U.S. FOOD & DRUG ADMINISTRATION

Office of International Programs

Periodic Meetings and Regulatory Education for Industry

VIII Pan American Network Drug Regulation Harmonization Conference October 19-21, 2016

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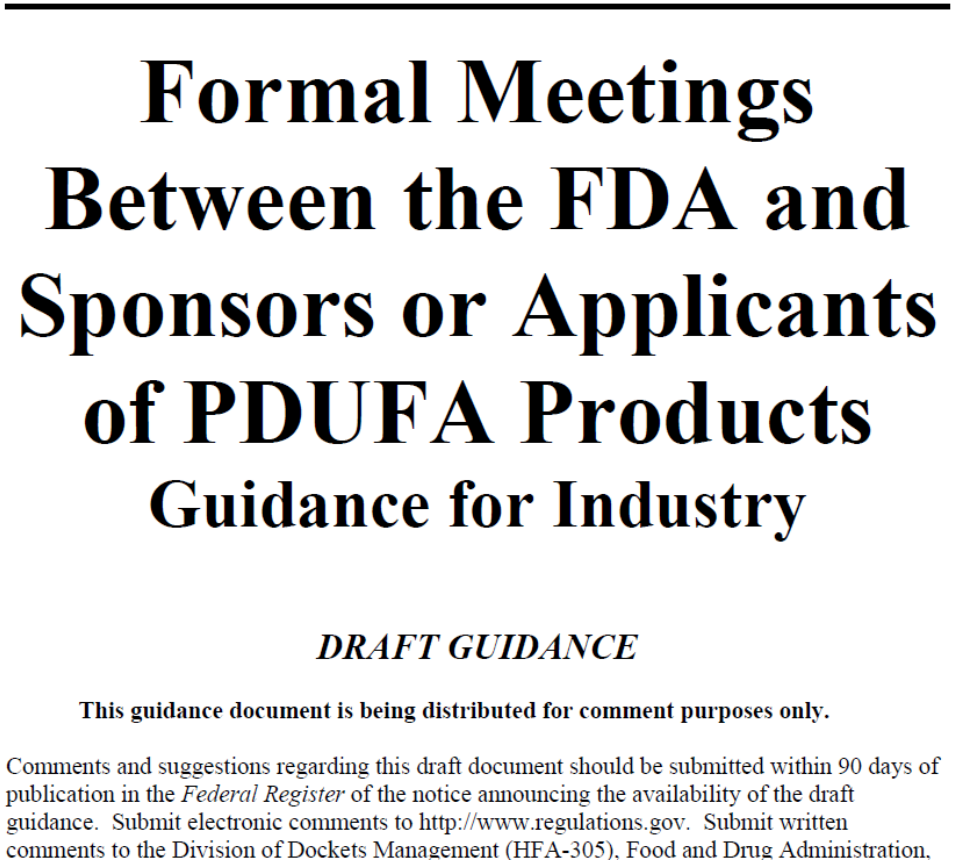
Latin America Office
Office of International Programs
US Food and Drug Administration

Outline

- Meeting request and types
- Advisory Committees
- Resources for Industry
- Small business

Meeting request and types



Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration,

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM437431.pdf

Types of Meetings

Type	A	B	C
Meeting Response: Grant/Deny	14 days	21 days	21 days
Held no later than	30 days	60 days	75 days
Briefing package	With meeting request	1 month	1 month
Description, Comments	Dispute resolution, Clinical holds, Special Protocol Assessment (SPA), Post action meeting (3 months post-action)	preIND¥, EOP1, EOP2, Pre NDA/BLA, REMS* or PMRs**	Any other than type A or B Can be granted as written response only (WRO)

*Risk Evaluation and Mitigation Strategy ** Post Marketing Requirements ¥ can be granted as WRO

Advisory Committee

- The FDA uses 50 committees and panels to obtain independent expert advice on scientific, technical, and policy matters.
- Types of membership.
- Meetings calendar.
- Human Drugs Advisory Committees. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/default.htm

Advisory Committees

Advisory Committee Calendar

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Confirmed Scheduled Advisory Meetings

Sign up for updates on advisory committee meetings

December 2016

- December 6, 2016: Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee

November 2016

- November 17-18, 2016: Blood Products Advisory Committee Meeting Announcement
- CANCELLED: November 16, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee
- November 9-10, 2016: Microbiology Devices Panel of the Medical Devices Advisory Committee Meeting Announcement
- November 7, 2016: Risk Communication Advisory Committee Meeting Announcement
- November 4, 2016: Meeting of the Antimicrobial Drugs Advisory Committee
- November 3, 2016: Meeting of the Pharmacy Compounding Advisory Committee Advisory Committee Meeting Announcement

