Publicly Available Pharmacovigilance Resources

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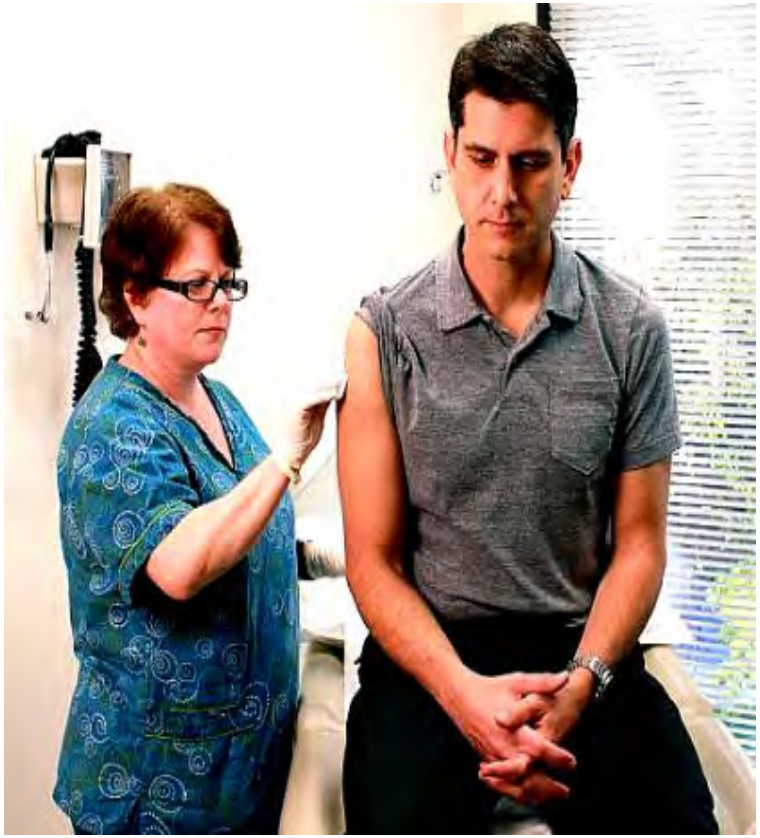
Objective

- Provide useful publicly available resources to assist you in pharmacovigilance activities

Vaccine Adverse Event Reporting System (VAERS)

- General information regarding VAERS can be found at: http://vaers.hhs.gov/about/faqs

