AMENDMENT TO H.R. 1499

OFFERED BY MR. RUSH OF ILLINOIS

Page 2, line 7, insert ''(or for two subsequent filers)'' after ''subsequent filer''.

Page 2, line 12, insert ''(or in the case of such an agreement between two subsequent filers, the other subsequent filer)'' after ''such holder''.

Page 2, line 13, strike ''an exclusive license'' and insert ''a license''.

Page 2, line 14, insert ''(A)'' after ''(2)''.

Page 2, line 19, strike the period at the end and insert ''; or''.

Page 2, after line 19, add the following:

(B) the subsequent filer agrees to market or sell an authorized generic version of the covered product in lieu of conducting research on, or developing, manufacturing, marketing, or selling, for any period of time, the covered product that is the subject of the application described in subparagraph (A) or (B) of subsection (f)(8).

Page 3, line 4, insert ''(or from one subsequent filer to another)'' after ''subsequent filer''.

Page 6, line 2, insert ''(if any such holder is a party to such order)'' after ''holder''.

Page 6, line 5, insert ''or an approved application that is deemed to be a license for a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148; 124 Stat. 817)'' after ''(f)(8)''.

Page 6, line 10, strike ''the subsequent filer'' and insert ''any subsequent filer that is a party to such order''.

Page 8, line 23, insert ''(or, in the case of an agreement between two subsequent filers, the subsequent filer who gave the value described in subsection (a)(1))'' after ''holder''.

Page 9, line 1, insert ''(or by such subsequent filer)'' after ''holder''.

Page 9, line 5, insert ''(or to the other subsequent filer)'' after ''subsequent filer''.

Page 9, line 9, insert ''(or, in the case of an agreement between two subsequent filers, the subsequent filer

who received the value described in subsection (a)(1))'' after ''filer''.

Page 9, line 23, insert ''(or, in the case of an agreement between two subsequent filers, the subsequent filer who gave the value described in subsection (a)(1))'' after ''holder''.

Page 9, line 24, insert ''(or, in the case of an agreement between two subsequent filers, the subsequent filer who received the value described in subsection (a)(1))'' after ''subsequent filer''.

Page 11, after line 14, insert the following (and make such conforming changes as may be necessary):

(2) AUTHORIZED GENERIC VERSION.—The term ''authorized generic version'', with respect to a covered product, has the meaning given the term ''authorized generic drug'', as that term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)(3)), except that references to the ''covered product'' shall be substituted for references to the ''listed drug''.

Page 11, line 20, insert ''(or, in the case of an agreement between two subsequent filers, by one subsequent filer to another)'' after ''subsequent filer''.

Page 11, beginning on line 22, strike ''application'' and all that follows through ''(5)(A)'' on line 23 and insert the following: ''application described in subparagraph (A) or (B) of paragraph (8)''.

Page 12, lines 1 through 4, strike ''application'' and all that follows through ''or'' and insert the following: ''application—

''(i) in the case of an agreement between a NDA or BLA holder and a subsequent filer, an infringes any patent owned by, or exclusively licensed to, the NDA or BLA holder of the covered product; or

''(ii) in the case of an agreement between two subsequent filers, infringes any patent owned by the subsequent filer; or''.

Page 12, line 5, insert ''in the case of an agreement between an NDA or BLA holder and a subsequent filer,'' before ''the covered product''.

Page 12, lines 9 through 16, amend paragraph (4) to read as follows:

(4) COVERED PRODUCT.—The term ''covered product'' means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), including a biological product (as

defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

Page 13, line 1, strike ''an application'' and insert ''a biologics license application''.

Page 13, line 12, strike ''the equivalent list'' and insert ''any list''.

Page 13, line 15, insert ''biologics license'' after ''associated with''.

Page 14, line 6, insert ''submission or'' before ''approval''.

Page 14, line 8, strike ''data exclusivity),'' and insert the following: ''exclusivity), clauses (ii) through (iv) of section 505(j)(5)(F) (5-year and 3-year exclusivity),''.

Page 14, line 13, insert ''355(j)(5)(F),'' before ''360cc''.

Page 14, line 14, strike ''or section'' and insert the following: ''or prohibitions on the submission or licensure of applications under section''.

Page 14, line 23, strike ''filed under'' and insert ''submitted pursuant to''.

Page 18, beginning on line 3, strike ''Medicare Prescription Drug Improvement and Modernization Act of

2003'' and insert ''Medicare Prescription Drug, Improvement, and Modernization Act of 2003''.