MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date: December 3, 2007

From: Maryann R. Gallagher, Consumer Safety Officer
Advertising and Promotional Labeling Branch (APLB), HFM-602,
Division of Case Management (DCM)

Through: Ele Ibarra-Pratt, RN, MPH, Branch Chief, APLB, HFM-602

To: Michael Schmitt, OVRR/DBPAP/LRSP HFM-437
Joseph Temenak, OVRR/DVRPA/OVRR HFM-478

Subject: Re-evaluation of proposed proprietary name **Kinrix ™** (Diphtheria and Tetanus Toxoids, Acellular Pertussis Adsorbed, Inactivated Poliovirus Vaccine Combined)
BLA STN 125260

Recommendation: ACCEPTABLE

Executive Summary:

APLB has performed a re-evaluation of the proposed proprietary name **Kinrix**, to determine if any new products have been approved since our previous review on March 27, 2007 (memo attached). APLB found that no new products have been approved that would change our previous recommendation. APLB recommends that the proposed proprietary name **Kinrix** be found **Acceptable.**

Proposed Proprietary Name Evaluation:

APLB re-reviewed the proprietary name because substantial time had passed since our last review and to ensure that our review is within 90 days of approval. The PDUFA goal date is February 7, 2008. There were no newly marketed products whose names resembled **Kinrix.**

Recommendation:

APLB recommends that the proposed proprietary name **Kinrix** be found acceptable at this time. No recently approved products whose names resemble **Kinrix** were found.

References used:

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (CDER and Biologic Approvals through October 31, 2007)

http://www.fda.gov/cber/products/htm (CBER New BLA, 510(k) Devices, NDA and PMA approvals lists through September 28, 2007).