- Inquiries for vaccine adverse events can be conducted through WONDER

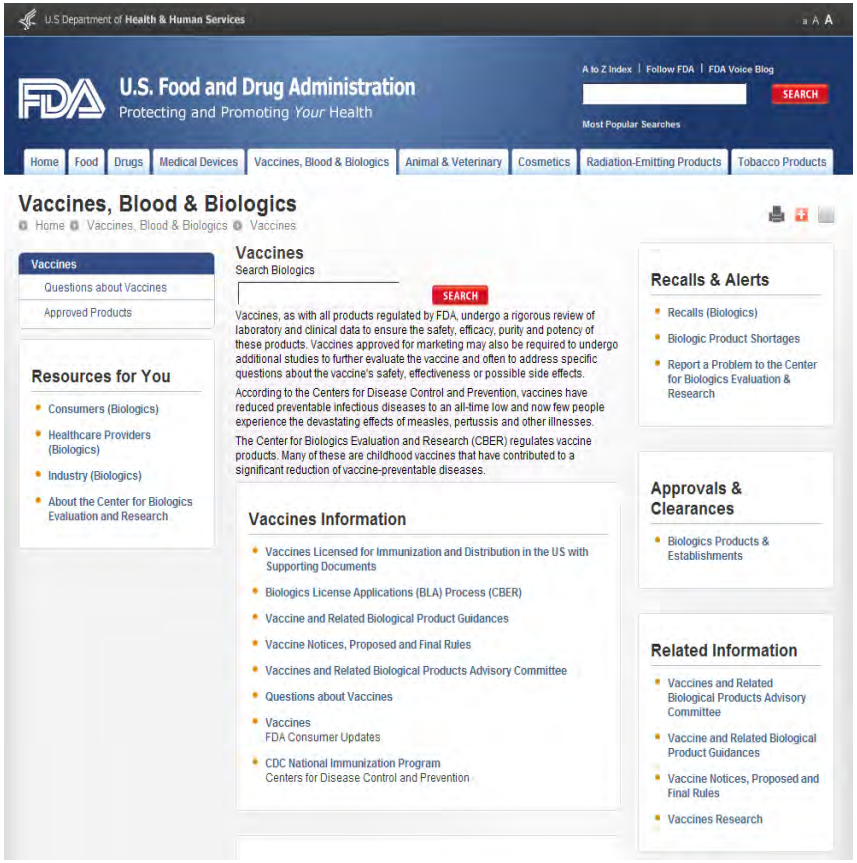


Source: Public Health Image Library

http://wonder.cdc.gov/

FDA Vaccines Web Page

- General information on U.S. licensed vaccines
- Vaccine-related guidance documents
- Question and Answer documents
- FDA consumer updates
- www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm



Biologics Safety and Availability Page

- FDA/CBER posts notices about important adverse event reporting, recalls, shortages, and biological product deviations.

http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/default.htm

Medical Product Safety Alerts

- **MedWatch Safety Alerts**
  - Timely new safety information on drugs, devices, vaccines and other biologics
  - Actionable information that may impact treatment and diagnostic choices
  - Archived by year

- **Drug Safety Info Page**

http://www.fda.gov/Safety/MedWatch/SafetyInformation/default.htm
http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/DrugSafetyInformation/default.htm

Useful Guidances for Industry

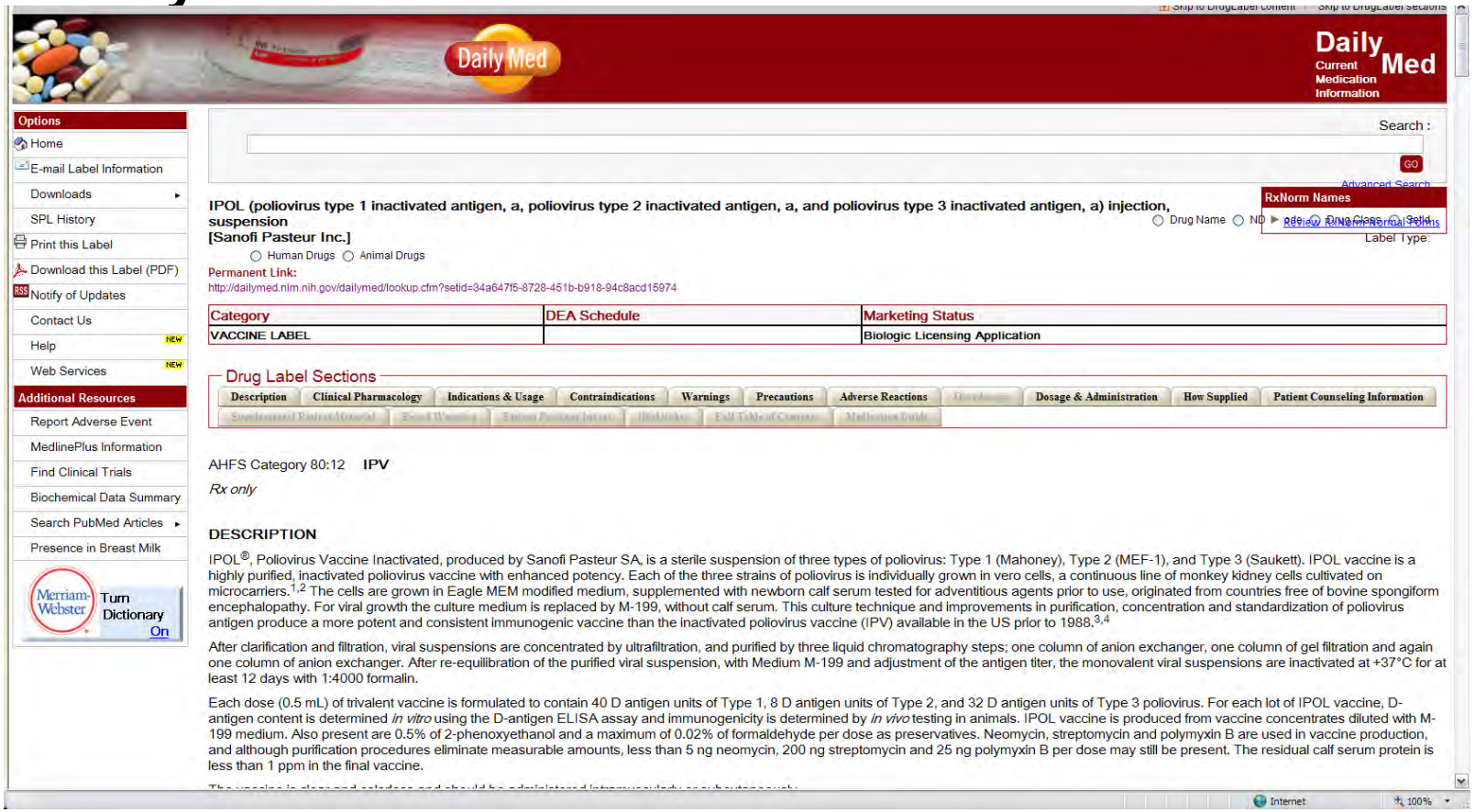
- **E2E Pharmacovigilance Planning Guidance**

