RAILSB020

July 27 11:30

P.9

AMENDMENTS TO H.R. 6444

OFFERED BY MR. RAILSBACK

[Technical Amendments]

Page 2, line 2, strike out ''paragraphs (2) and (3)'' and insert in lieu thereof ''paragraphs (3) and (4)''.

Page 2, line 4, strike out ''a regulatory review period'' and insert in lieu thereof ''regulatory review''.

Page 2, line 6, strike out ''subject to a regulatory review period''.

Page 2, insert at the end of line 6 the following: ''from the original expiration date of the patent''.

Page 2, line 8, strike out ''recipient of marketing approval'' and insert in lieu thereof ''product sponsor''.

Page 2, strike out lines 11 through 13 and insert in lieu thereof the following:

''(B) the product has been subjected to regulatory review pursuant to statute before its commercial marketing or use;

Page 2, strike out lines 20 through 24 and insert in lieu thereof the following:

''(2) The rights derived from any claim of any patent extended under paragraph (1) shall be limited--

''(A) in the case of any patent, to the scope of such claim which relates to the product subject to regulatory review, and

''(B) in the case of a patent which encompasses within its scope a product--

''(i) which is subject to regulatory review under the Federal Food, Drug, and Cosmetic Act, to the uses of the product which may be regulated by the chapter of such Act under which the regulatory review occurred, or

''(ii) which is subject to regulatory review under any other statute, to the uses of the product which may be regulated by the statute under which the regulatory review occurred.

Page 2, line 25, strike out ''(2)'' and insert in lieu thereof ''(3)''.

Page 3, line 1, strike out ''or method''.

Page 3, line 7, strike out ''extension of a'' and insert in lieu thereof ''term of any extended''.

Page 3, beginning in line 13, strike out ''or method''.

Page 3, line 15, strike out ''(3)'' and insert in lieu thereof ''(4)''.

Page 3, strike out line 23 and all that follows through ''has ended.'' on line 1 on page 4, and insert in lieu thereof the following:

''(b)(1) To obtain an extension of the term of a patent under subsection (a), the product sponsor shall notify the Commissioner under oath, within ninety days after the termination of the regulatory review period for the product to which the patent relates, that the regulatory review period has ended.

Page 4, beginning in line 1, strike out ''recipient of marketing approval'' and insert in lieu thereof ''product sponsor''; and in line 6 on that page, strike out ''or regulation''.

Page 4, insert before the semicolon in line 7 the following: ''or, if the regulatory review occurred under the Federal Food, Drug, and Cosmetic Act, the chapter of the Act under which the review occurred''; and in line 10 of that page strike out ''and the statutory use''.

Page 4, strike out lines 12 and 13 and insert in lieu thereof the following:

''(D) state that the requirements of the statute under which the regulatory review referred to in subsection (a)(1)(B) occurred have been satisfied and commercial marketing or use of the product is not prohibited; and

Page 4, line 14, strike out ''the claim or claims'' and insert in lieu thereof ''the patent and any claim thereof''.

Page 4, line 20, strike out ''or method''.

Page 4, line 22, strike out ''(A) publish the information noticed'' and insert in lieu thereof ''publish''; and in line 24 on that page, strike out '', and (B)'' and insert in lieu thereof the following: ''the information contained in such notice. Unless the

requirements of this section have not been met, the Commissioner shall''.

Page 5, line 2, strike out ''statutory use and the claim or claims'' and insert in lieu thereof the following: ''statute under which regulatory review occurred and specifying any claim''.

Page 5, line 4, strike out ''each patent'' and insert in lieu thereof ''the patent so''; and in that line strike out ''such certificate''.

Page 5, strike out lines 7 through 11 and insert in lieu thereof the following:

''(1) The term 'product' means any machine, manufacture, or composition of matter for which a patent may be obtained and includes the following:

Page 5, line 20, strike out ''155'' and insert in lieu thereof ''151''.

Page 5, line 21, strike out ''any'' and insert in lieu thereof ''Any''.

Page 6, line 1, strike out ''any'' and insert in lieu thereof ''Any''.

