



# Fees Associated with Human Drug Compounding By Registered Outsourcing Facilities

Webinar: Overview of Fees and Information for  
Small Businesses

# Agenda

- The purpose of this webinar is to highlight key aspects of fees applicable to drug compounding outsourcing facilities registered under section 503B of the Food, Drug, and Cosmetic Act.
- This webinar will cover:
  - Fees applicable to registered drug compounding outsourcing facilities
  - Reduction in fees available to qualifying small businesses.



# The Compounding Quality Act

What is it?

# The Legislation

- On November 27, 2013 the President signed the Drug Quality and Security Act (DQSA) which contained provisions related to human drug compounding.
- Title I of the DQSA, titled the “Compounding Quality Act,” created a new category of drug compounder that may choose to register as an outsourcing facility under section 503B of the Food, Drug, and Cosmetic Act.

# A Registered Outsourcing Facility

- Must comply with CGMP requirements;
- Will be inspected by FDA according to a risk-based schedule; and
- Must meet certain other conditions to be exempt from the new drug approval requirements and the requirements for adequate directions for use.

# Outsourcing Facility Fees

- An outsourcing facility will not be considered registered until it has paid the applicable annual establishment fee.
- An outsourcing facility may register without paying a fee until September 30, 2014, however, because fees are not required until October 1, 2014.
- Establishment fee is \$15,000 adjusted for inflation and small business reductions.
- Statute also authorized reinspection fees.



# Compounding Fee Guidance

# Compounding Fee Guidance

- On April 1, 2014, FDA published a draft guidance for industry titled “Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act”.
- The draft guidance is available here:  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf>.

# Compounding Fee Guidance, Continued...

- Among other things, the draft guidance describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, how outsourcing facilities may submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility may qualify as a small business to obtain a reduction in fees.



# Fees Associated with Human Drug Compounding

# Annual Establishment Fee

- An annual establishment fee from each “outsourcing facility”.
  - To be deemed an outsourcing facility, entities must register and pay annual establishment fee.
  - Must be paid every year at the time of registration (registration period between October 1<sup>st</sup> and December 31<sup>st</sup>).
    - Note, may register outside of this period but fee is still \$15,000.

# Annual Establishment Fee, Continued

- Once an entity registers, FDA will send an invoice via email within 3 business days of registration.
- Entity should submit payment as soon as possible to ensure it is placed on registration list.
- Annual establishment fee = \$15,000 x inflation adjustment factor + small business adjustment.

# Annual Establishment Fee: Small Business Reduction

- Annual establishment fee will be reduced if entity qualifies as a “small business” and submits request by April 30<sup>th</sup> of the previous fiscal year (FY).
- Small business is an entity with gross annual sales totaling \$1,000,000 or less in the 12 months ending on April 1 of the FY immediately preceding the FY in which the annual establishment fee is assessed. 744K(c)(4)(A).
  - \$1,000,000 includes sales of affiliates.

# Annual Establishment Fee: Small Business Reduction

- *Gross annual sales* is defined as the “total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all of the affiliates of the outsourcing facility.”
- *Affiliate* is defined as a “business entity that has a relationship with a second business entity if, directly or indirectly—(A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has power to control, both of the business

# Annual Establishment Fee: Small Business Reduction

- If an entity believes that it qualifies as a small business, it should submit FDA Form 3908 to FDA ([CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov)) certifying that it meets the qualifications.
  - Form 3908 is attached to the draft guidance, see Appendix I.
- Must submit a complete request by April 30<sup>th</sup> to qualify for a reduction of the establishment fee for the next FY.
  - For example, to receive a reduction for FY 2015 (beginning on October 1, 2014), an entity must submit a request by April 30, 2014.

# Annual Establishment Fee: Small Business Reduction

- FDA will review the form and information and send a letter granting or denying the reduction request within 60 days.
- Entities that submit by April 30 and meet the requirements will be granted a reduction.

# Reinspection Fee

An outsourcing facility will be charged a reinspection fee each time it is subject to a reinspection because of noncompliance. § 744K(a)(1)(B).

- a) This fee is \$15,000 x the inflation adjustment factor, for each reinspection. § 744K(c)(1)(B).
  - No reduction of this fee for small businesses.



# Adjustment Factors

# Inflation Adjustment Factor

- Inflation Adjustment Factor
  - Adjusts establishment and reinspection fees up for inflation.
  - Must be calculated yearly and published in the FR.

# Inflation Adjustment Factor, Continued...

- The inflation adjustment factor is equal to the sum of
  - 1, plus
  - The average annual percent change in the cost per FDA FTE for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of compensation and benefits costs to total costs of an average FDA FTE for the first 3 years of the preceding 4 fiscal years, plus
  - The average annual percent change in the consumer price index for urban consumers for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs of the FDA (not including personnel compensation and benefits) to total costs of an average FDA FTE for the first 3 years of the preceding 4 fiscal years.

– See § 744K(c)(2).

# Inflation Adjustment Factor, Continued...

- The inflation adjustment will compound every year. In other words, the inflation adjustment factor determined in one FY will be added to the total inflation-adjusted fee from the preceding FY.

# Small Business Adjustment Factor

- Available to subsidize the fee for small businesses.
- For businesses that do not qualify for the small business reduction, adjusts establishment fee up to cover fees lost by granting small business reductions to small businesses.

# Small Business Adjustment Factor, Continued...

- SB Adjustment Factor will be established by FDA yearly based on an estimate of 1) the number of small businesses that will pay a reduced fee in an FY, and 2) the positive adjustment to the establishment fee necessary to achieve fees equaling the total fees FDA would have collected if no entity qualified for the adjustment. § 744K(c)(3).

# What Will FDA Use the Fees For?

- The fees under this section will be available “solely to pay for the costs of oversight of outsourcing facilities.” See § 744K(d).

# Questions?

- For fee-related questions, contact CDER's Division of User Fee Management and Budget Formulation at [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov) or 301-796-7900.
- All other questions regarding compounding should be directed to [Compounding@fda.hhs.gov](mailto:Compounding@fda.hhs.gov).