RAPS' Regulatory Convergence

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CDER Formal Dispute Resolution: Appeals Above the Division Level

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Outline

- What is Formal Dispute Resolution
- Formal Dispute Resolution: Regulatory Framework and Guidance
- Who manages Formal Dispute Resolution Requests (FDRRs) in CDER?
- Considerations prior to submitting a FDRR
- How to submit a FDRR
- FDRR timelines
- FDRR process
- What are the options if my FDRR is denied?
- Statistics

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What is Formal Dispute Resolution

- Created in response to passage of section 562 of the Federal Food, Drug, and Cosmetic Act
- Formal Review of scientific and/or medical disputes
- Related to applications for user fee products
- Applications reviewed by CDER and CBER

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Formal Dispute Resolution: Regulatory Framework and Guidance

- Code of Federal Regulations (CFR)
  - 21 CFR 10.75 - Internal agency review of decision
  - 21 CFR 312.48 - Investigational New Drug Application (IND) - Dispute Resolution
  - 21 CFR 314.103 - New Drug Application (NDA)/Abbreviated New Drug Application (ANDA) – Dispute Resolution

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Formal Dispute Resolution: Regulatory Framework and Guidance

- Guidance for Industry
  - CDER/CBER Guidance for Industry and Review Staff - Formal Dispute Resolution: Appeals Above the Division Level
    - Draft (Revision 1) guidance published in March 2013
    - Draft (Revision 2) guidance published in September 2015

Draft Guidance for Industry and Review Staff Formal Dispute Resolution: Appeals Above the Division Level

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm343101.pdf

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Who Manages FDRRs in CDER

CDER Formal Dispute Resolution Project Manager

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http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/ucm444092.htm

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Considerations Prior to Submitting a FDRR

- What is/are the exact dispute issue(s)?
- Is working informally with the Ombudsman more appropriate at this time?
- Has FDA taken a regulatory action?
- Am I engaging in “parallel processing”?
  - Only one regulatory/legal pathway
  - Should not be engaged with the division or any other entity within the FDA on any matter that is the subject of a FDRR

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Considerations Prior to Submitting a FDRR

- Have I requested reconsideration of the decision by the division?
- Do I have new information/new analysis of previously reviewed information?
- Do I want to request a Type A meeting with the deciding official of the FDRR?
- Do I want to request that the scientific matter be reviewed by an advisory committee (AC)?

How to Submit a FDRR

- Submit to administrative file (IND, NDA, BLA, ANDA) as an amendment with a copy to the Formal Dispute Resolution Project Manager
- Key information to include in the submission
  - Description of scientific and/or medical dispute to be resolved
  - Steps taken to resolve the scientific and/or medical dispute
  - Identification of a possible solution/proposed outcome
  - Statement whether a Type A meeting or AC meeting is requested
- Submission need only be 10-15 pages

Note: Draft FDR Guidance for Industry provides a complete list of background information to include in submission

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FDRR Timelines

- **Major Dispute Resolution Goals**
  - **Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act (BsUFA) :** Respond to 90% of the requests within 30 calendar days of the receipt of the FDRR
  - **Generic Drug User Fee Amendments (GDUFA)** : FDA will aspire to provide a response within 30 days of receipt of the FDRR when possible
  - **FDRRs Not covered by a user fee program:** FDA intends to respond as quickly as resources permit

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FDRR Process

Scenario 1: Sponsor submits a FDRR

- Deciding official identified
- Accept/Not Accept the FDRR
  - Notify sponsor in writing
- If Accepted, Grant/Deny the FDRR within 30 days
  - User fee major dispute resolution goals apply, as appropriate

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FDRR Process

Scenario 2: Sponsor submits a FDRR and a Type A meeting request (MR)

- Deciding official identified
- Accept/Not Accept the appeal *AND* Grant/Deny MR
  - Notify sponsor in writing
- Hold meeting within 30 days of receipt of the FDRR
  - User fee meeting goals apply, as appropriate
- Grant/Deny the FDRR within 30 days of the meeting date
  - User fee major dispute goals apply, as appropriate

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FDRR Process

Scenario 3: FDA may issue Interim responses

- FDA requests clarifying information
- FDA requests a meeting
- FDA requires limited discussion with one or more AC members or internal/external experts
- FDA seeks AC review

