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