



U.S. Food and Drug Administration
Protecting and Promoting Public Health



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



CDC WONDER

[WONDER Home](#)

[FAQ](#)

[Help](#)

[Contact Us](#)

[Search](#)

WONDER online databases utilize a rich ad-hoc query system for the analysis of public health data. Reports and other query systems are also available.

[WONDER Systems](#)

[Topics](#)

[A-Z Index](#)

● WONDER Online Databases

- ▶ [AIDS Public Use Data](#)
- ▶ [Births](#)
- ▶ [Cancer Statistics](#)

Environment

- ▶ [Daily Air Temperatures](#)

Mortality

Underlying Cause of Death

- ▶ [Detailed Mortality](#)
- ▶ [Compressed Mortality](#)
- ▶ [Multiple cause of death \(Detailed Mortality\)](#)
- ▶ [Infant Deaths \(Linked Birth/Infant Death Records\)](#)
- ▶ [Online Tuberculosis Information System](#)

Population

- ▶ [Bridged-Race Population \(from NCHS\)](#)
- ▶ [Population \(from Census\)](#)
- ▶ [Sexually Transmitted Disease Morbidity](#)
- ▶ [Vaccine Adverse Event Reporting](#)

▶ *Denotes numerical data available to query or download*

● Reports and References

- [Prevention Guidelines \(archive\)](#)
- [Scientific Data and Documentation](#)

● Other Query Systems

- ▶ [Healthy People 2010](#)
- ▶ [MMWR Morbidity Tables](#)
- ▶ [MMWR Mortality Tables](#)

This page last reviewed: Friday, January 20, 2012

<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

The screenshot shows the FDA website's 'Vaccines, Blood & Biologics' section. The header includes the FDA logo and navigation links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main content area is titled 'Vaccines, Blood & Biologics' and includes a search bar, a 'Recalls & Alerts' section, and a 'Vaccines Information' section. The 'Vaccines Information' section lists various resources such as 'Vaccines Licensed for Immunization and Distribution in the US with Supporting Documents', 'Biologics License Applications (BLA) Process (CBER)', and 'Vaccine and Related Biological Product Guidances'. The 'Recalls & Alerts' section lists 'Recalls (Biologics)', 'Biologic Product Shortages', and 'Report a Problem to the Center for Biologics Evaluation & Research'. The 'Approvals & Clearances' section lists 'Biologics Products & Establishments'. The 'Related Information' section lists 'Vaccines and Related Biological Products Advisory Committee', 'Vaccine and Related Biological Product Guidances', 'Vaccine Notices, Proposed and Final Rules', and 'Vaccines Research'.

Biologics Safety and Availability Page

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

The screenshot shows the FDA/CBER website interface. At the top, there is a navigation menu with tabs for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. Below this, the page is titled "Vaccines, Blood & Biologics" and includes a breadcrumb trail: Home > Vaccines, Blood & Biologics > Safety & Availability (Biologics). A search bar is present with a red "SEARCH" button. The main content area is divided into several sections: "Safety & Availability (Biologics)" with a list of links (Recalls, Shortages, Report a Problem, Security, Pandemics, Blood Safety, Tissue Safety, Vaccine Safety, HIV Kits), "Spotlight" (Fraudulent H1N1 Products Widget), "Recalls & Alerts" (Recalls, Shortages, Report a Problem), and "Approvals & Clearances". A red box highlights the "2011" section, which lists three items: "Information for Health Care Professionals: Anticipated Short Supply of Coral Snake Antivenom (Pfizer Inc.)", "Fluzone Vaccine Safety", and "Important Safety Information: Risk of Thrombotic Adverse Events with Subcutaneous or Inappropriate Intravenous Use of Vivaglobin (Immune Globulin Subcutaneous)".

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](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](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**

The screenshot displays the Daily Med website interface. At the top, there is a search bar and navigation options. The main content area shows the product name and manufacturer. Below this, there are tabs for 'Drug Label Sections' including Description, Clinical Pharmacology, Indications & Usage, Contraindications, Warnings, Precautions, Adverse Reactions, Dosage & Administration, How Supplied, and Patient Counseling Information. The 'DESCRIPTION' section is currently selected and contains detailed text about the vaccine's composition and production process.