Drugs

- Anesthetic and Analgesic Drug Products Advisory Committee
- Antimicrobial Drugs Advisory Committee (formerly known as the Anti-Infective Drugs Advisory Committee)
- Antiviral Drugs Advisory Committee
- Arthritis Advisory Committee
- Bone, Reproductive and Urologic Drugs Advisory Committee
- Cardiovascular and Renal Drugs Advisory Committee
- Dermatologic and Ophthalmic Drugs Advisory Committee
- Drug Safety and Risk Management Advisory Committee
- Endocrinologic and Metabolic Drugs Advisory Committee
- Gastrointestinal Drugs Advisory Committee
- Medical Imaging Drugs Advisory Committee
- Nonprescription Drugs Advisory Committee

Human Drug Advisory Committees

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Advisory committees provide FDA with independent opinions and recommendations from outside experts on applications to market new drugs, and on FDA policies. The marketing applications include data to show the safety and effectiveness of human drugs. The outside experts receive summary information about the applications and copies of FDA's review of the application documents. Based on this information, advisory committees may recommend approval or disapproval of a drug's marketing application. FDA generally follows an advisory committee's recommendation, but is not bound to do so.

- CDER Advisory Committee Staff
- Committee Membership Information on consumer, patient, and industry representatives
- FDA Advisory Committee Calendar Meeting information includes center, date, time and location, agenda, presentation procedures, contact persons, and links to *Federal Register* notices.
- FDA Advisory Committees

Resources for Industry

- Regulation
- Guidances
- Databases
- On-line training and continuing education
  - CDERLearn
  - CDER World

http://www.fda.gov/Drugs/ResourcesForYou/Industry/default.htm

Resources for Industry

Resources for Industry

CDERLearn

Resources for You

- About the Center for Drug Evaluation and Research
- Training

CDERLearn

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Welcome to CDERLearn, the web page for educational tutorials offered by the Center for Drug Evaluation and Research (CDER). CDER's primary mission is to make certain that safe and effective drugs are available to the American people. There is, however, a strategic initiative to inform and educate people about the safe use of medicine, the drug regulatory process, the vital role health care professionals play to assist FDA in fulfilling its duties, and many other important issues. Online training is one way to share FDA expertise with many more people than face-to-face classroom sessions would allow, and we will offer additional CDERLearn courses in the future.