  http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073107.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=FDA Guidance for Industry: E2E Pharmacovigilance Planning, April 2005&utm_content=1

- **Postmarketing Studies and Clinical Trials Guidance**
  - (Postmarketing Studies and Clinical Trials Guidance—Implementation of Section 505(o)(3) of the Federal Food Drug and Cosmetic Act)
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=see FDA Guidance for Industry: Postmarketing Studies and Clinical Trials – Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act&utm_content=1

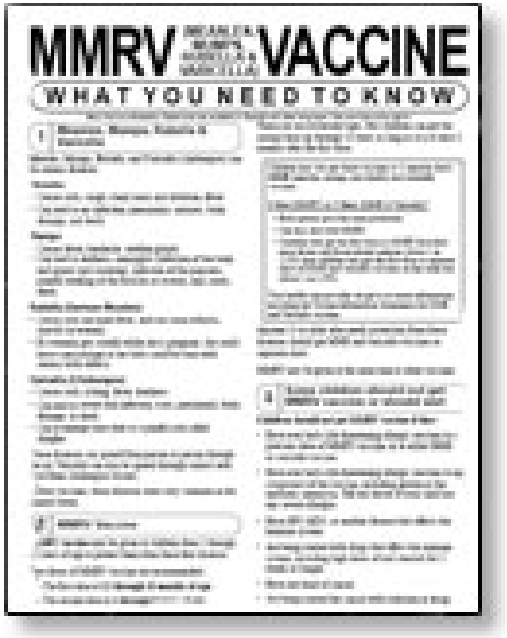
Vaccine Product Information: Prescriber Information

- **Daily Med**



http://dailymed.nlm.nih.gov/dailymed/about.cfm

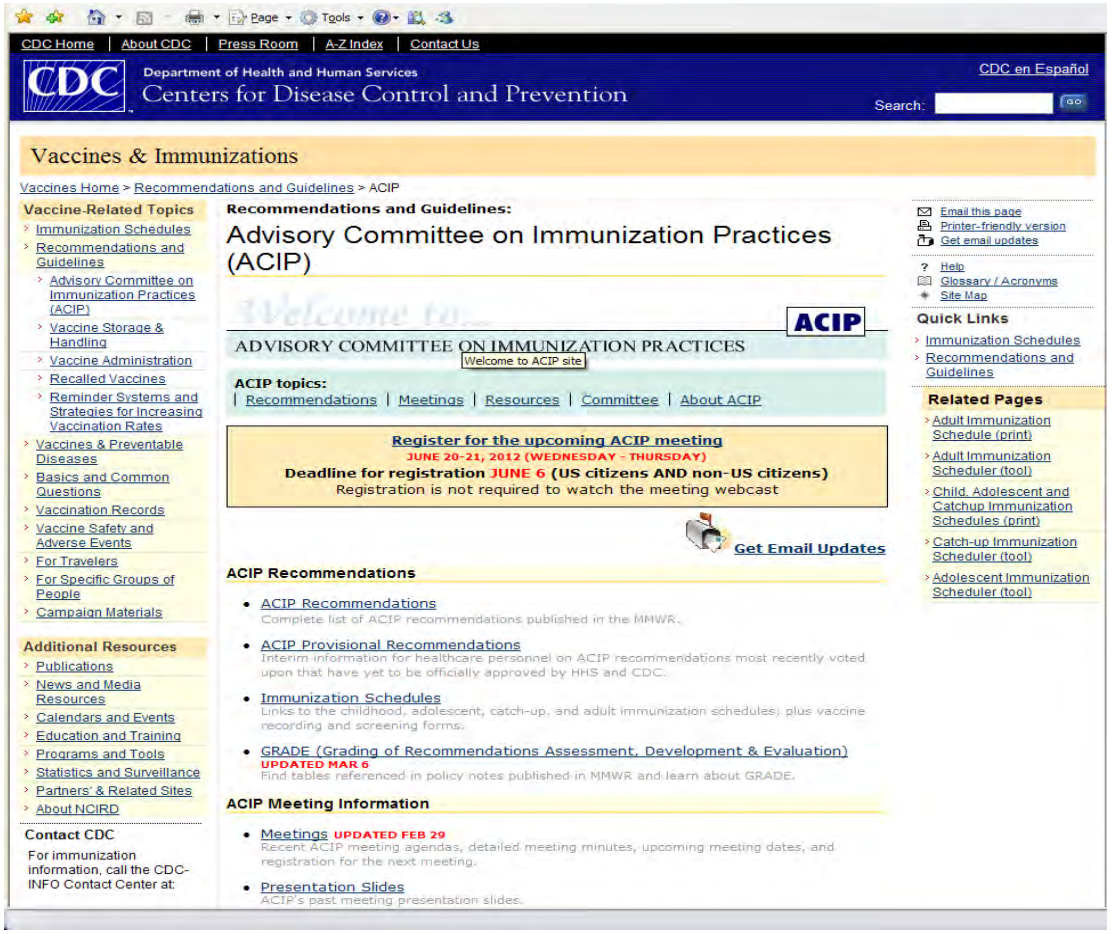
Vaccine Product Information: Vaccine Information Statements


