.Ph</b> Designated Federal Officer AVDAC
8:15 a.m. – 8:30 a.m.	Introduction/Background	<b>Debra B. Birnkrant, M.D.</b> Director Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND) Center for Drug Evaluation & Research (CDER) Food and Drug Administration (FDA)
8:30 a.m. – 10:00 a.m.	<b>Sponsor Presentation</b>	<b>Vertex Pharmaceuticals, Inc.</b>
	Introduction	<b>Robert S. Kauffman, M.D., Ph.D.</b> Chief Medical Officer, Clinical Vertex Pharmaceuticals, Inc.
	Hepatitis C Virus — Disease Background and Treatment Landscape	<b>Ira M. Jacobson, M.D.</b> Chief, Division of Gastroenterology and Hepatology Weill Medical College of Cornell University
	Development Program Overview	<b>Robert S. Kauffman, M.D., Ph.D.</b> Chief Medical Officer, Clinical Vertex Pharmaceuticals, Inc.
	Phase 3 Efficacy	<b>Shelley George, M.D.</b> Vice President, HCV Therapeutic Area Lead Vertex Pharmaceuticals, Inc.
	Safety	<b>Priya Singhal, M.D., M.P.H.</b> Senior Director, Global Patient Safety Vertex Pharmaceuticals, Inc.

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**AGENDA (cont.)**

	Benefit Risk Assessment	<b>Robert S. Kauffman, M.D., Ph.D.</b> Chief Medical Officer, Clinical Vertex Pharmaceuticals, Inc.
10:00 a.m. – 10:15 a.m.	Clarifying Questions from the Committee to Sponsor	
10:15 a.m. – 10:30 a.m.	<b>Break</b>	
10:30 a.m. – 11:45 a.m.	<b>Presentation</b>	<b>FDA</b>  <b>Russell Fleischer, P.A.-C., M.P.H.</b> Senior Clinical Analyst Division of Antiviral Products (DAVP) OAP, OND, CDER, FDA
	Telaprevir NDA 201-917	and  <b>Pravin Jadhav, Ph.D.</b> Pharmacometrics Team Leader Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS) CDER, FDA
11:45 a.m. – 12:00 p.m.	Clarifying Questions from the Committee to FDA	
12:00 p.m. – 1:00 p.m.	<b>Lunch</b>	
1:00 p.m. – 2:00 p.m.	Open Public Hearing Session	
2:00 p.m. – 2:30 p.m.	Questions from Committee to Sponsor and FDA	
2:30 p.m. – 2:45 p.m.	Charge to Committee	<b>Debra B. Birnkrant, M.D.</b> Director Division of Antiviral Products (DAVP) OAP, OND, CDER, FDA
2:45 p.m. – 5:00 p.m.	Discussion/Questions to the Committee	
5:00 p.m.	<b>Adjournment</b>	