Course List

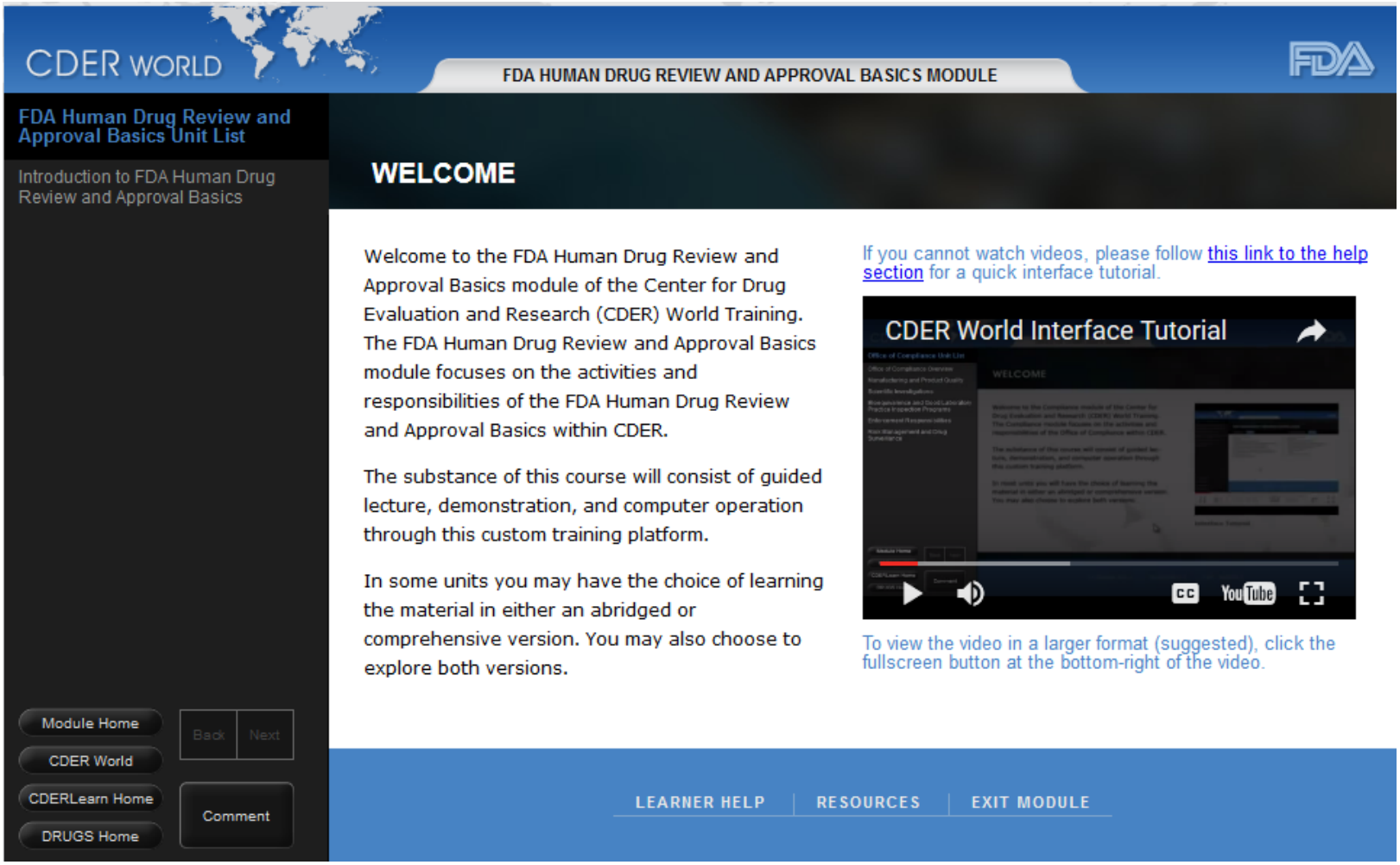
- **FDA's Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond**
  The purpose of this continuing education (CE) course is to educate a national audience of health care providers, industry, and consumers about the basics of the FDA drug regulatory process and the science that supports CDER's mission. The course will also educate the nation's health care providers about their role in communicating drug information to their patients. This updated CDERLearn course replaces the former CDERLearn course, "The Past, Present, and Future of Human Drug Regulation."
- **FDA Overview of Biosimilar Products**
  This continuing education (CE) course provides an understanding of biological products and biosimilar products and a description of FDA's general approach to the development and approval of biosimilar products. The target audience for this course is healthcare professionals, including physicians, physician assistants, nurses, nurse practitioners, and pharmacists.

Contact FDA

Toll Free
(855) 543-3784, or
(301) 796-3400
druginfo@fda.hhs.gov

Human Drug Information
Division of Drug Information
(CDER)
Office of Communications
Feedback Form
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

Resources for Industry



Small Business

- Direct communication services
- Webinars. Small Business and Industry Education Series
- Workshops and Conferences
- Small Biz Buzz
- CDER Small Business Chronicles

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm

Small Business

Small Business

FDA Small Business Regulatory Education for Industry (REdI) Conference September 2016

