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# 21 U.S. Code § 360fff-2

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## Eligibility determinations; data submission; filing

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### **(a) Eligibility determinations**

#### **(1) In general**

Not later than 60 calendar days after the date of receipt of a request under section 360fff-1 of this title, the Secretary shall—

- (A) determine, in accordance with paragraph (2), whether the request is eligible for further review under subsection (b) and section 360fff-3 of this title;
- (B) notify the sponsor of the determination of the Secretary; and
- (C) make such determination publicly available in accordance with paragraph (3) and subsection (b)(1).

#### **(2) Criteria for eligibility**

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

To be eligible for review under subsection (b) and section 360fff-3 of this title, a request shall be for a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof, that—

- (i) is not included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen; and
- (ii) has been used to a material extent and for a material time under such conditions, as described in section 321(p)(2) of this title.

##### **(B) Establishment of time and extent**

A sponsor shall include in a request under section 360fff-1 of this title the information required under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations) to meet the standard described in subparagraph (A)(ii).

#### **(3) Public availability**

##### **(A) Redactions for confidential information**

If a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is determined under paragraph (1)(A) to be eligible for further review, the Secretary shall make the request publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, section 1905 of title 18, or section 331(j) of this title.

##### **(B) Identification of confidential information by sponsor**

At the time that a request is made under section 360fff-1 of this title, the sponsor of such request shall identify any information that such sponsor considers to be confidential information described in subparagraph (A).

### **(C) Confidentiality during eligibility review**

The information contained in a request under section 360fff–1 of this title shall remain confidential during the Secretary’s consideration under this section of whether the request is eligible for further review consistent with section 330.14 of title 21, Code of Federal Regulations (or any successor regulations).

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