
21 U.S. Code § 360fff-4

Guidance; other provisions

(a) Guidance

(1) In general

(A) Draft guidance

Not later than 1 year after November 26, 2014, the Secretary shall issue draft guidance on the implementation of, and compliance with, the requirements with respect to sunscreen under this part, including guidance on—

- (i) the format and content of information submitted by a sponsor in support of a request under section 360fff-1 of this title or a pending request;
- (ii) the data required to meet the safety and efficacy standard for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;
- (iii) the process by which a request under section 360fff-1 of this title or a pending request is withdrawn; and
- (iv) the process by which the Secretary will carry out section 360fff-3(c) of this title, including with respect to how the Secretary will address the total number of requests received under section 360fff-1 of this title and pending requests.

(B) Final guidance

The Secretary shall finalize the guidance described in subparagraph (A) not later than 2 years after November 26, 2014.

(C) Inapplicability of Paperwork Reduction Act

Chapter 35 of title 44 shall not apply to collections of information made for purposes of guidance under this subsection.

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