MMRV VACCINE

WHAT YOU NEED TO KNOW

http://www.cdc.gov/vaccines/pubs/vis/

Advisory Committee on Immunization Practices (ACIP)



http://www.cdc.gov/vaccines/recs/acip/default.htm

Vaccine Safety Datalink (VSD)

- Group of geographically diverse HMOs conducting surveillance and hypothesis testing
- Information on VSD and VSD studies can be found at: http://www.cdc.gov/vaccinesafety/Activities/VSD.html

Mini-Sentinel and Sentinel

- **Mini-Sentinel**
  - 5 year pilot to design surveillance system and begin transition to increased use of active surveillance tools.
  - For more information: http://www.minisentinel.org/default.aspx

Mini-Sentinel

Sentinel Initiative

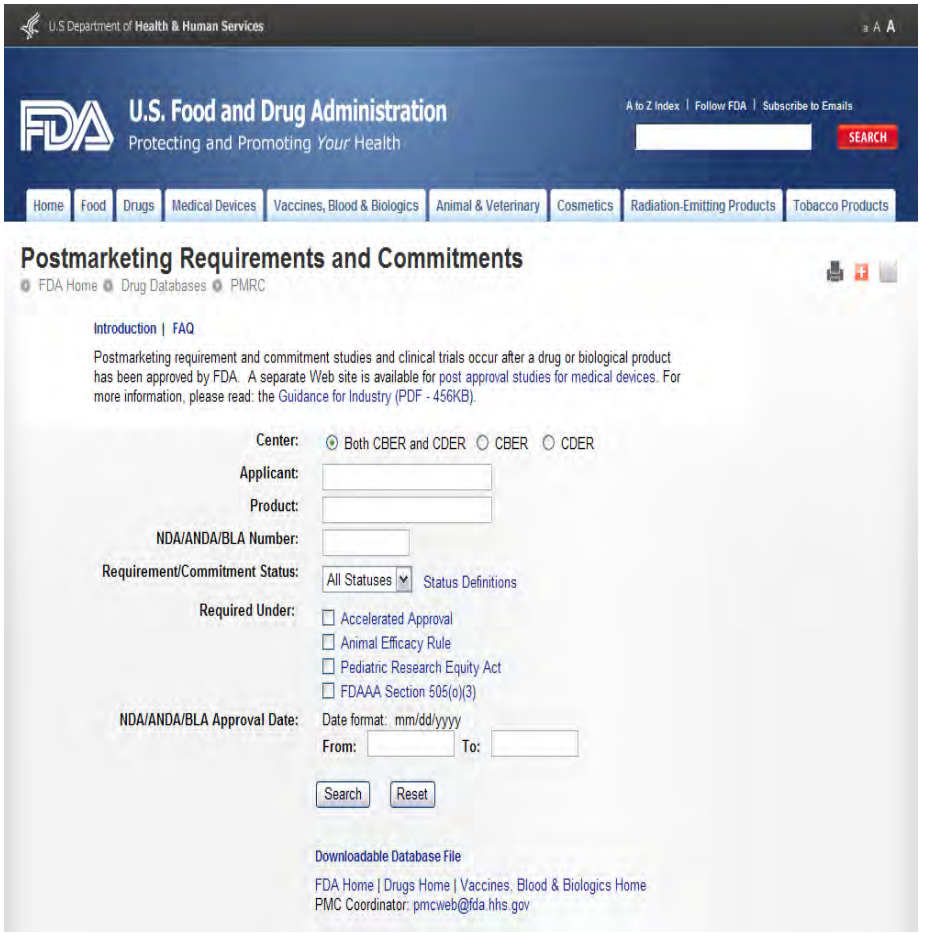
Transforming how we monitor the safety of FDA-regulated products

