**FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program**
**September 16, 2011, 11:30 am – 1:00pm**
**Teleconference**

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**Purpose**

To review the proposed draft justification document accompanying the proposed draft statutory language for a 351(k) user fee program.

**Participants**

| FDA | Center | Industry | Company/Affiliation |
|---|---|---|---|
| Sunanda Bahl | CDER | Philip Ball | Watson |
| Sandra Benton | CDER | Sandi Dennis | BIO |
| Daniel Brounstein | CDER | John Finkbohner | MedImmune |
| Amanda Edmonds | OCC | Jeffrey Francer | PhRMA |
| John Jenkins | CDER | Debbie Jaskot | Teva |
| Brian Kehoe | OL | Gordon Johnston | GPhA |
| Andrew Kish | CDER | Yatika Kohli | Apotex |
| Sue Lim | CDER | Bruce Leicher | Momenta |
| Theresa Mullin | CDER | Laura McKinley | Pfizer |
| Rokhsana Safaai-Jazi | CDER | John Pakulski | Sandoz/Novartis |
| Jay Sitlani | CDER | Vince Suneja | Mylan |
| Manju Thomas | CDER | | |
| Ann Wion | OCC | | |
| Robert Yetter | CBER | | |

**Draft Justification Document for a Biosimilar Biological Product User Fee Program**

FDA and industry stakeholders discussed industry comments on the proposed draft justification document that accompanies the proposed draft statutory language authorizing a biosimilar biological product user fee program for fiscal years 2013 to 2017. Several comments and questions were identified and discussed; all were relatively minor and could be readily addressed. FDA agreed to revise the justification document based on the discussion.