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**November 20, 2003**

**HAAC ACTION ALERT:  
Demand FDA Approve Long-Delayed, Lower-Cost Generic Ribavirin for the Treatment of  
Hepatitis C**

It has been twenty-two months since the original patents and market exclusivities on Rebetol (brand ribavirin) have expired and twenty-eight months since generic drug makers submitted their applications to the Food and Drug Administration (FDA) to approve marketing of generic lower-cost ribavirin. **CONTACT YOUR CONGRESSPERSON AND SENATORS TO DEMAND THAT THE FDA stop playing into pharmaceutical industry delay tactics and approve generic ribavirin for the treatment of Hepatitis C NOW!**

**TAKE ACTION!**

**Send a letter to the following decision makers:**

Your Congressperson

Your Senators

(For contact information for your representatives, go to "Contacting the Congress" at <http://www.visi.com/juan/congress/>)

Mark B. McClellan, M.D., Ph.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane, Room 14-65  
Rockville, MD 20857

Phone: 301-827-2410

Fax: 301-443-3100

e-mail: [commissioner@fda.gov](mailto:commissioner@fda.gov)

**SAMPLE LETTER:**

Hepatitis C Action & Advocacy Coalition (HAAC)  
53 Divisadero Street  
San Francisco, CA 94117

November 20, 2003

[Decision maker's name, title, address]

RE: Demand FDA Approve Long-Delayed, Lower-Cost Generic Ribavirin for the Treatment of Hepatitis C

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Dear [insert decision makers name and proper title]

As community advocates for people living with Hepatitis C (HCV), we are writing to request that you immediately contact FDA Commissioner Mark McClellan and ask that he commit and synchronize the resources and departments necessary at the FDA to quickly finalize the drug labeling, and issue the long-delayed final approval, for generic ribavirin capsules, an antiviral drug commonly used together with interferon alfa for the treatment of Hepatitis C. Once generic ribavirin is available, millions of public and private health care dollars will be saved, and many patients who are economically barred from treatment for their HCV will have access to potentially life-saving treatment.

Hepatitis C affects over four million Americans and 200 million people worldwide. Many people infected with HCV also struggle with HIV/AIDS. If a person with HCV can afford it and has access to it, standard treatment of Hepatitis C using brand pharmaceutical interferon in combination with ribavirin currently runs nearly \$30,000 a year per patient.

The average time for approval of an Abbreviated New Drug Application (ANDA) for a generic drug is eighteen months. However, ANDAs for ribavirin capsules from three generic drug makers (Three Rivers, Geneva, and Teva) have been languishing for over twenty-eight months now.

The generic drug makers successfully survived the many frivolous patent infringement lawsuits filed against them by the brand pharmaceutical makers of ribavirin, Schering-Plough and ICN/Ribapharm, the last of such litigation having been concluded in July 2003. Subsequent to losing the litigation, in a last desperate effort to protect its monopoly, ICN/Ribapharm filed a "Citizen Petition" with FDA that further delayed the introduction of generic ribavirin. These brand pharmaceutical companies successfully "gamed the system" and added additional labeling issues to further burden the FDA work load. Now the biggest challenge is getting the FDA to complete the review process it started twenty-eight months ago and grant final approval so that generic ribavirin capsules can be made available to dramatically lower the cost of HCV treatment.

***Other than FDA providing guidance on minor labeling issues so that the generic makers can prepare final printed labeling, no other hurdle exists for the generic ribavirin to be approved by the FDA.***

Please help us by asking the FDA to complete its review process and approve generic ribavirin so that people living with Hepatitis C can have access to this lower cost, life-saving treatment.

Thank you for your attention and assistance.

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Very truly yours,

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cc:

Mark B. McClellan, M.D., Ph.D.  
Commissioner  
Food and Drug Administration

**Statement of Purpose**

The Hepatitis C Action & Advocacy Coalition (HAAC) is a grassroots, all-volunteer group of individuals committed to non-violent direct action to end the Hepatitis C crisis. We work to provide access to life-extending treatments to people with Hepatitis C, foster effective prevention efforts, encourage sound public health policies, and to ensure adequate funding and resources for the care, treatment, and prevention of Hepatitis C. We work cooperatively with government and industry when progress is being made, and take to focused, non-violent direct action when progress is stalled. We accept no money from pharmaceutical companies. Ending the Hepatitis C crisis is our highest priority.