New Guidance on Antiviral Product Development

FDA published, this week, a final ***Guidance for Industry on Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency*** to assist sponsors in the development of antiviral drugs and biological products (i.e., therapeutic proteins and monoclonal antibodies) from the initial pre-IND through the new drug application (NDA) and postmarketing stages.

The guidance serves as a starting point for understanding what nonclinical and clinical virology data are important to support the submission of an Investigational New Drug Application (IND), New Drug Application (NDA), or Biologics License Application (BLA) for approval of an antiviral product. The guidance focuses on nonclinical and clinical virology study reports and makes recommendations for collecting and submitting resistance data to the Food and Drug Administration (FDA). Nonclinical and clinical virology study reports, based on collected data, are essential for FDA's review of antiviral drug investigational and marketing applications. Specific topics discussed in the guidance include:

* Defining the mechanism of action
* Establishing specific antiviral activity of the investigational product
* Assessing the potential for antagonism of other antiviral products that might be used in combination with the investigational product
* Providing data on the development of viral resistance to the investigational product
* Providing data that identify cross-resistance to approved antiviral products having the same target

The guidance document, and specific topic attachments are available on the FDA web site through the following links:

The Guidance

The Guidance Attachment -Submitting HIV Resistance Data

The Guidance Attachment- Submitting Influenza Resistance Data

The Guidance Attachment- Submitting HBV Resistance Data

The Guidance Attachment- Submitting HCV Resistance Data

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An archive of past list serve announcements is available on the FDA web site at http://www.fda.gov/oashi/aids/listserve/archive.html

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