

Recent FDA Enforcement Actions

CBER

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Division of Case Management
Office of Compliance and Biologics Quality

CBER Products

- Vaccines
- Coagulation Factors
- Plasma Derivatives
- Allergenic Extracts
- Human Tissue & Cellular Products (cord blood)
- Gene Therapy Products
- Biological Devices and Test Kits
- Blood Bank Products (e.g., anticoagulants)

FY 2017 Compliance Action



Warning Letter

October 14, 2016

FDA



InterSol

Platelet Additive Solution (PAS 3)

INTERSOL



- *InterSol is an isotonic solution designed to replace a portion of the plasma used in the storage of AMICUS™-derived leukoreduced apheresis platelets under standard blood banking conditions.*
- *There is no direct therapeutic effect to be expected from the formulation.*
- *The solution should never be infused into a patient.*

INTERSOL (cont.)

- *Promotional material is misleading because it presents efficacy claims for InterSol, but omits all risk information for InterSol.*
- *Violations are concerning from a public health perspective because they create a misleading impression about the safety and effectiveness of InterSol.*

Moreover, we are concerned by your continued violative promotion of your product. Fenwal, Inc. was cited for similar violations in a Warning Letter dated June 1, 2012.



Striving for Voluntary Compliance

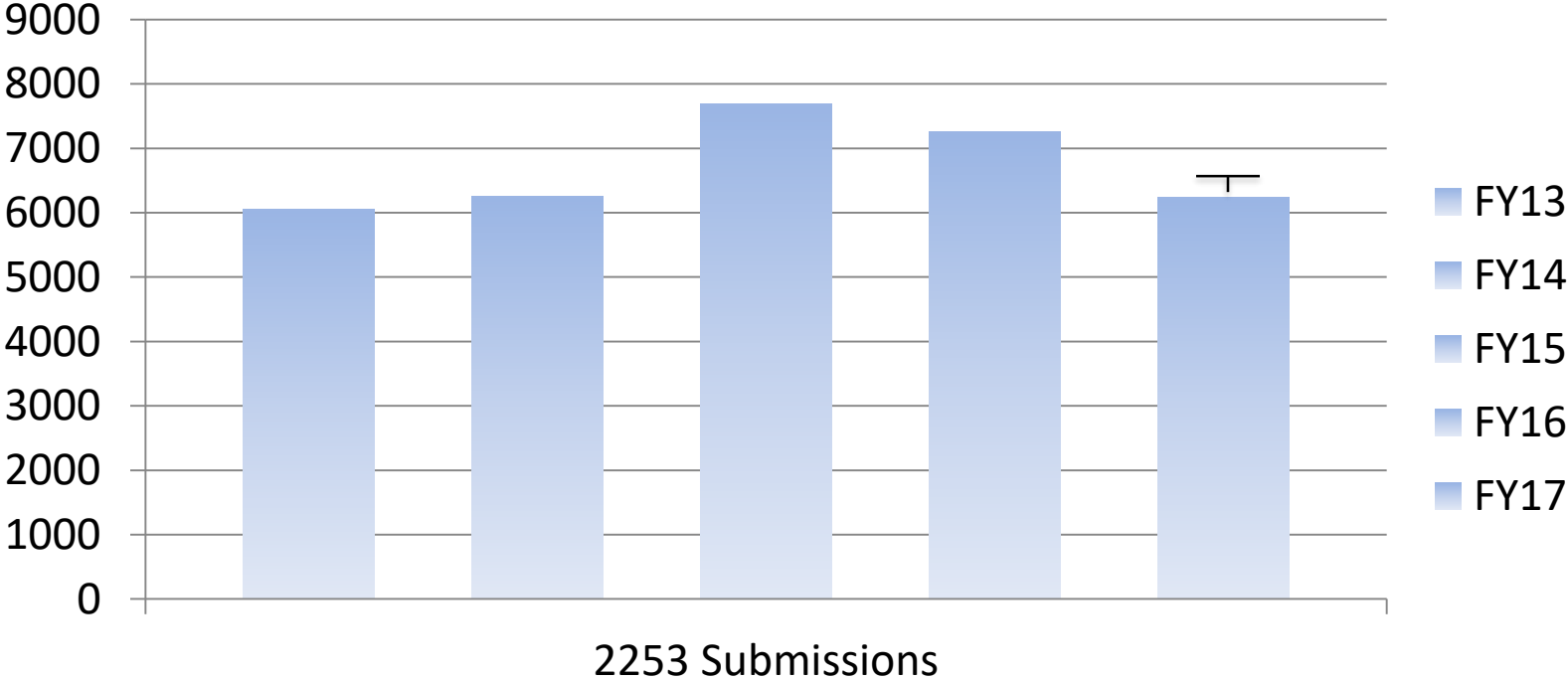


- Common problems in promotional materials
 - Absence of Risk Information
 - Misleading presentation of efficacy
- FDA will provide advice on draft promotional materials
 - Voluntary
 - Requests must be in writing

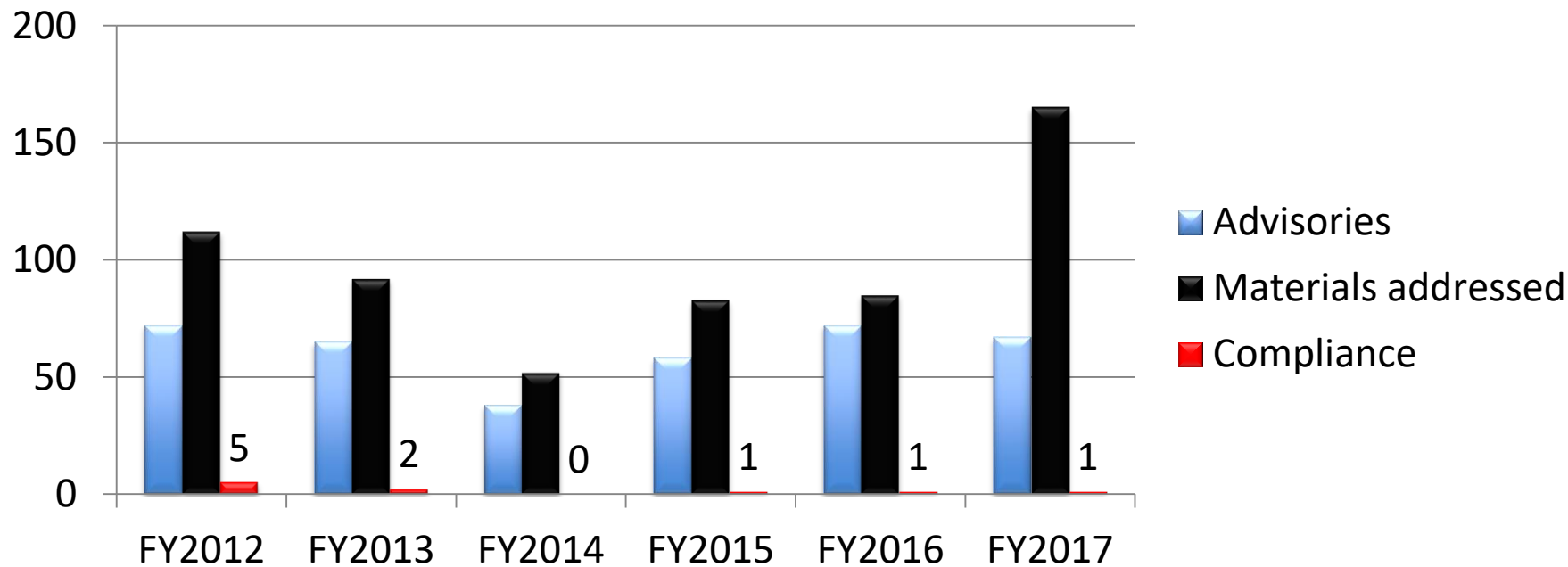
Promotional Material



FY13 - FY17 (to 9/11/17)



Advice





Resources

Guidance

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

Compliance Letters

<http://www.fda.gov/cber/efoi/adpromo.htm>

<https://www.accessdata.fda.gov/scripts/warningletters/wlFilterByOffice.cfm>

APLB Website

<http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/AdvertisingLabelingPromotionalMaterials/ucm164120.htm>

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Contact Information

The logo for the Food and Drug Administration (FDA), consisting of the letters "FDA" in white on a blue square background.

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