Food and Drug Administration
Center for Biologics Evaluation and Research
SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
Meeting # 107: May 18, 2006
Hilton Hotel, Gaithersburg, MD

Committee Members
Dr. Monica M. Farley, Acting Chair
Dr. Walter Royal III
Dr. Philip S. LaRussa
Ms. Cindy Lyn Province *
Dr. Bonnie M. Word

FDA Participants
Dr. Nancy Miller

Acting Industry Representative
Dr. Samuel Maldonado

Absent
Dr. Ruth A. Karron
Dr. Steven Self
Dr. John Modlin
Dr. Seth Hetherington

Consultants
Dr. Bruce Gellin
Dr. Pamela McInnes
Dr. Melinda Wharton
Dr. Scott Emerson
Dr. Dr. Michael Greene
Ms. Susan Krivacic **
Dr. Lauri Markowitz
Dr. Kenneth Noller
Dr. Elizabeth Unger

Sponsor Speakers
Dr. Eliav Barr
Dr. Patrick Brill-Edwards

Executive Secretary
Christine Walsh, R.N.

Committee Management Specialist
Denise Royster

These summary minutes for the May 18, 2006 Meeting of the Vaccines and Related Biological products Advisory Committee were approved on _____.

I certify that I participated in the May 18, 2006 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____
Christine Walsh, R.N.
Executive Secretary

_____
Monica M. Farley, M.D.
Acting Chair

* Consumer Representative

** Patient Representative

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on May 18, 2006 at the Hilton Hotel North Washington, 620 Perry Parkway, Gaithersburg, MD. In open session, the committee heard presentations and made recommendations on the safety and efficacy of a human papillomavirus recombinant vaccine manufactured by Merck & Co., Inc.

Following is a summary of the discussion. Additional information and specific details may be obtained from the transcript of the meeting. The transcript may be viewed on the World Wide Web at:
http://www.fda.gov/ohrms/dockets/ac/cber06.html#VaccinesandRelatedBiological.

**Open Session**

The Vaccines and Related Biological Products Advisory Committee meeting was called to order by the Acting Chair, Dr. Monica M. Farley, at 9:00 a.m. on May 18, 2006. Dr. Nancy Miller, FDA, opened the meeting by providing a brief introduction to the days' topic; safety and efficacy of a human papillomavirus recombinant vaccine manufactured by Merck & Co., Inc., and ended by presenting questions being posed to the committee in the afternoon session. Following Dr. Miller, Dr. Eliav Barr and Dr. Patrick Brill-Edwards represented the sponsor, Merck &Co. Inc. in a presentation to the committee which included a summary of proposed indications of their product Gardasil™; Phase III clinical trial results; overall benefit/risk profile; and a proposed pharmacovigilance program. Following the sponsor presentation, Dr. Miller presented for the FDA. Dr. Miller concluded the morning session by providing an overview for the panel which included a description of the vaccine; proposed indications; safety and immunogenicity studies; efficacy analysis; safety results; and FDA review conclusions.

To open the afternoon session, an Open Public Hearing was offered. Prior to the meeting, four written statements had been submitted from Ms. Andrea Ureno; Susan Lee Ivy, MD, MHSA representing the American Medical Women's Association; Ms. Robbin Rogers; and Lisa Mayfield, J.D. Copies of each of their statements have been made part of the official meeting record. There were additionally nine members of the public who registered and made public comment. They were as follows: Dr. Bobbi Gostout, representing the Society of Gynecologic Oncologists; Ms. Susan E. Holleran, representing the Coalition of Labor Union Women; Dr. Beth Jordan, representing the Association of Reproductive Health Professionals; Mr. Sean Tipton, representing the American Society for Reproductive Medicine; Ms. Martha Nolan, representing the Society for Women's Health Research; Ms. Kathryn Guccione, representing Women in Government; Ms. Amy Allina, representing the National Women's Health Network; and Ms. Ellen Stoval, representing the National Coalition for Cancer Survivorship. There was additionally one audience member who made public comment.

After re-presentation of the questions, the committee held discussion and made recommendations regarding the days' topic. Based on information presented to the

committee regarding available data from studies 005, 007, 013, and 015 to support the efficacy of Gardasil™ for the prevention of HPV 16/18 related cervical cancer, cervical AIS, and CIN 2/3 or worse in females 16 – 26 years of age, the committee recommended:

- The committee unanimously recommended (13 votes in favor, 0 against, 0 abstained) that the data were adequate to support the efficacy of Gardasil™ for the prevention of HPV 16/18 related cervical cancer, cervical AIS, and CIN 2/3 or worse in females 16 – 26 years of age.

Based on information presented to the committee regarding available data from studies 007, 013, and 015 to support the efficacy of Gardasil™ for the prevention of HPV 6/11/16/18 related VIN 2/3 and VaIN 2/3 in females 16 – 26 years of age, the committee recommended:

- The committee unanimously recommended (13 votes in favor, 0 against, 0 abstained) that the data were adequate to support the efficacy of Gardasil™ for the prevention of HPV 6/11/16/18 related VIN 2/3 and VaIN 2/3 in females 16 – 26 years of age.

Based on information presented to the committee regarding available data from studies 007, 013, and 015 to support the efficacy of Gardasil™ for the prevention of HPV 6/11/16/18 related to condyloma acuminata, VIN 1 and VaIN 1, the committee recommended:

- The committee unanimously recommended (13 votes in favor, 0 against, 0 abstained) that the data were adequate to support the efficacy of Gardasil™ for the prevention of HPV 6/11/16/18 related to condyloma acuminata, VIN 1 and VaIN 1.

Based on information presented to the committee regarding the immunogenicity data from studies 016 and 018 to support bridging of the younger female population (9 – 15 years of age) to the efficacy population (females 16 – 26 years of age), the committee recommended:

- The committee unanimously recommended (13 votes in favor, 0 against, 0 abstained) that the immunogenicity data were adequate to support bridging of the younger female population (9 – 15 years of age) to the efficacy population (females 16 – 26 years of age).

Based on information presented to the committee regarding safety data from studies 007, 013, 015, 016, and 018 to support the safety of Gardasil™ for use in females 9 – 26 years of age, the committee recommended:

- The committee unanimously recommended (13 votes in favor, 0 against, 0 abstained) that the safety data were adequate to support the safety of Gardasil™ for use in females 9 – 26 years of age.

Regarding comments on post-marketing commitments, the committee recommended that labeling should be clear that the vaccine is not a replacement for cervical cancer screening, stressing that screening must continue; and the need for post-marketing surveillance.

This completed committee discussions and recommendations. The meeting was adjourned by the Chair at 3:20 p.m.