- Provide an interim response within 30 days of receipt of the FDRR
- Grant/Deny within 30 days of receipt of information, meeting, limited discussion or advisory committee meeting date
  - User fee major dispute goals apply, as appropriate

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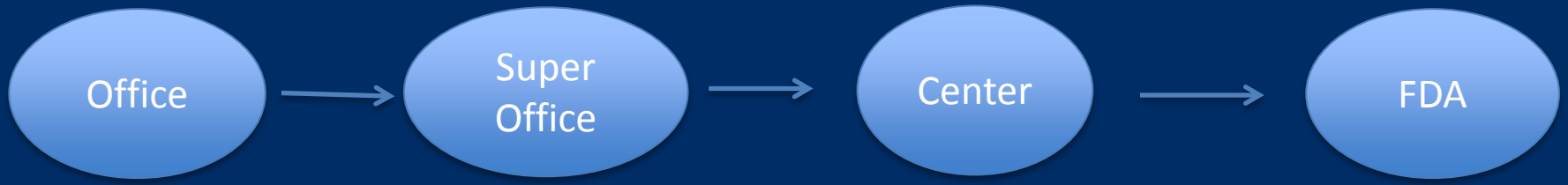
Options if the FDRR is Denied

- Often a path forward is provided in the FDRR denied letter
- Sponsor may appeal to the next level of management



Statistics

Appeal Family - An appeal family encompasses all of the appeals and 30-day goals associated with a scientific and/or medical dispute.

FDRR/Appeal - An FDRR/Appeal is any request for appeal of a scientific and/or medical dispute related to an application for a user fee product. If a sponsor appeals the same issue through multiple levels of management, each of these appeal submissions is considered a *unique appeal*.

30 Day-Goal(s) - A 30-day goal is opened each time CDER receives an initial appeal; a specific request associated with an appeal (e.g., a sponsor requests a meeting); a response submitted by a sponsor to an interim response (i.e., after CDER issues an information request).