- **Sentinel**
  - An active electronic safety monitoring system to strengthen FDA's ability to monitor post-market adverse events
  - www.fda.gov/Safety/FDAsSentinelInitiative/default.htm

FDA PMR/PMC Database Query Web Page

- FDA can require Post-Market Requirement studies under FDAAA

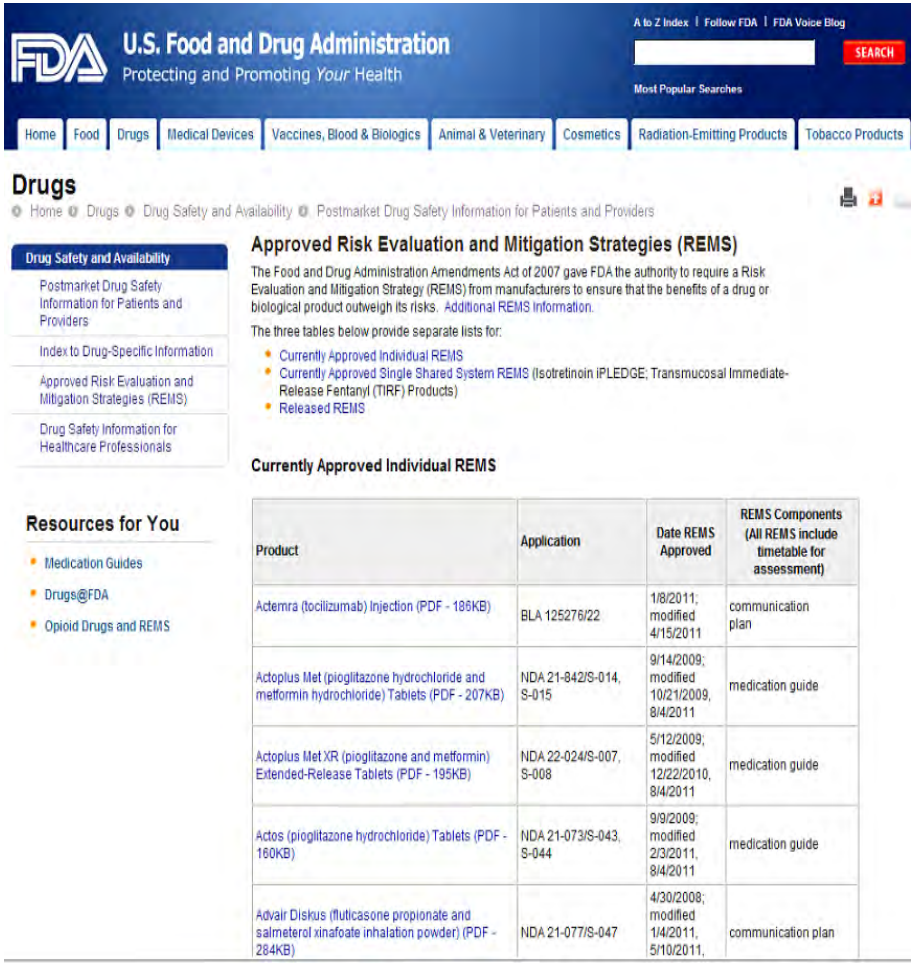
- Status of these studies can be found at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm



Risk Evaluation and Mitigation Strategies (REMS)

- REMS may be required by FDA to ensure that benefits continue to outweigh risks

- For any product with a REMS, details can be found at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=REMS&utm_content=1



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Drugs

Home › Drugs › Drug Safety and Availability › Postmarket Drug Safety Information for Patients and Providers

Drug Safety and Availability
- Postmarket Drug Safety Information for Patients and Providers
- Index to Drug-Specific Information
- Approved Risk Evaluation and Mitigation Strategies (REMS)
- Drug Safety Information for Healthcare Professionals

Resources for You
- Medication Guides
- Drugs@FDA
- Opioid Drugs and REMS

Approved Risk Evaluation and Mitigation Strategies (REMS)

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. Additional REMS Information.