Options

- Home
- E-mail Label Information
- Downloads
- SPL History
- Print this Label
- Download this Label (PDF)
- Notify of Updates
- Contact Us
- Help
- Web Services

Additional Resources

- Report Adverse Event
- MedlinePlus Information
- Find Clinical Trials
- Biochemical Data Summary
- Search PubMed Articles
- Presence in Breast Milk

Merriam-Webster **Tum Dictionary** **On**

Daily Med
Current Medication Information

Search: _____ GO

Advanced Search

RxNorm Names

IPOL (poliovirus type 1 inactivated antigen, a, poliovirus type 2 inactivated antigen, a, and poliovirus type 3 inactivated antigen, a) injection, suspension [Sanofi Pasteur Inc.]

Drug Name NDC Drug Classification Suffix

Label type: _____

Permanent Link:
<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=34a647f5-8728-451b-b918-94c8acd15974>

Category	DEA Schedule	Marketing Status
VACCINE LABEL		Biologic Licensing Application

Drug Label Sections

Description Clinical Pharmacology Indications & Usage Contraindications Warnings Precautions Adverse Reactions Dosage & Administration How Supplied Patient Counseling Information

AHFS Category 80:12 **IPV**

Rx only

DESCRIPTION

IPOL[®], Poliovirus Vaccine Inactivated, produced by Sanofi Pasteur SA, is a sterile suspension of three types of poliovirus: Type 1 (Mahoney), Type 2 (MEF-1), and Type 3 (Saukett). IPOL vaccine is a highly purified, inactivated poliovirus vaccine with enhanced potency. Each of the three strains of poliovirus is individually grown in vero cells, a continuous line of monkey kidney cells cultivated on microcarriers.^{1,2} The cells are grown in Eagle MEM modified medium, supplemented with newborn calf serum tested for adventitious agents prior to use, originated from countries free of bovine spongiform encephalopathy. For viral growth the culture medium is replaced by M-199, without calf serum. This culture technique and improvements in purification, concentration and standardization of poliovirus antigen produce a more potent and consistent immunogenic vaccine than the inactivated poliovirus vaccine (IPV) available in the US prior to 1988.^{3,4}

After clarification and filtration, viral suspensions are concentrated by ultrafiltration, and purified by three liquid chromatography steps; one column of anion exchanger, one column of gel filtration and again one column of anion exchanger. After re-equilibration of the purified viral suspension, with Medium M-199 and adjustment of the antigen titer, the monovalent viral suspensions are inactivated at +37°C for at least 12 days with 1:4000 formalin.

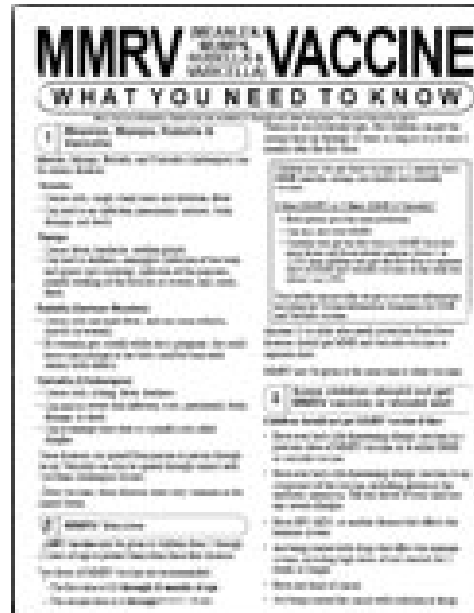
Each dose (0.5 mL) of trivalent vaccine is formulated to contain 40 D antigen units of Type 1, 8 D antigen units of Type 2, and 32 D antigen units of Type 3 poliovirus. For each lot of IPOL vaccine, D-antigen content is determined *in vitro* using the D-antigen ELISA assay and immunogenicity is determined by *in vivo* testing in animals. IPOL vaccine is produced from vaccine concentrates diluted with M-199 medium. Also present are 0.5% of 2-phenoxyethanol and a maximum of 0.02% of formaldehyde per dose as preservatives. Neomycin, streptomycin and polymyxin B are used in vaccine production, and although purification procedures eliminate measurable amounts, less than 5 ng neomycin, 200 ng streptomycin and 25 ng polymyxin B per dose may still be present. The residual calf serum protein is less than 1 ppm in the final vaccine.