Page 6, strike out lines 13 through 16 and and insert in lieu thereof of the following:

''(4) The term 'product sponsor' means any person who initiates testing or investigations, claims an exemption, or submits an application, petition, protocol, request, or notice described in paragraph (5) of this subsection.''

Page 6, line 18, insert after ''a'' the following: ''product which is a''.

Page 6, beginning on line 20, strike out ''recipient of marketing approval'' and insert in lieu thereof ''first product sponsor''.

Page 6, line 21, strike out ''initiated'' and insert in lieu theroef ''initiates''.

Page 6, beginning on line 22, strike out ''for the specific method for use for which such product is approved or licensed under such statutes''.

Page 6, beginning in line 25, strike out ''or a method for using or of producing such product''; and beginning in line 3 on page 7, strike out ''or a method for using or of producing such product''.

Page 7, beginning on line 1, strike out ''such statutes'' and insert in lieu thereof ''the Federal Food, Drug, and Cosmetic Act, Public Health Service Act, or the Act of March 4, 1913''.

Page 7, line 5, strike out ''or licenses'' and insert in lieu thereof ''or the product is licensed''; and beginning in line 5, strike out ''the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of March 4, 1913,'' and insert in lieu thereof ''such statutes''.

Page 7, line 16, insert after ''a'' the following: ''product which is a''.

Page 7, strike out lines 18 through 25 and insert in lieu thereof the following:

the date the first product sponsor (i) initiates a major health or environmental effects test on the product, but

only if the data from such test is submitted in a petition referred to in clause (iii) of this subparagraph, (ii) claimed an exemption for an investigation with respect to such product, or (iii) submits a petition with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation for use of the product, and ending on the date such regulation becomes effective or, if objections are filed to such regulation, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

Page 8, line 1, after ''to'' insert the following: ''a product which is''.

Page 8, strike out lines 3 through 18 and insert in lieu thereof the following:

on the earliest of the date the first product sponsor (i) claims an exemption for investigation of the product or requests authority to prepare an experimental product

under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of March 4, 1913, or (ii) submits an application or petition with respect to the product under such statutes, and ending on the date such application or petition with respect to the product is approved or the product is licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

Page 8, line 19, insert after ''to a'' the following: ''product which is a''.

Page 8, beginning in line 20, strike out ''recipient of marketing approval'' and insert in lieu thereof ''first product sponsor''; beginning in line 22 on that page, strike out ''such product or method for using such product'' and insert in lieu thereof ''the product''; in line 24, strike out ''or (ii)'' and insert in lieu thereof ''(ii) initiated a clinical investigation on humans, or (iii)''; and in line 25, strike out ''such'' and insert in lieu thereof ''the''.

Page 9, line 1, strike out ''or method for using such product''; and beginning in line 3, strike out ''such product or a method for using such product'' and insert in lieu thereof ''the product''.

Page 9, line 6, insert after ''a'' the following: ''product which is a''; beginning in line 7 on that page, strike out ''recipient of marketing approval'' and insert in lieu thereof ''first product sponsor''; and in line 10, strike out ''the data from which'' and insert in lieu thereof ''but only if the data from such test''.

Page 9, line 14, insert ''for the pesticide'' after ''permit''.

Page 9, line 19, insert after ''a'' the following: ''product which is a''; and beginning in line 25 on that page, strike out ''recipient of marketing approval'' and insert in lieu thereof ''first product sponsor''.

Page 10, line 12, strike out ''recipient of marketing approval'' and insert in lieu thereof ''first product sponsor''; in line 16 on that page, insert ''chemical'' after ''such''; and in line 17 on that page, strike out

''the data from which'' and insert in lieu thereof ''but only if the data from such test''.

Page 11, beginning in line 3, strike out ''or the method of use of such product subject to the regulatory review period.'' and insert in lieu thereof ''which is subject to regulatory review, for the method for using such product, or for the method for producing such product''.

Page 11, line 5, strike out ''In'' and insert in lieu thereof ''Notwithstanding subsection (a)(1)(D), in''.