

**(B) Procedure for updating regulations**

After the Secretary amends and finalizes the regulations under part 352 of title 21, Code of Federal Regulations under section 360fff-5 of this title and such regulations become effective, the Secretary may use direct final rulemaking to include in such regulations any nonprescription sunscreen active ingredients that are the subject of effective final sunscreen orders.

(June 25, 1938, ch. 675, §586C, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2039.)

**§ 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 Guidance; other provisions****(a) Guidance****(1) In general****(A) Draft guidance**

Not later than 1 year after November 26, 2014, the Secretary shall issue draft guidance on the implementation of, and compliance with, the requirements with respect to sunscreen under this part, including guidance on—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- (iii) the process by which a request under section 360fff-1 of this title or a pending request is withdrawn; and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.

**(2) Submissions pending issuance of final guidance**

Irrespective of whether final guidance under paragraph (1) has been issued—

- (A) persons may, beginning on November 26, 2014, make submissions under this part; and
- (B) the Secretary shall review and act upon such submissions in accordance with this part.

**(b) Rules of construction****(1) Currently marketed sunscreens**

Nothing in this part shall be construed to affect the marketing of sunscreens that are marketed in interstate commerce on or before No-

vember 26, 2014, except as otherwise provided in this part.

**(2) Ensuring safety and effectiveness**

Nothing in this part shall be construed to alter the authority of the Secretary with respect to prohibiting the marketing of a sunscreen that is not safe and effective or is misbranded, or with respect to imposing restrictions on the marketing of a sunscreen to ensure safety and effectiveness, except as otherwise provided in this part, including section 360fff-3(e) of this title.

**(3) Other drugs**

Except as otherwise provided in section 360fff-6 of this title, nothing in this part shall be construed to affect the authority of the Secretary under this chapter or the Public Health Service Act (42 U.S.C. 201 et seq.) with respect to a drug other than a nonprescription sunscreen.

**(4) Effect on drugs otherwise approved**

Nothing in this part shall affect the marketing of a drug approved under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262].

**(c) Timelines**

The timelines for the processes and procedures under paragraphs (1), (2), (5), and (6) of section 360fff-3(a) of this title shall not apply to any requests submitted to the Secretary under section 360fff-1 of this title after the date that is 6 years after November 26, 2014.

(June 25, 1938, ch. 675, §586D, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2044.)

## REFERENCES IN TEXT

The Public Health Service Act, referred to in subsection (b)(3), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

**§ 360fff-5. Sunscreen monograph****(a) In general**

Not later than 5 years after November 26, 2014, the Secretary shall amend and finalize regulations under part 352 of title 21, Code of Federal Regulations concerning nonprescription sunscreen that are effective not later than 5 years after November 26, 2014. The Secretary shall publish such regulations not less than 30 calendar days before the effective date of such regulations.

**(b) Reports**

If the regulations promulgated under subsection (a) do not include provisions related to the effectiveness of various sun protection factor levels, and do not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug approval under section 355 of this title, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the rationale for such provisions not being in-

cluded in such regulations, and a plan and timeline to compile any information necessary to address such provisions through final regulations.

(June 25, 1938, ch. 675, §586E, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2045.)

**§ 360fff-6. Non-sunscreen time and extent applications**

**(a) Pending time and extent applications**

**(1) In general**

**(A) Request for framework for review**

If, prior to November 26, 2014, an application was submitted pursuant to section 330.14 of title 21, Code of Federal Regulations for a GRASE determination for a drug other than a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients and such drug was found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations, the sponsor of such application may request that the Secretary provide a framework under paragraph (2) for the review of such application.

**(B) Request requirements**

A request for a framework for review of an application made under subparagraph (A) shall be made within 180 calendar days of November 26, 2014, and shall include the preference of such sponsor as to whether such application is reviewed by the Secretary in accordance with—

(i) the processes and procedures set forth for pending requests under section 360fff-3(b) of this title, except that specific timelines shall be determined in accordance with other applicable requirements under this section;

(ii) the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations);

(iii) an initial filing determination under the processes and procedures described in section 360fff-2(b) of this title and the processes and procedures set forth for pending requests under section 360fff-3(b) of this title, except that specific timelines shall be determined in accordance with other applicable requirements under this section; or

(iv) an initial filing determination under the processes and procedures described in section 360fff-2(b) of this title and the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations).

**(C) No request**

If a sponsor described in subparagraph (A) does not make such request within 180 calendar days of November 26, 2014, such application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when such regulations are finalized under subsection (b).

**(2) Framework**

Not later than 1 year after November 26, 2014, the Secretary shall provide, in writing, a framework to each sponsor that submitted a request under paragraph (1). Such framework shall set forth the various timelines, in calendar days, with respect to the processes and procedures for review under clauses (i), (ii), (iii), and (iv) of paragraph (1)(B) and—

(A) such timelines shall account for the considerations under paragraph (5); and

(B) the timelines for the various processes and procedures shall not be shorter than the timelines set forth for pending requests under sections 360fff-2(b) and 360fff-3(b) of this title, as applicable.

**(3) Governing processes and procedures for review**

**(A) Election**

Not later than 60 calendar days after the Secretary provides a framework to a sponsor under paragraph (2), such sponsor may provide an election to the Secretary regarding the processes and procedures for review under clause (i), (ii), (iii), or (iv) of paragraph (1)(B). If such sponsor makes such election, the Secretary shall review the application that is the subject of such election pursuant to the processes and procedures elected by such sponsor and the applicable timelines in calendar days set forth under such framework, which the Secretary shall confirm in writing to the sponsor not later than the date upon which the Secretary provides a report under paragraph (4). If such sponsor does not make such election, such application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when such regulations are finalized under subsection (b).

**(B) Different processes and procedures**

At any time during review of an application, the Secretary may review such application under different processes and procedures under clause (i), (ii), (iii), or (iv) of paragraph (1)(B) than the processes and procedures the sponsor elected in accordance with subparagraph (A), so long as the Secretary proposes, in writing, the change and the sponsor agrees, in writing, to such change.

**(C) Inclusion of ingredients in monographs**

If the sponsor elects to use the processes and procedures for review in accordance with clause (i) or (iii) of paragraph (1)(B), the Secretary may incorporate any resulting final order into a regulation addressing the conditions under which other drugs in the same therapeutic category are GRASE and not misbranded, including through direct final rulemaking, and the final order so incorporated shall cease to be effective on the effective date of the final regulation that addresses such drug.

**(4) Letter regarding pending applications**

Not later than 18 months after November 26, 2014, the Secretary shall report to the Committee on Health, Education, Labor, and Pen-