CODIFICATION

Section was classified to section 263n of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, §19(a)(4), which renumbered section 263n of Title 42, The Public Health and Welfare, as this section.

1990—Pub. L. 101–629, §19(a)(1)(B), (2)(H), substituted ''section 360kk'' for ''section 263f'' and ''this part'' for ''this subpart''.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360pp of this title.

PART D—DISSEMINATION OF TREATMENT INFORMATION

TERMINATION OF PART

For termination of part by section 401(e) of Pub. L. 105–115, see Effective and Termination Dates note set out under section 360aaa of this title.

§ 360aaa. Requirements for dissemination of treatment information on drugs or devices

(a) In general

Notwithstanding sections 331(d), 352(f), and 355 of this title, and section 262 of title 42, a manufacturer may disseminate to—

(1) a health care practitioner;

(2) a pharmacy benefit manager;

(3) a health insurance issuer;

(4) a group health plan; or

(5) a Federal or State governmental agency;

written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device if the manufacturer meets the requirements of subsection (b) of this section.

(b) Specific requirements

A manufacturer may disseminate information under subsection (a) of this section on a new use only if—

(1)(A) in the case of a drug, there is in effect for the drug an application filed under subsection (b) or (j) of section 355 of this title or a biologics license issued under section 262 of title 42; or

(B) in the case of a device, the device is being commercially distributed in accordance with a regulation under subsection (d) or (e) of section 360c of this title, an order under subsection (f) of such section, or the approval of an application under section 360e of this title;

(2) the information meets the requirements of section 360aaa–1 of this title;

(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

(4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary—

(A) a copy of the information to be disseminated; and

(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

(5) the manufacturer has complied with the requirements of section 360aaa–3 of this title (relating to a supplemental application for such use);

(6) the manufacturer includes along with the information to be disseminated under this subsection—

(A) a prominently displayed statement that discloses—

(i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;

(ii) if applicable, that the information is being disseminated at the expense of the manufacturer;

(iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

(iv) the official labeling for the drug or device and all updates with respect to the labeling;

(v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1) of this section; and

(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated; and

(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

(c) Additional information

If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B) of this section, with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and balanced, the Secretary may require the manufacturer to disseminate—

(1) additional objective and scientifically sound information that pertains to the safety

or effectiveness of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary or, where appropriate, a summary of such information or any other information that the Secretary has authority to make available to the public; and

(2) an objective statement of the Secretary, based on data or other scientifically sound information available to the Secretary, that bears on the safety or effectiveness of the new use of the drug or device.

(June 25, 1938, ch. 675, § 551, as added Pub. L. 105–115, title IV, § 401(a), Nov. 21, 1997, 111 Stat. 2356.)

TERMINATION OF SECTION

For termination of section by section 401(e) of Pub. L. 105–115, see Effective and Termination Dates note below.

EFFECTIVE AND TERMINATION DATES

Section 401(d) of Pub. L. 105–115 provided that: ''The amendments made by this section [enacting this part and amending section 331 of this title] shall take effect 1 year after the date of enactment of this Act [Nov. 21, 1997], or upon the Secretary's issuance of final regulations pursuant to subsection (c) [section 401(c) of Pub. L. 105–115 set out below], whichever is sooner.''

Section 401(e) of Pub. L. 105–115 provided that: ''The amendments made by this section [enacting this part and amending section 331 of this title] cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c) [section 401(c) of Pub. L. 105–115 set out below], whichever is later.''

REGULATIONS

Section 401(c) of Pub. L. 105–115 provided that: ''Not later than 1 year after the date of enactment of this Act [Nov. 21, 1997], the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section [enacting this part and amending section 331 of this title].''

STUDIES AND REPORTS

Section 401(f) of Pub. L. 105–115 provided that:

''(1) GENERAL ACCOUNTING OFFICE.—

''(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine the impact of subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360aaa et seq.], as added by this section, on the resources of the Department of Health and Human Services.

''(B) REPORT.—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce [now Committee on Energy and Commerce] of the House of Representatives a report of the results of the study.

''(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—

''(A) IN GENERAL.—In order to assist Congress in determining whether the provisions of such subchapter should be extended beyond the termination date specified in subsection (e) [section 401(e) of Pub. L. 105–115, set out above], the Secretary of Health and Human Services shall, in accordance with subparagraph (B), arrange for the conduct of a study of the scientific issues raised as a result of the enactment of such subchapter including issues relating to—

''(i) the effectiveness of such subchapter with respect to the provision of useful scientific information to health care practitioners;

''(ii) the quality of the information being disseminated pursuant to the provisions of such subchapter;

''(iii) the quality and usefulness of the information provided, in accordance with such subchapter, by the Secretary or by the manufacturer at the request of the Secretary; and

''(iv) the impact of such subchapter on research in the area of new uses, indications, or dosages, particularly the impact on pediatric indications and rare diseases.

''(3) PROCEDURE FOR STUDY.—

''(A) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (2), and to prepare and submit the report required by subparagraph (B), under an arrangement by which the actual expenses incurred by the Institute of Medicine in conducting the study and preparing the report will be paid by the Secretary. If the Institute of Medicine is unwilling to conduct the study under such an arrangement, the Comptroller General of the United States shall conduct such study.

''(B) REPORT.—Not later than September 30, 2005, the Institute of Medicine or the Comptroller General of the United States, as appropriate, shall prepare and submit to the Committee on Labor and Human Resources of the Senate, the Committee on Commerce [now Committee on Energy and Commerce] of the House of Representatives, and the Secretary a report of the results of the study required by paragraph (2). The Secretary, after the receipt of the report, shall make the report available to the public.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360aaa–1, 360aaa–2, 360aaa–3, 360aaa–4, 360aaa–6 of this title.

§ 360aaa–1. Information authorized to be disseminated

(a) Authorized information

A manufacturer may disseminate information under section 360aaa of this title on a new use only if the information—

(1) is in the form of an unabridged—

(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal (as defined in section 360aaa–5(5) of this title), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or

(B) reference publication, described in subsection (b) of this section, that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation; and

(2) is not false or misleading and would not pose a significant risk to the public health.

(b) Reference publication

A reference publication referred to in subsection (a)(1)(B) of this section is a publication that—

(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug or device;

(2) has not been edited or significantly influenced by such a manufacturer;