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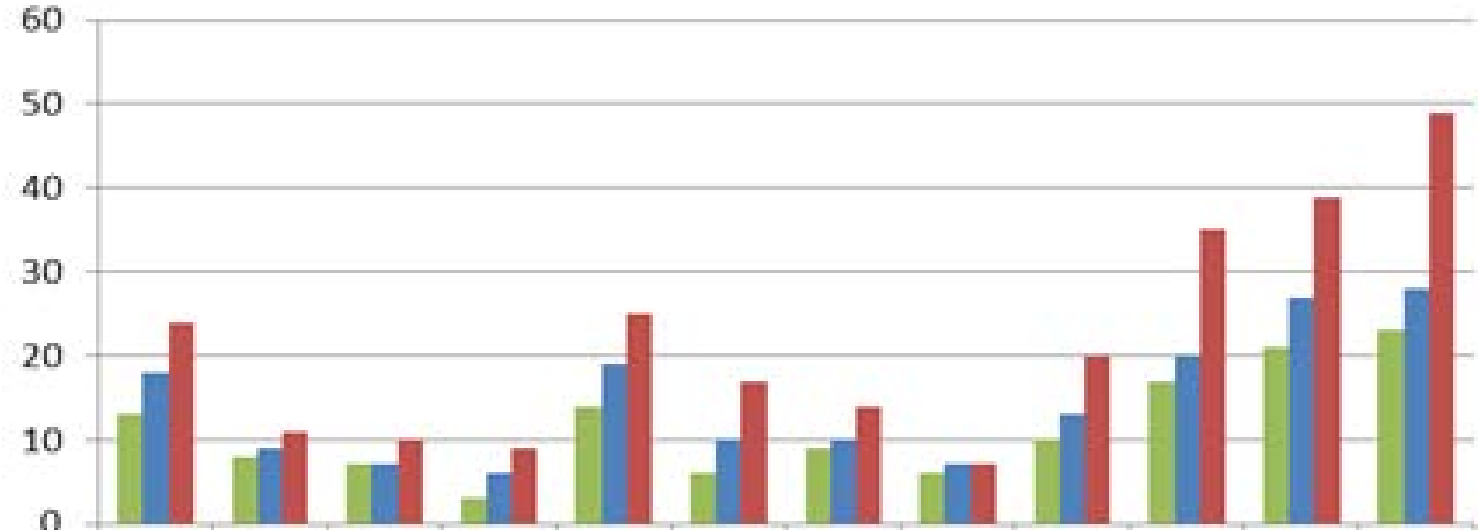
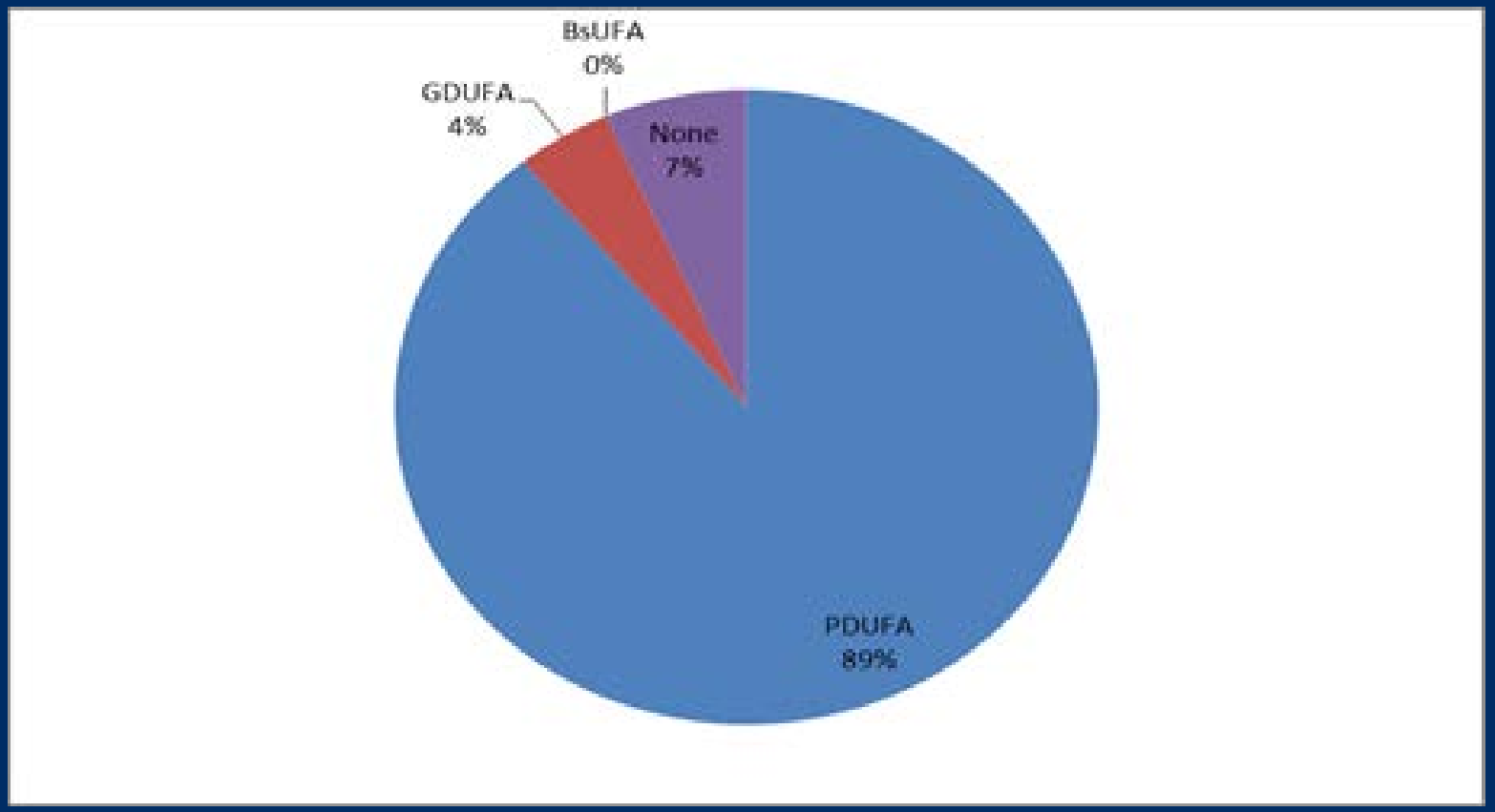
Appeal Families, FDRRs/Appeals and 30-Day Goals by FY from FY 2003- 2014