The complete, approved, and detailed information should be obtained from the manufacturer's package insert.

Internet 100%

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

Vaccine Product Information: Vaccine Information Statements



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



Advisory Committee on Immunization Practices (ACIP)

The screenshot shows the CDC website's 'Vaccines & Immunizations' section. The main heading is 'Advisory Committee on Immunization Practices (ACIP)'. Below this, there is a 'Welcome to' message and a box for an upcoming meeting on June 20-21, 2012. The page is organized into several columns: a left sidebar with 'Vaccine-Related Topics' and 'Additional Resources'; a central main content area with 'Recommendations and Guidelines' and 'ACIP Meeting Information'; and a right sidebar with 'Quick Links' and 'Related Pages'. The top of the page features the CDC logo, navigation links, and a search bar.

<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>

Managed Care Organization Sites



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>



*Transforming how we monitor the safety
of FDA-regulated products*

- **Sentinel**

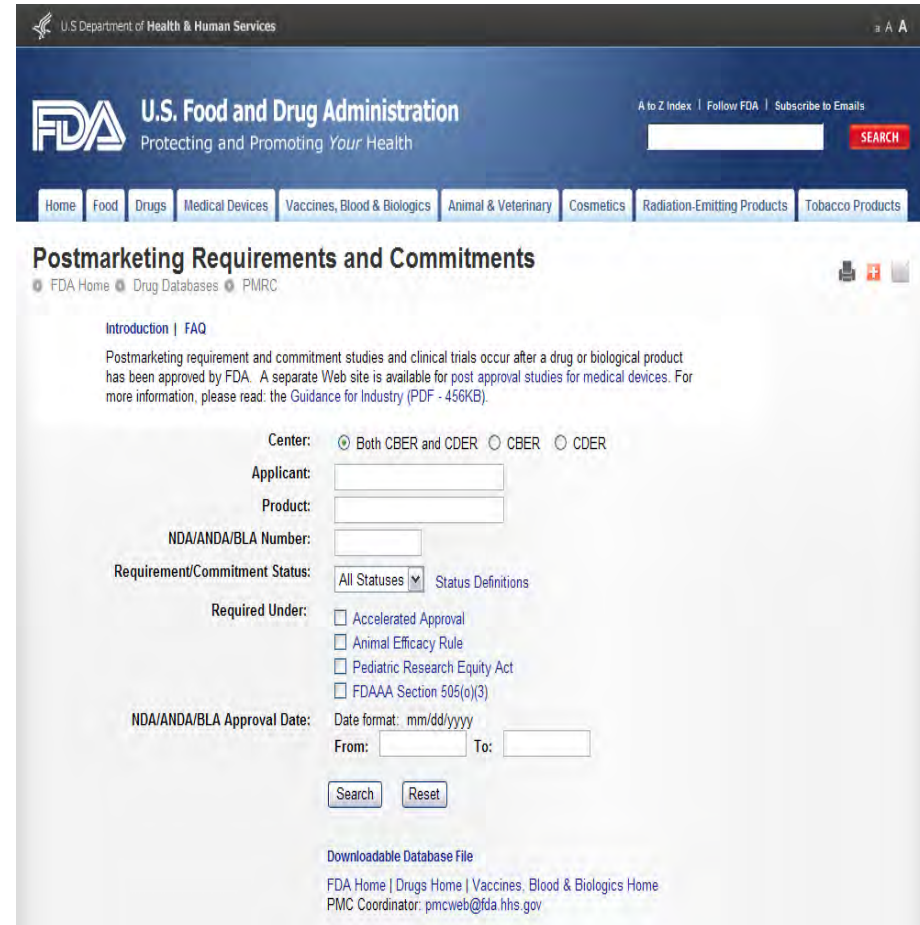
- An active electronic safety monitoring system to strengthen FDA's ability to monitor post-market adverse events
- www.fda.gov/Safety/FDAsSentinelInitiative/default.htm

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>



The screenshot shows the FDA website's navigation bar with the logo and tagline "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below the navigation bar, there is a search bar and a menu with links to Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main content area is titled "Postmarketing Requirements and Commitments" and includes a breadcrumb trail: FDA Home > Drug Databases > PMRC. There are links for "Introduction" and "FAQ". A paragraph explains that postmarketing requirement and commitment studies and clinical trials occur after a drug or biological product has been approved by FDA. Below this is a search form with the following fields and options:

