Advancing Hope Act of 2016

[Public Law 114–229]

[As Amended Through P.L. 114–255, Enacted December 13, 2016]

[Currency: This publication is a compilation of the text of Public Law 114-229. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

AN ACT To extend the pediatric priority review voucher program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. [21 U.S.C. 301 note] SHORT TITLE.

This Act may be cited as the "Advancing Hope Act of 2016".

SEC. 2. REAUTHORIZATION OF PROGRAM FOR PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) IN GENERAL.—Section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

(1) in subsection (a)—

(A) in paragraph (3), by amending subparagraph (A) to read as follows:

"(A) The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents."; and

(B) in paragraph (4)(F), by striking "Prescription Drug User Fee Amendments of 2012" and inserting "Advancing Hope Act of 2016";

(2) in subsection (b)—

(A) by striking paragraph (4) and inserting the following:

"(4) NOTIFICATION.—

"(A) SPONSOR OF A RARE PEDIATRIC DISEASE PRODUCT.—

"(i) IN GENERAL.—Beginning on the date that is 90 days after the date of enactment of the Advancing Hope Act of 2016, the sponsor of a rare pediatric disease product application that intends to request a pri-

ority review voucher under this section shall notify the Secretary of such intent upon submission of the rare pediatric disease product application that is the basis of the request for a priority review voucher.

"(ii) APPLICATIONS SUBMITTED BUT NOT YET APPROVED.—The sponsor of a rare pediatric disease product application that was submitted and that has not been approved as of the date of enactment of the Advancing Hope Act of 2016 shall be considered eligible for a priority review voucher, if—

"(I) such sponsor has submitted such rare pediatric disease product application—

"(aa) on or after the date that is 90 days after the date of enactment of the Prescription Drug User Fee Amendments of 2012; and

"(bb) on or before the date of enactment of the Advancing Hope Act of 2016; and

"(II) such application otherwise meets the criteria for a priority review voucher under this section.

"(B) SPONSOR OF A DRUG APPLICATION USING A PRIORITY REVIEW VOUCHER.—

"(i) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay the user fee to be assessed in accordance with this section.

"(ii) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under clause (i) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification."; and

(B) by striking paragraph (5) and inserting the following:

"(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after December 31, 2016."; and

(3) in subsection (g), by inserting before the period ", except that no sponsor of a rare pediatric disease product application may receive more than one priority review voucher issued under any section of this Act with respect to the drug for which the application is made."

(b) [21 U.S.C. 360ff note] RULE OF CONSTRUCTION.—Nothing in this Act, or the amendments made by this Act, shall be construed to affect the validity of a priority review voucher that was issued under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) before the date of enactment of this Act.