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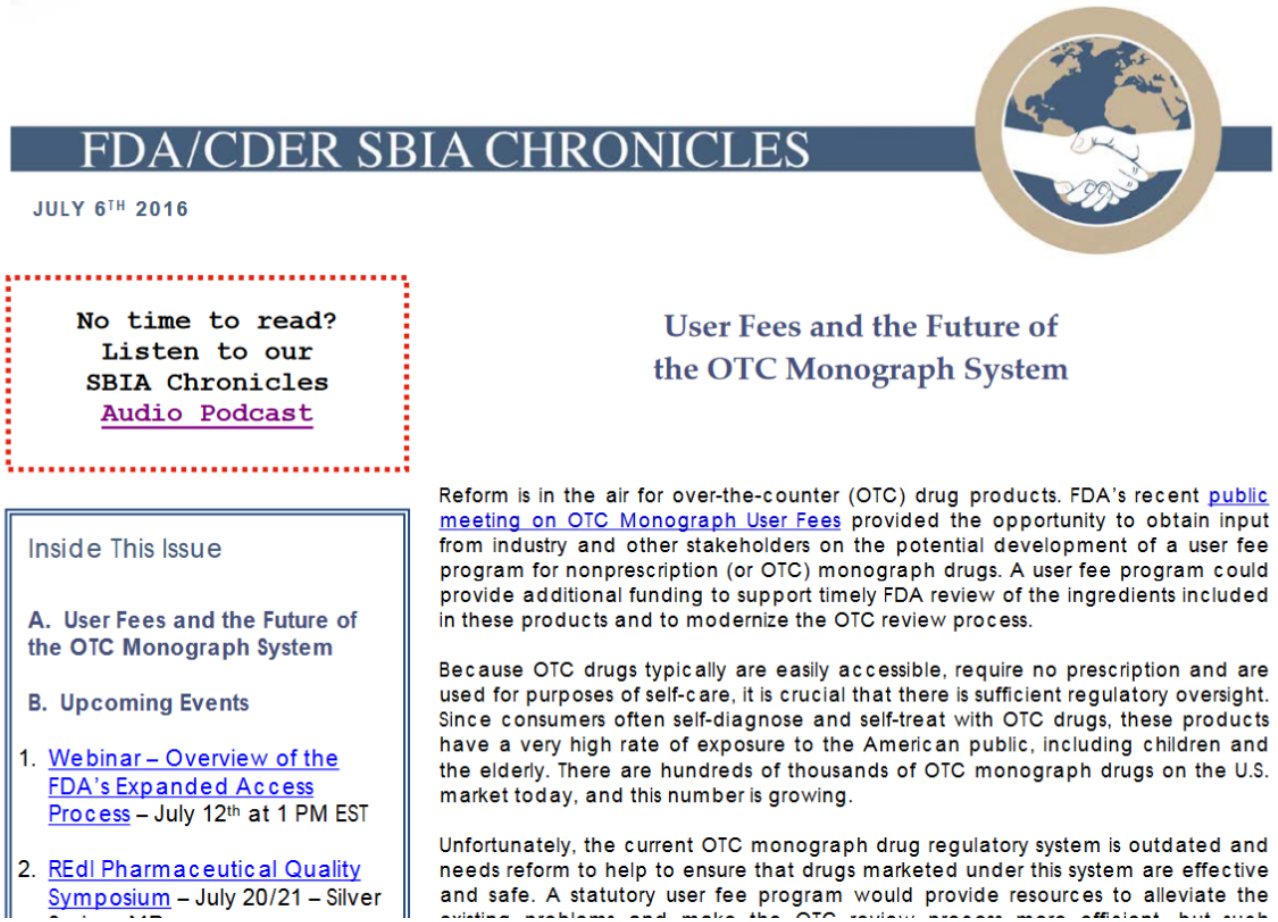
REGISTER HERE! **AGENDA**

The Food and Drug Administration's (FDA's)
Center for Drug Evaluation and Research Small Business and Industry Assistance (CDER SBIA),
—— and ——
Center for Devices and Radiological Health (CDRH) Division of Industry and Consumer Education (DICE)
are pleased to announce a co-sponsored event developed just for you:

This is a LIVE event and will be webcast and recorded. This Event is FREE!

This 2-day conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

Small Business



FDA/CDER SBIA CHRONICLES

JULY 6TH 2016

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SBIA Chronicles
Audio Podcast

Inside This Issue

User Fees and the Future of the OTC Monograph System

Reform is in the air for over-the-counter (OTC) drug products. FDA's recent public meeting on OTC Monograph User Fees provided the opportunity to obtain input from industry and other stakeholders on the potential development of a user fee program for nonprescription (or OTC) monograph drugs. A user fee program could provide additional funding to support timely FDA review of the ingredients included in these products and to modernize the OTC review process.

Because OTC drugs typically are easily accessible, require no prescription and are used for purposes of self-care, it is crucial that there is sufficient regulatory oversight. Since consumers often self-diagnose and self-treat with OTC drugs, these products have a very high rate of exposure to the American public, including children and the elderly. There are hundreds of thousands of OTC monograph drugs on the U.S. market today, and this number is growing.