- Center: Both CBER and CDER CBER CDER
- Applicant:
- Product:
- NDA/ANDA/BLA Number:
- Requirement/Commitment Status: [Status Definitions](#)
- Required Under:
 - Accelerated Approval
 - Animal Efficacy Rule
 - Pediatric Research Equity Act
 - FDAAA Section 505(o)(3)
- NDA/ANDA/BLA Approval Date: Date format: mm/dd/yyyy
 - From:
 - To:

Buttons for "Search" and "Reset" are located below the form. At the bottom, there is a link for "Downloadable Database File" and footer text: "FDA Home | Drugs Home | Vaccines, Blood & Biologics Home" and "PMC Coordinator: pmcweb@fda.hhs.gov".



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

U.S. Food and Drug Administration
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Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Drugs

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

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

Resources for You

- Medication Guides
- Drugs@FDA
- Opioid Drugs and REMS



Post-marketing Drug & Biologics Safety Evaluations Page

- Summary findings from Comprehensive Safety Reviews (18 months post-approval)
- <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Surveillance/ucm204091.htm>

The screenshot shows the FDA website page for Postmarketing Drug Safety Evaluations. The page is part of the U.S. Department of Health & Human Services website, specifically the U.S. Food and Drug Administration section. The breadcrumb trail is: Home > Drugs > Guidance, Compliance & Regulatory Information > Surveillance. The page title is "Postmarketing Drug Safety Evaluations". The main content area includes a list of frequently asked questions: "What is FDA Posting?", "Why is FDA posting this summary information?", "What information is provided on this web site?", "What information does FDA consider for these postmarketing safety evaluations?", "How is the information analyzed?", and "Postmarketing Drug Safety Evaluation Summaries". Below this is a section titled "What is FDA posting?" which explains that the website provides summary information about ongoing and completed postmarketing safety evaluations of adverse drug experience reports made to FDA for New Drug Applications (NDAs) and Biologic License Applications (BLAs) approved since September 27, 2007. It notes that these evaluations are done to determine if there are any new serious adverse events not previously identified during product development, known side effects reported in unusual number, or potential new safety concerns now that the products are being used in the general population. In accordance with Title IX, section 915 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) which created a new section 505(r) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355(r)), these postmarketing evaluations are performed 18 months after approval of the drug or after its use by 10,000 individuals, whichever is later. A second section titled "Why is FDA posting this summary information?" explains that FDA is posting this information in accordance with section 505(r) of the FDCA. This section of the statute directs FDA to improve the transparency of information about drugs and to provide patients and health care providers better access to information about drugs by developing a web site with specified types of drug safety information. It concludes by stating that in response to the statutory requirement, FDA developed the Postmarket Drug Safety Information for Patients and Providers web site, which has links to a wide variety of drug safety information, including this web page.

U.S. Department of Health & Human Services | www.hhs.gov

FDA U.S. Food and Drug Administration | A-Z Index | Search

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Drugs | Share | Email this Page | Print this page | Change Font Size

Home > Drugs > Guidance, Compliance & Regulatory Information > Surveillance

Guidance, Compliance & Regulatory Information

- Surveillance
 - Postmarketing Surveillance Programs
 - Regulations and Policies and Procedures for Postmarketing Surveillance Programs
 - Staff Manual Guide: Chapter 53; Postmarketing Surveillance and Epidemiology: Human Drugs
 - Postmarketing Drug Safety Evaluations**
 - Adverse Events Reporting System (AERS)
 - Drug Marketing, Advertising, and Communications

Resources for You

- Questions and Answers on FDA's Postmarketing Safety Summaries of Recently Approved Drugs and Biologics

Postmarketing Drug Safety Evaluations

- What is FDA Posting?
- Why is FDA posting this summary information?
- What information is provided on this web site?
- What information does FDA consider for these postmarketing safety evaluations?
- How is the information analyzed?
- Postmarketing Drug Safety Evaluation Summaries

What is FDA posting?