The three tables below provide separate lists for:
- Currently Approved Individual REMS
- Currently Approved Single Shared System REMS (Isotretinoin iPLEDGE; Transmucosal Immediate-Release Fentanyl (TIRF) Products)
- Released REMS

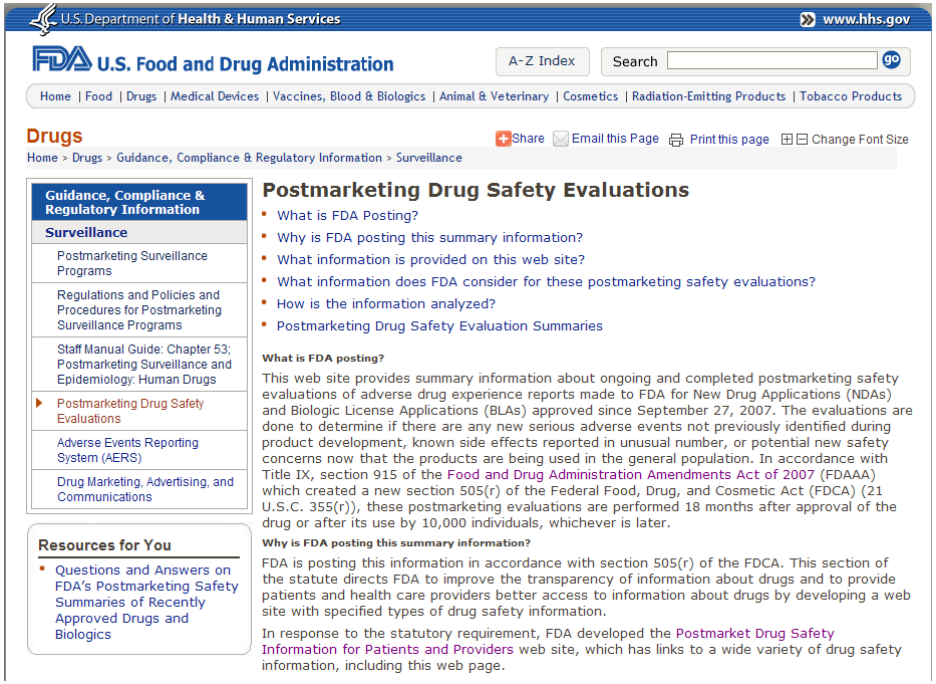
Currently Approved Individual REMS

Product	Application	Date REMS Approved	REMS Components (All REMS include timetable for assessment)
Actemra (tocilizumab) Injection (PDF - 186KB)	BLA 125276/22	1/8/2011; modified 4/15/2011	communication plan
Actoplus Met (pioglitazone hydrochloride and metformin hydrochloride) Tablets (PDF - 207KB)	NDA 21-842/S-014, S-015	9/14/2009; modified 10/21/2009, 8/4/2011	medication guide
Actoplus Met XR (pioglitazone and metformin) Extended-Release Tablets (PDF - 195KB)	NDA 22-024/S-007, S-008	5/12/2009; modified 12/22/2010, 8/4/2011	medication guide
Actos (pioglitazone hydrochloride) Tablets (PDF - 160KB)	NDA 21-073/S-043, S-044	9/9/2009; modified 2/3/2011, 8/4/2011	medication guide
Advair Diskus (fluticasone propionate and salmeterol xinafoate inhalation powder) (PDF - 284KB)	NDA 21-077/S-047	4/30/2008; modified 1/4/2011, 5/10/2011,	communication plan

