

may provide for fines, imprisonment, or civil penalties; and

(D) may regulate activities of licensed entities in a manner that is consistent with product tracing requirements under section 360eee-1 of this title.

**(c) Exception**

Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under section 353(e) of this title or this part (or regulations issued thereunder).

(June 25, 1938, ch. 675, §585, as added Pub. L. 113-54, title II, §205, Nov. 27, 2013, 127 Stat. 638.)

PART I—NONPRESCRIPTION SUNSCREEN AND OTHER ACTIVE INGREDIENTS

**§ 360fff. Definitions**

In this part—

(1) the term “Advisory Committee” means the Nonprescription Drug Advisory Committee of the Food and Drug Administration or any successor to such Committee;

(2) the term “final sunscreen order” means an order published by the Secretary in the Federal Register containing information stating 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; or

(B) is not GRASE and is misbranded;

(3) the term “GRASE” means generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of a drug as described in section 321(p) of this title;

(4) the term “GRASE determination” means, with respect to a nonprescription active ingredient or a combination of nonprescription active ingredients, a determination of whether such ingredient or combination of ingredients is GRASE;

(5) the term “nonprescription” means not subject to section 353(b)(1) of this title;

(6) the term “pending request” means each request with respect to a nonprescription sunscreen active ingredient submitted under section 330.14 of title 21, Code of Federal Regulations (as in effect on November 26, 2014) for consideration for inclusion in the over-the-counter drug monograph system—

(A) that was determined to be eligible for such review by publication of a notice of eligibility in the Federal Register prior to November 26, 2014; and

(B) for which safety and effectiveness data have been submitted to the Secretary prior to November 26, 2014;

(7) the term “proposed sunscreen order” means an order containing a tentative determination published by the Secretary in the

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—