

## EFFECTIVE DATE OF 2012 AMENDMENT

Pub. L. 112-144, title XI, §1142(b), July 9, 2012, 126 Stat. 1130, provided that: “The amendments made by subsection (a) [amending this section] apply beginning on October 1, 2012.”

## EFFECTIVE DATE

Section effective Oct. 1, 2007, see section 701(c) of Pub. L. 110-85, set out as an Effective Date of 2007 Amendment note under section 355 of this title.

### § 379d-2. Policy on the review and clearance of scientific articles published by FDA employees

#### (a) Definition

In this section, the term “article” means a paper, poster, abstract, book, book chapter, or other published writing.

#### (b) Policies

The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

#### (c) Timing of submission for review

If an officer or employee, including a Staff Fellow and a contractor who performs staff work, of the Food and Drug Administration is directed by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

#### (d) Timing for review and clearance

The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

#### (e) Non-timely review

If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).

#### (f) Effect

Nothing in this section shall be construed as affecting any restrictions on such publication or presentation provided by other provisions of law.

(June 25, 1938, ch. 675, §713, as added Pub. L. 110-85, title XI, §1101, Sept. 27, 2007, 121 Stat. 971.)

### § 379d-3. Streamlined hiring authority

#### (a) In general

In addition to any other personnel authorities under other provisions of law, the Secretary may, without regard to the provisions of title 5 governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

#### (b) Activities described

The activities described in this subsection are—

- (1) activities under this chapter related to the process for the review of device applications (as defined in section 379i(8) of this title); and
- (2) activities under this chapter related to human generic drug activities (as defined in section 379j-41 of this title).

#### (c) Objectives specified

The objectives specified in this subsection are—

- (1) with respect to the activities under subsection (b)(1), the goals referred to in section 379j-1(a)(1) of this title; and
- (2) with respect to the activities under subsection (b)(2), the goals referred to in section 379j-43(a) of this title.

#### (d) Internal controls

The Secretary shall institute appropriate internal controls for appointments under this section.

#### (e) Sunset

The authority to appoint employees under this section shall terminate on the date that is 3 years after July 9, 2012.

(June 25, 1938, ch. 675, §714, as added and amended Pub. L. 112-144, title II, §208, title III, §307, July 9, 2012, 126 Stat. 1007, 1025.)

## AMENDMENTS

2012—Subsec. (b). Pub. L. 112-144, §307(1), amended subsec. (b) generally. Prior to amendment, text read as follows: “The activities described in this subsection are activities under this chapter related to the process for the review of device applications (as defined in section 379i(8) of this title).”

Subsec. (c). Pub. L. 112-144, §307(2), amended subsec. (c) generally. Prior to amendment, text read as follows: “The objectives specified in this subsection are with respect to the activities under subsection (b), the goals referred to in section 379j-1(a)(1) of this title.”

## EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by section 307 of Pub. L. 112-144 effective Oct. 1, 2012, see section 305 of Pub. L. 112-144, set out as an Effective and Termination Dates note under section 379j-41 of this title.

## EFFECTIVE DATE

Section effective Oct. 1, 2012, see section 206 of Pub. L. 112-144, set out as an Effective Date of 2012 Amendment note under section 379i of this title.

### § 379d-4. Reporting requirements

#### (a) Generic drugs

Beginning with fiscal year 2013 and ending after fiscal year 2017, not later than 120 days

after the end of each fiscal year for which fees are collected under subpart 7 of part C, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning, for all applications for approval of a generic drug under section 355(j) of this title, amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year—

(1) the number of such applications that met the goals identified for purposes of subpart 7 of part C, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record;

(2) the average total time to decision by the Secretary for applications for approval of a generic drug under section 355(j) of this title, amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter;

(3) the total number of applications under section 355(j) of this title, amendments to such applications, and prior approval supplements with respect to such applications that were pending with the Secretary for more than 10 months on July 9, 2012; and

(4) the number of applications described in paragraph (3) on which the Food and Drug Administration took final regulatory action in the previous fiscal year.

#### (b) Biosimilar biological products

##### (1) In general

Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year for which fees are collected under subpart 8 of part C, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—

(A) the number of applications for approval filed under section 262(k) of title 42; and

(B) the percentage of applications described in subparagraph (A) that were approved by the Secretary.

##### (2) Additional information

As part of the performance report described in paragraph (1), the Secretary shall include an explanation of how the Food and Drug Administration is managing the biological product review program to ensure that the user fees collected under subpart 2<sup>1</sup> are not used to

review an application under section 262(k) of title 42.

(June 25, 1938, ch. 675, § 715, as added and amended Pub. L. 112-144, title III, § 308, title IV, § 408, July 9, 2012, 126 Stat. 1025, 1039.)

#### AMENDMENTS

2012—Subsec. (b). Pub. L. 112-144, § 408, added subsec. (b).

#### EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by section 408 of Pub. L. 112-144 effective Oct. 1, 2012, see section 405 of Pub. L. 112-144, set out as an Effective and Termination Dates note under section 379j-51 of this title.

#### EFFECTIVE DATE

Section effective Oct. 1, 2012, see section 305 of Pub. L. 112-144, set out as an Effective and Termination Dates note under section 379j-41 of this title.

#### § 379d-5. Guidance document regarding product promotion using the Internet

Not later than 2 years after July 9, 2012, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.

(Pub. L. 112-144, title XI, § 1121, July 9, 2012, 126 Stat. 1112.)

#### CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

#### PART B—COLORS

#### § 379e. Listing and certification of color additives for foods, drugs, devices, and cosmetics

##### (a) Unsafe color additives

A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics, be deemed unsafe for the purposes of the application of section 342(c), 351(a)(4), or 361(e) of this title, as the case may be, unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c) of this section, for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a

<sup>1</sup> So in original. Probably means subpart 2 of part C.