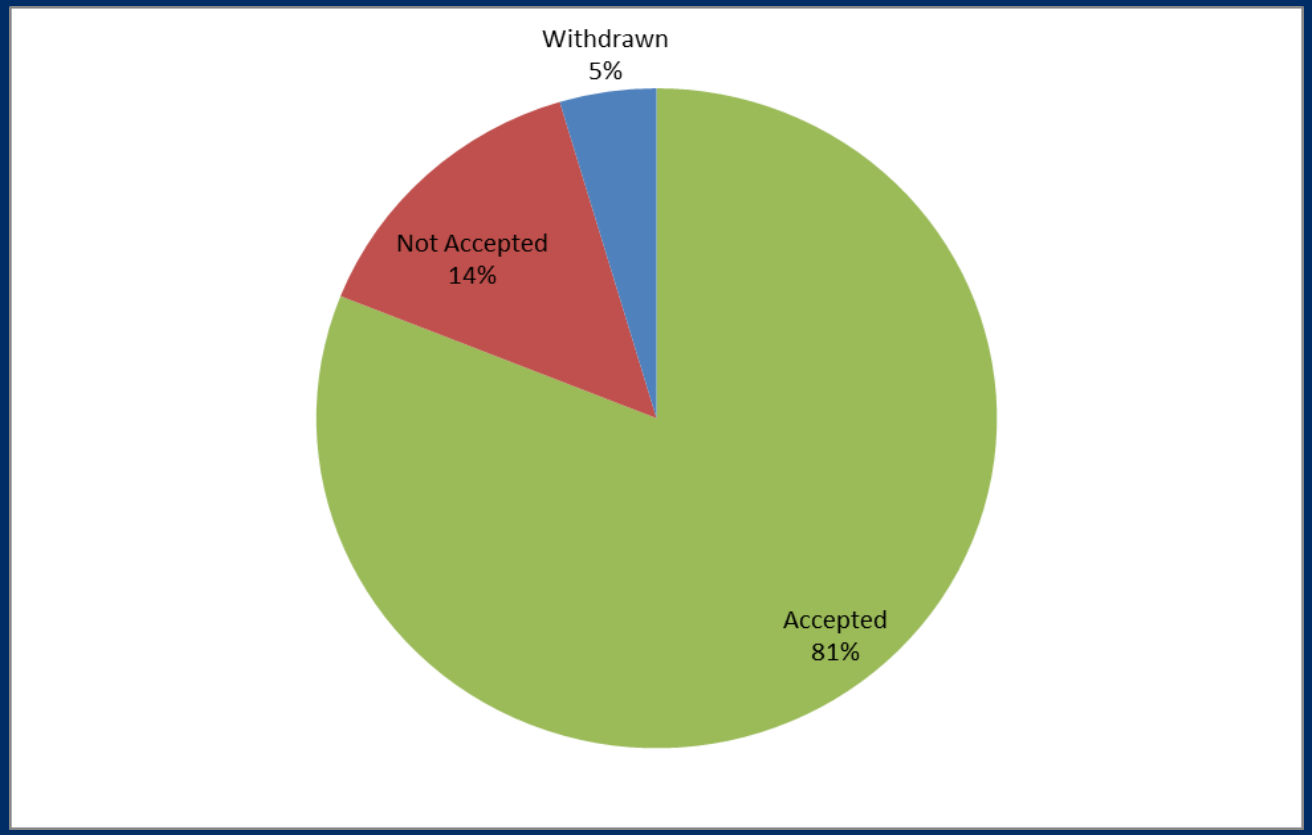


	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
Appeal Families	13	8	7	3	14	6	9	6	10	17	21	23
Appeal Submissions	18	9	7	6	19	10	10	7	13	20	27	28
Goals	24	11	10	9	25	17	14	7	20	35	39	49

