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# 21 U.S. Code § 379j-72

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## Authority to assess and use OTC monograph fees

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### **(a) Types of fees**

Beginning with fiscal year 2021, the Secretary shall assess and collect fees in accordance with this section as follows:

#### **(1) Facility fee**

##### **(A) In general**

Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility as determined under subsection (c).

##### **(B) Exceptions**

###### **(i) Facilities that cease activities**

A fee shall not be assessed under subparagraph (A) if the identified OTC monograph drug facility—

(I) has ceased all activities related to OTC monograph drugs prior to December 31 of the year immediately preceding the applicable fiscal year; and

(II) has updated its registration to reflect such change under the requirements for drug establishment registration set forth in section 360 of this title.

###### **(ii) Contract manufacturing organizations**

The amount of the fee for a contract manufacturing organization facility shall be equal to two-thirds of the amount of the fee for an OTC monograph drug facility that is not a contract manufacturing organization facility.

##### **(C) Amount**

The amount of fees established under subparagraph (A) shall be established under subsection (c).

##### **(D) Due date**

###### **(i) For first program year**

For fiscal year 2021, the facility fees required under subparagraph (A) shall be due on the later of—

(I) the first business day of July of 2020; or

(II) 45 calendar days after publication of the Federal Register notice provided for under subsection (c)(4)(A).

###### **(ii) Subsequent fiscal years**

For each fiscal year after fiscal year 2021, the facility fees required under subparagraph (A) shall be due on the later of—

(I) the first business day of June of such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and

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obligation of fees under this section for such year.

## **(2) OTC monograph order request fee**

### **(A) In general**

Each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of such fee shall be—

- (i) for a Tier 1 OTC monograph order request, \$500,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)); and
- (ii) for a Tier 2 OTC monograph order request, \$100,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)).

### **(B) Due date**

The OTC monograph order request fees required under subparagraph (A) shall be due on the date of submission of the OTC monograph order request.

### **(C) Exception for certain safety changes**

A person who is named as the requestor in an OTC monograph order shall not be subject to a fee under subparagraph (A) if the Secretary finds that the OTC monograph order request seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen—

- (i) a contraindication, warning, or precaution;
- (ii) a statement about risk associated with misuse or abuse; or
- (iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

### **(D) Refund of fee if order request is recategorized as a Tier 2 OTC monograph order request**

If the Secretary determines that an OTC monograph request initially characterized as Tier 1 shall be re-characterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee in accordance with subparagraph (A)(i), the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees determined under subparagraphs (A)(i) and (A)(ii), respectively.

### **(E) Refund of fee if order request refused for filing or withdrawn before filing**

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any order request which is refused for filing or was withdrawn before being accepted or refused for filing.

### **(F) Fees for order requests previously refused for filing or withdrawn before filing**

An OTC monograph order request that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest.

### **(G) Refund of fee if order request withdrawn**

If an order request is withdrawn after the order request was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the order request after the application was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

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