AMENDMENT TO H.R. 1503

OFFERED BY MS. KELLY OF ILLINOIS

Strike page 1, line 7, through page 2, line 21, and insert the following:

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

''(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

''(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

''(B) a full list of the articles used as components of such drug;

''(C) a full statement of the composition of such drug;

''(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

''(E) such samples of such drug and of the articles used as components thereof as the Secretary may require;

''(F) specimens of the labeling proposed to be used for such drug;

''(G) any assessments required under section 505B; and

''(H) patent information, consistent with the following requirements:

''(i) The applicant shall file with the application the patent number and the expiration date of—

''(I) any patent which claims the drug for which the applicant submitted the application and is a drug substance (including active ingredient) patent or a drug product (including formulation and composition) patent; and

''(II) any patent which claims the method of using such drug.

''(ii) The applicant shall not include in such application any patent to the extent such patent claims a device that is used for the delivery of the drug.

''(iii) If an application is filed under this subsection for a drug and a patent of the type described in clause (i) which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include such patent information.

Upon approval of the application, the Secretary shall publish the information submitted under subparagraph (H). The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by subparagraph (A).''.

Page 2, after line 21, insert the following:

(b) CONFORMING CHANGES TO REQUIREMENTS FOR SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended—

(1) by inserting after ''the patent number and the expiration date of any patent which'' the following: ''fulfills the criteria in subsection (b) and'';

(2) by inserting after the first sentence the following: ''Patent information that is not the type of

patent information required by subsection (b) shall not be submitted.''; and

(3) by inserting after ''could not file patent information under subsection (b) because no patent'' the following: ''of the type required to be submitted in subsection (b)''.

Page 2, line 22, redesignate subsection (b) as subsection (c).

Page 3, line 4, strike ''clause (iii) or (iv)'' and insert ''clause (ii), (iii), or (iv)''.

Page 3, line 8, strike ''clause (iii) or (iv)'' and insert ''clause (ii), (iii), or (iv)''.

Page 3, line 13, redesignate subsection (c) as subsection (d).

Page 3, line 19, strike ''promptly notify'' and insert ''notify within 14 days''.

Page 3, line 22, after ''a decision'' insert ''from which no appeal has been or can be taken''.

Page 3, line 24, strike ''may be taken'' and insert ''has been or can be taken''.

Page 4, line 9, strike ''clause (iv) or (v) of paragraph (5)(B)'' and insert ''paragraph (5)(B)(iv)''.

Page 4, line 23, strike ''review'' and insert ''solicit public comment regarding''.

Page 5, lines 3 and 4, strike ''report to the Congress on the results of such review'' and insert ''transmit to the Congress an evaluation of such comments''.

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