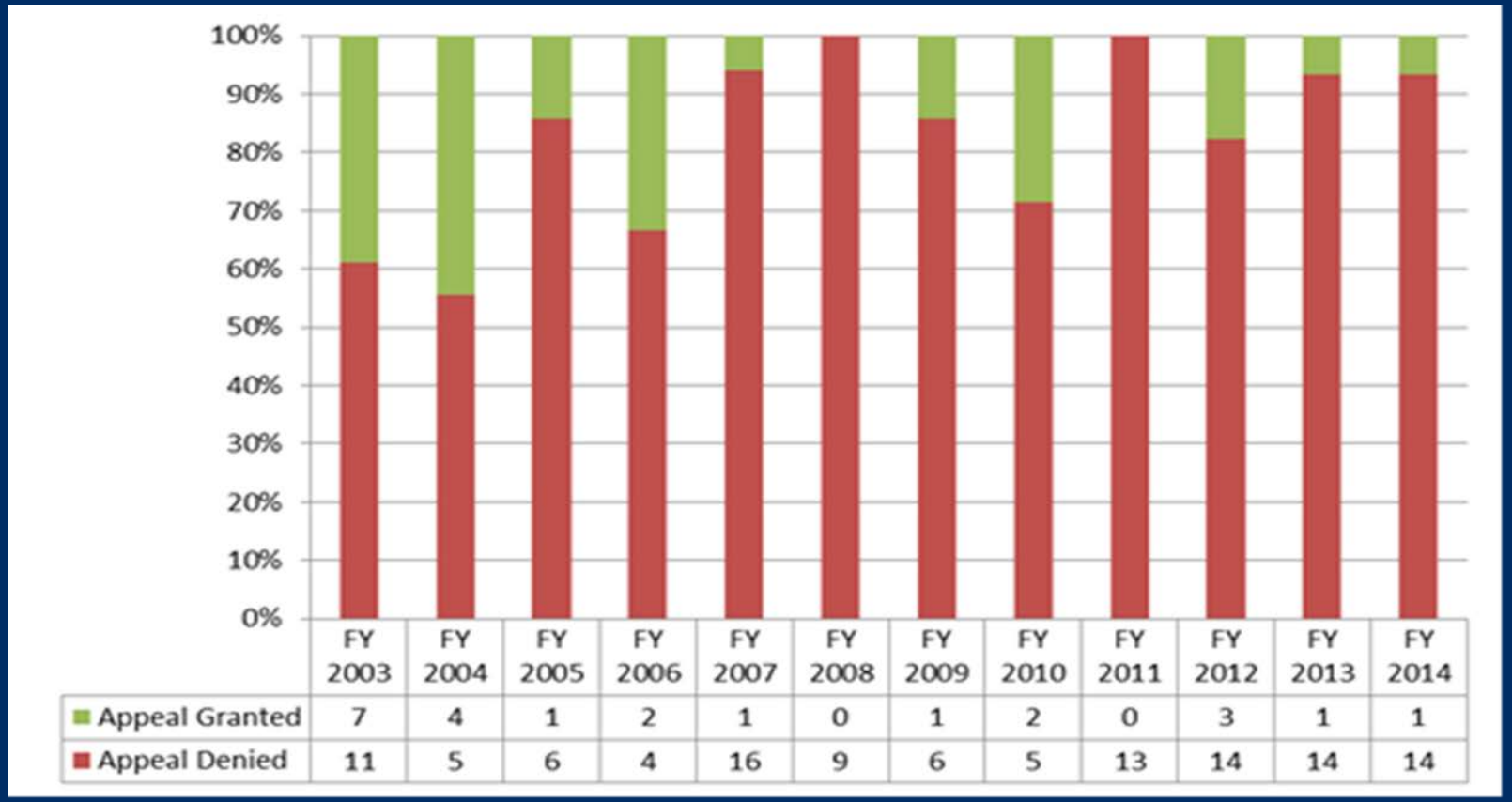
Appeal Family by User Fee Programs FY 2003-2014



FDRRs/Appeals Accepted, Not Accepted, Withdrawn FY 2003-2014



Number of FDRRs/Appeals Granted and Denied FY 2003-2014



	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
Appeal Granted	7	4	1	2	1	0	1	2	0	3	1	1
Appeal Denied	11	5	6	4	16	9	6	5	13	14	14	14

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