Dear Trade Press Constituents:

On January 16, 2013, the U.S. Food and Drug Administration published a Federal Register notice setting fiscal year (FY) 2013 fee rates for generic drug active pharmaceutical ingredient (API) and finished dosage form (FDF) facilities as required by the Generic Drug User Fee Amendments (GDUFA) of 2012. The Federal Register notice can be found at http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm319566.htm.

Any person that owns a facility that is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more human generic drug FDFs and/or APIs is required to pay facility fee(s).
The FY 2013 fees are:

- Domestic FDF facility: $175,389
- Foreign FDF facility: $190,389
- Domestic API facility: $26,458
- Foreign API facility: $41,458

GDUFA specifies that the amount of the fee for a facility located outside the United States and its territories and possessions shall not be less than $15,000 and not more than $30,000 higher than the amount of the fee for a domestic facility. The difference is designed to reflect the higher anticipated costs of inspections funded, in part, through GDUFA. In FY 2013, the cost differential is $15,000. It may be adjusted in future years.

In order to calculate the FDF fee, FDA has used the data submitted by generic drug facilities through the self-identification process mandated in the GDUFA statute and specified in a Notice of Requirement published on October 2, 2012. The facility fees were calculated based on data submitted by generic drug facilities through the self-identification process. Additional information can be found in the Federal Register notice.
Questions about GDUFA can be sent to AskGDUFA@fda.hhs.gov.