

AMENDMENT TO H.R. 1520
OFFERED BY M . _____

Page 2, line 3, strike “60” and insert “180”.

Page 2, beginning on line 6, strike “electronically” and insert “in a searchable, electronic format”.

Page 2, line 9, strike “the official and proprietary name” and insert “the nonproprietary or proper name”.

Page 2, line 12, insert “, or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009,” after “effect”.

Page 2, strike lines 14 through 23 and insert the following:

- 1 “(II) the date of approval of the
2 marketing application and the applica-
3 tion number; and
4 “(III) the marketing or licensure
5 status of the biological product for
6 which a biologics license under sub-
7 section (a) or this subsection is in ef-
8 fect or that has been deemed to be li-

1 censed under this section pursuant to
2 section 7002(e)(4) of the Biologics
3 Price Competition and Innovation Act
4 of 2009.

Page 3, line 5, strike “When” and insert “Not later than 30 days after”.

Page 3, line 10, strike “subparagraph, the Secretary” and insert the following: “subparagraph, such information shall be provided to the Secretary, and the Secretary”.

Page 3, after line 13, add the following:

5 “(iv) LISTING OF EXCLUSIVITIES.—
6 For each biological product included on the
7 list published under this subparagraph, the
8 Secretary shall specify each exclusivity pe-
9 riod that is applicable and has not con-
10 cluded under paragraph (6) or paragraph
11 (7).”.

Page 3, strike line 14 and all that follows through page 4, line 7.

Page 4, line 8, strike “(C)” and insert “(B)”.

Page 4, line 14, insert “, the reference product sponsor shall notify the Secretary that” after “list”.

Page 4, line 15, strike “it” and insert “the biological product”.

Page 4, line 19, strike “listed drug” and insert “biological product”.

Page 5, line 8, strike “complete a review of,” and all that follows through “removed from” on line 10 and insert the following: “solicit public comment regarding the type of information that should be included in”.

Page 5, strike lines 14 and 15 and insert the following:

- 1 (2) transmit to Congress an evaluation of such
- 2 comments, including any recommendations about the
- 3 types of information that should be included on or
- 4 removed from the list.