Unfortunately, the current OTC monograph drug regulatory system is outdated and needs reform to help to ensure that drugs marketed under this system are effective and safe. A statutory user fee program would provide resources to alleviate the

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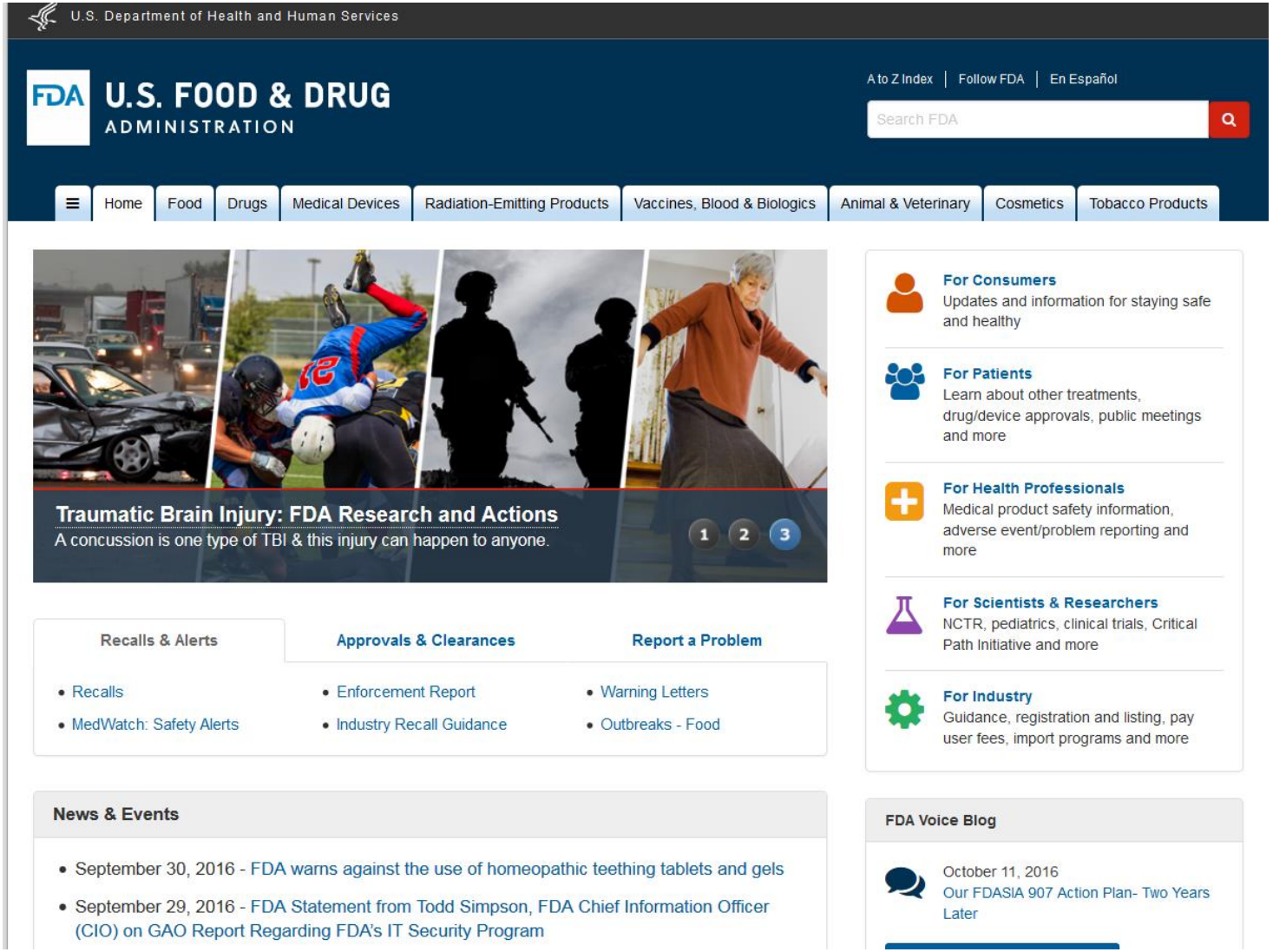
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Traumatic Brain Injury: FDA Research and Actions
A concussion is one type of TBI & this injury can happen to anyone.
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MedWatch: Safety Alerts
Enforcement Report
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Outbreaks - Food
News & Events
September 30, 2016 - FDA warns against the use of homeopathic teething tablets and gels
September 29, 2016 - FDA Statement from Todd Simpson, FDA Chief Information Officer (CIO) on GAO Report Regarding FDA's IT Security Program
FDA Voice Blog
October 11, 2016
Our FDASIA 907 Action Plan- Two Years Later


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