This web site provides summary information about ongoing and completed postmarketing safety evaluations of adverse drug experience reports made to FDA for New Drug Applications (NDAs) and Biologic License Applications (BLAs) approved since September 27, 2007. The evaluations are done to determine if there are any new serious adverse events not previously identified during product development, known side effects reported in unusual number, or potential new safety concerns now that the products are being used in the general population. In accordance with Title IX, section 915 of the **Food and Drug Administration Amendments Act of 2007** (FDAAA) which created a new section 505(r) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355(r)), these postmarketing evaluations are performed 18 months after approval of the drug or after its use by 10,000 individuals, whichever is later.

Why is FDA posting this summary information?

FDA is posting this information in accordance with section 505(r) of the FDCA. This section of the statute directs FDA to improve the transparency of information about drugs and to provide patients and health care providers better access to information about drugs by developing a web site with specified types of drug safety information.

In response to the statutory requirement, FDA developed the **Postmarket Drug Safety Information for Patients and Providers** web site, which has links to a wide variety of drug safety information, including this web page.

Good Pharmacovigilance Practices

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

Guidance for Industry

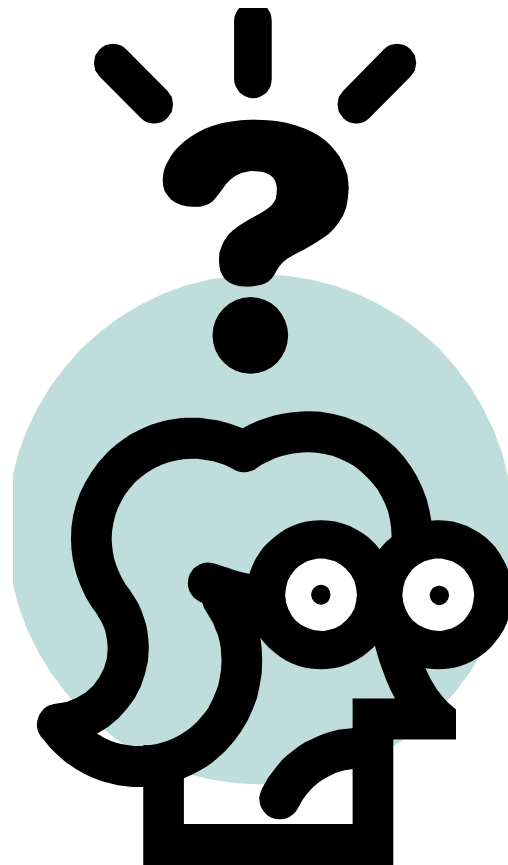
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

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



Questions?





U.S. Food and Drug Administration
Protecting and Promoting Public Health



FDAAA 2007

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

The screenshot shows the FDA website's regulatory information page for the FDAAA of 2007. The header includes the FDA logo, the text "U.S. Food and Drug Administration Protecting and Promoting Your Health", and navigation links for "A to Z Index", "Follow FDA", and "FDA Voice Blog". A search bar with a "SEARCH" button is also present. Below the header is a navigation menu with links for "Home", "Food", "Drugs", "Medical Devices", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", "Radiation-Emitting Products", and "Tobacco Products".

Regulatory Information

Home Regulatory Information Legislation Federal Food, Drug, and Cosmetic Act (FD&C Act)

Legislation

- Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Significant Amendments to the FD&C Act
- Food and Drug Administration Amendments Act (FDAAA) of 2007
- Full Text of FDAAA Law
- FDAAA Implementation Chart

Food and Drug Administration Amendments Act (FDAAA) of 2007

On September 27, 2007, President George W. Bush signed into law H.R. 3580, the Food and Drug Administration Amendments Act of 2007. This new law represents a very significant addition to FDA authority. Among the many components of the law, the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA) have been reauthorized and expanded. These programs will ensure that FDA staff have the additional resources needed to conduct the complex and comprehensive reviews necessary to new drugs and devices.

Two other important laws were reauthorized: the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Both of these are designed to encourage more research into, and more development of, treatments for children.

Overall, this new law will provide significant benefits for those who develop medical products, and for those who use them.

What is FDA Doing?

- FDAAA Implementation Chart
- FDAAA Implementation - Highlights Two Years After Enactment
- FDAAA Implementation - Highlights One Year After Enactment
- Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007
- Renewed Legislation Improves Safety of FDA-Regulated Products

Resources for You

- FDAAA Information for Drugs
- Download Microsoft Media Player