Federal Register containing information proposing that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

(A) is GRASE and is not misbranded if marketed in accordance with such order;

(B) is not GRASE and is misbranded; or

(C) is not GRASE and is misbranded because the data are insufficient to classify such ingredient or combination of ingredients as GRASE and not misbranded and additional information is necessary to allow the Secretary to determine otherwise;

(8) the term ''sponsor'' means the person that submitted—

(A) a request under section 360fff–1 of this title;

(B) a pending request; or

(C) any other application subject to this part;

(9) the term ''sunscreen'' means a drug containing one or more sunscreen active ingredients; and

(10) the term ''sunscreen active ingredient'' means an active ingredient that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering ultraviolet radiation.

(June 25, 1938, ch. 675, § 586, as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2035.)

CONSTRUCTION

Pub. L. 113–195, § 2(b), Nov. 26, 2014, 128 Stat. 2045, provided that: ''Nothing in the amendment made by this section [enacting this section and sections 360fff–1 to 360fff–5 of this title] shall be construed to—

''(1) limit the right of a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360fff(8)], as added by subsection (a)) to request that the Secretary of Health and Human Services convene an advisory committee; or

''(2) limit the authority of the Secretary of Health and Human Services to meet with a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)).''

§ 360fff–1. Submission of requests

Any person may submit a request to the Secretary for a determination of whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof (including dosage form, dosage strength, and route of administration) is GRASE and should be included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen.

(June 25, 1938, ch. 675, § 586A, as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2036.)

§ 360fff–2. Eligibility determinations; data submission; filing

(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).

(b) Data submission and filing of requests

(1) In general

In the case of a request under section 360fff–1 of this title that is determined to be eligible