

21 U.S. Code § 379j-62

Authority to assess and use outsourcing facility fees

(a) Establishment and reinspection fees

(1) In general

For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

- (A) an annual establishment fee from each outsourcing facility; and
- (B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.

(2) Multiple reinspections

An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

(b) Establishment and reinspection fee setting

The Secretary shall—

- (1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and
- (2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.

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