FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Antiviral Drugs Advisory Committee
Hilton Washington, DC/Silver Spring
December 2, 2008
Questions to the Committee
OPEN SESSION

Open Session Questions for the Panel:

1.

a. The risk of cross species infection associated with the presence of PPV or PCV in the pancrelipase product appears to be very low, but could be further reduced by testing for infectivity and ensuring limited patient exposure to these viruses. In that light, should testing for infectious PPV and/or PCV 1 and 2 be conducted for pancrelipase batch release testing? **Vote Yes or No**

b. If "Yes", which viruses should be tested?
   1) PPV
   2) PCV1
   3) PCV2

   Discuss

c. If testing is warranted, should the acceptance criteria for lot release allow for a limited number of infectious virus? **Vote Yes or No**

d. If "Yes", is there a viral load below which cross species infectivity is less likely to occur? **Discuss**

e. Are there any other viruses of concern that have not thus far shown zoonotic potential, but should be tested on a routine basis? **Vote Yes or No (If Yes, specify which additional viruses)**

2.

a. To control the risk from unidentified emerging viruses, Solvay has proposed a number of options for animal disease surveillance programs and continued risk assessment evaluations for source animals. Should a detailed plan for these programs be required? **Vote Yes or No**

b. If "Yes", please identify additional measures that should be implemented to mitigate risk. For example, Solvay could use appropriate indicator cell lines and animal testing to evaluate the presence of unknown viruses in the product that might infect humans. **Discuss**

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3.

a. Solvay has not formally submitted a plan for continued viral risk identification and evaluation in patients taking Creon in the post-marketing setting. Should such a plan be provided? **Vote Yes or No**

b. If "Yes", what components should be included in the plan? For example, what additional studies could be performed post approval in order to better understand the risks? **Discuss**

4.

a. Currently, no information regarding the risk from viral contamination is provided to physicians and patients in product labeling. Is there sufficient concern that such information should be provided? **Vote Yes or No**

b. If "Yes", can you provide guidance on what information should be provided to the patients, their caregivers, and to the public? **Discuss**