Post-marketing Drug & Biologics Safety Evaluations Page

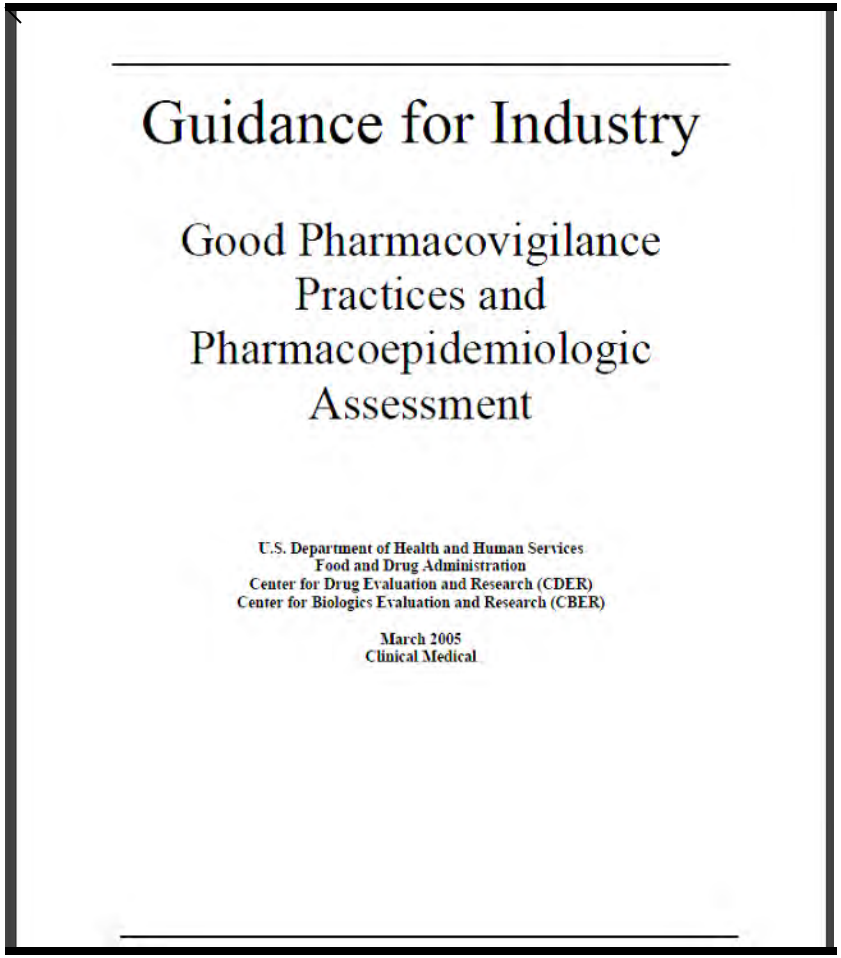
- Summary findings from Comprehensive Safety Reviews (18 months post-approval)

- http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm204091.htm



Good Pharmacovigilance Practices

- Identifying and describing safety signals
- Investigating a signal through observational studies
- Interpreting safety signals
- Developing a pharmacovigilance plan



Guidance for Industry

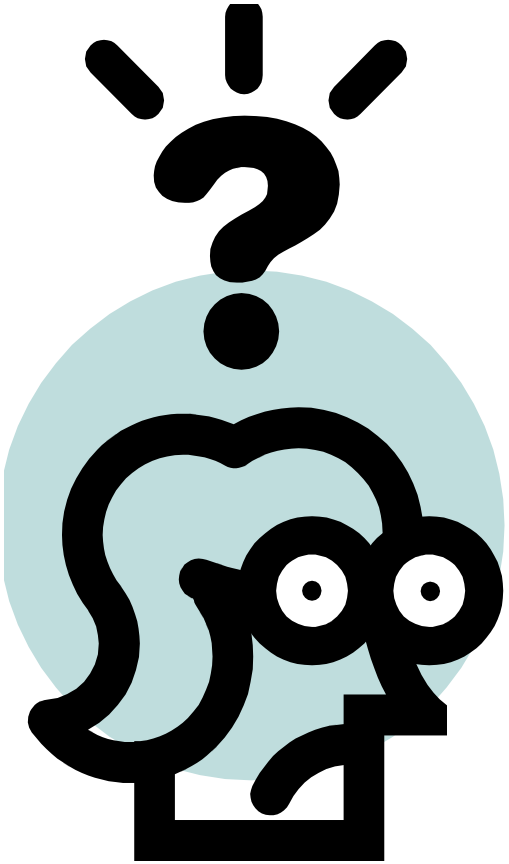
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

March 2005
Clinical Medical

http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126834.pdf

Questions?



FDAAA 2007

- FDAAA 2007 increased FDA authority to study and evaluate post-market events
- http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=fdaaa&utm_content=1