

**FDA BACKGROUND PACKAGE**  
**Joint Drug Safety and Risk Management & Dermatologic and Ophthalmic Drugs**  
**Advisory Committees Meeting**  
**February 26 & 27, 2004**

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***Division of Dermatologic and Dental Drug Products Materials***

**Tab 1:** Background of Isotretinoin Teratogenic Risk Management Plan  
(Isotretinoin Historical Summary)

**Tab 2:** Letter from Dr. Janet Woodcock to Hoffman-La Roche, Inc.  
Dated: October 6, 2000  
Subject: Need for registry, linkage of pregnancy status with drug dispensing

*( Note to Committee: registry not implemented per innovator due to  
HIPAA and other constraints, so S.M.A.R.T.™ program evolved over 1 year  
prior to implementation)*

**Tab 3:** Letter from Dr. Jonathan Wilkin to Hoffman-La Roche, Inc.  
Dated: October 30, 2001  
Subject: Approval letter for Accutane® (Isotretinoin) – NDA 18-662/S-044

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Letter from Dr. Janet Woodcock to Ellen J. Flannery, Esq.  
Dated: November 8, 2002  
Subject: Response to Citizen Petition, dated February 25, 2002  
Re: Procedures and Standards; Abbreviated New Drug Approvals (NDAs)

**Section C:**  
***Office of Pharmacoepidemiology and Statistical Science***  
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Executive Overview – Office of Drug Safety (ODS)  
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**Tab 4:** PID D030417, Drug: Isotretinoin, Topic: Isotretinoin Utilization, dated 2/2/04

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**Tab 6:** PID D030417, Drug: Isotretinoin, Topic: Review of Prescription Survey Materials and Data with Interest in Compliance during the First Year of the System to Manage Accutane® Related Teratology (S.M.A.R.T.)™ Program, dated 2/2/04

**Tab 7:** A Synopsis of the Elements of the S.T.E.P.S.® (System for Thalidomide Education and Prescribing Safety) Program, dated 2/2/04

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