

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

FDA ERRATA to December 2, 2008 Briefing Documents for AVDAC

OPEN SESSION:

Page 10: Open Session

Changed from:

Facilities

The sourcing and manufacturing facilities are dedicated to the processing of swine tissue. However, FDA does not believe procedures are not in place to prevent cross contamination between individual lots during manufacturing of the drug substance.

To:

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Page 4: Open Session: Influenza A

Changed from:

Menagel virus is limited. Given the occurrence of these viruses in European and U.S. sourced swine, we believe that the risk associated from this associated with the use of Creon should be reduced.

To:

Menagel virus is limited. Given the occurrence of these viruses in European and U.S. sourced swine, we believe that the risk associated from the use of Creon should be reduced.