AMENDMENT TO H.R. 5333

OFFERED BY MR. LATTA OF OHIO

Page 3, line 5, strike ''paragraph (6)'' and insert ''paragraph (2)''.

Page 4, line 8, insert ''by'' before ''an order''.

Page 4, line 17, through page 5, line 2, amend paragraph (2) to read as follows:

''(2) TREATMENT OF SUNSCREEN DRUGS.—With respect to sunscreen drugs subject to this section, the applicable requirements shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations, subject to the requirements of subsections (b), (c), and (k).

Page 7, lines 13 to 17, amend clause (iii) to read as follows:

''(iii) in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time within the meaning of section 201(p)(2); or

Page 10, lines 6 and 7, strike ''specified in'' and insert ''under''.

Page 11, lines 1 to 5, amend clause (i) re read as follows:

''(i) make reasonable efforts to notify informally, not later than 2 business days before the issuance of the proposed order, the sponsors of drugs who have a listing in effect under section 510(j) for the drugs or combination of drugs that will be subject to the administrative order;

Page 24, lines 3 to 8, amend subparagraph (F) to read as follows:

''(F) TIMING.—

''(i) FINAL ORDER AND HEARING.—The Secretary shall—

''(I) not later than 6 months after the date on which the comment period closes under subparagraph (A)

or (B), issue a final order in accordance with paragraph (1); and

''(II) not later than 12 months after the date on which such final order is issued, complete any hearing under subparagraph (E).

''(ii) DISPUTE RESOLUTION REQUEST.—The Secretary shall specify in an interim final order issued under subparagraph (A) or (B) such shorter periods for requesting dispute resolution under subparagraph (D)(iii) as are necessary to meet the requirements of this subparagraph.

Page 26, line 20, strike ''if such drug is'' and insert ''if, absent such a changed condition of use, such drug is''.

Page 26, lines 21 and 22, strike ''absent such a changed condition of use,''.

Page 32, lines 1 to 3, and page 32, lines 16 to 18, strike ''(except for an approval changing a drug from prescription to nonprescription status)'' each place it appears.

Page 33, after line 2, insert the following:

''(vii) GAO STUDY.—Not later than 4 years after the date of enactment of the Over-the-Counter Monograph, Safety, Innovation, and Reform Act of 2018, the Comptroller General of the United States shall submit a study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate addressing the effectiveness and overall impact of exclusivity under this section, including its impact on consumer access. Such study shall include—

''(I) the number of nonprescription drug products that were granted exclusivity and the indication for which the nonprescription drug products were determined to be generally recognized as safe and effective;

''(II) whether the exclusivity for such drug products was granted for—

''(aa) a new active ingredient (including any ester or salt of the active ingredient); or

''(bb) changes in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor were essential;

''(III) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the drug product;

''(IV) an analysis of the implementation of the exclusivity provision in this subparagraph, including—

''(aa) the resources used by the Food and Drug Administration;

''(bb) the impact of such provision on innovation, as well as research and development in the nonprescription drug market;

''(cc) the impact of such provision on competition in the nonprescription drug market;

''(dd) the impact of such provision on consumer access to nonprescription drug products;

''(ee) the impact of such provision on the prices of nonprescription drug products; and

''(ff) whether the administrative orders initiated by requestors under this section have been sufficient to encourage the development of nonprescription drug products that would likely not be otherwise developed, or developed in as timely a manner; and

''(V) whether the administrative orders initiated by requestors under this section have been sufficient incentive to encourage innovation in the nonprescription drug market.

Page 37, lines 14 to 21, strike subparagraph (A) and insert the following subparagraphs (and redesignate the subsequent subparagraphs accordingly and make such conforming changes as may be necessary):

''(A) IN GENERAL.—A final monograph or tentative final monograph described in subparagraph (B) shall be deemed to be a final administrative order under this subsection and may be amended, revoked, or otherwise modified in

accordance with the procedures of this subsection.

''(B) MONOGRAPHS DESCRIBED.—For purposes of subparagraph (A), a final monograph or tentative final monograph is described in this subparagraph if it—

''(i) establishes conditions of use for a drug described in paragraph (1) or (2) of subsection (a); and

''(ii) represents the most recently promulgated version of such conditions, including as modified, in whole or in part, by any proposed or final rule.

Page 41, line 4, strike ''BY REQUESTORS'' and insert ''TO THE SECRETARY''.

Beginning on page 41, line 16, amend paragraph (2) to read as follows:

''(2) PUBLIC AVAILABILITY.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall—

''(i) make any information submitted by a requestor in support of a request under subsection (b)(5)(A) available to the

public not later than the date on which the proposed order is issued; and

''(ii) make any information submitted by any other person with respect to an order requested (or initiated by the Secretary) under subsection (b), available to the public upon such submission.

''(B) LIMITATIONS ON PUBLIC AVAILABILITY.—Information described in subparagraph (A) shall not be made public if—

''(i) the information pertains to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is generally recognized as safe and effective within the meaning of section 201(p)(1);

''(ii) the information is submitted in a requestor-initiated request, but the requestor withdraws such request, in accordance with withdrawal procedures established by the Secretary, before the Secretary issues the proposed order;

''(iii) the Secretary requests and obtains the information under subsection (c) and such information is not submitted in

relation to an order under subsection (b); or

''(iv) the information is of the type contained in raw datasets.''.

Page 45, lines 14 to 23, amend subparagraph (B) to read as follows:

''(B) Regulations in effect on the day before the date of the enactment of this section, establishing requirements for specific nonprescription drugs marketed pursuant ot this section (including such requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders under subsection (b), only as they apply to drugs—

''(i) subject to paragraph (1), (2), (3), or (4) of subsection (a); or

''(ii) otherwise subject to an order under this section.

Page 47, line 14, strike ''(5), or (6)'' and insert ''or (5)''.

Page 48, after line 16, insert the following new subsection (and redesignate the subsequent subsections ac-

cordingly and make such conforming changes as may be necessary):

''(n) INVESTIGATIONAL NEW DRUGS.—A drug is not subject to this section if an exemption for investigational use under section 505(i) is in effect for such drug.

Page 49, lines 20 and 21, strike ''inserting after paragraph (dd)'' and insert ''adding at the end''.

Page 49, line 24, through page 50, line 1, strike ''or an exemption under section 505(i)''.

Page 51, line 10, strike ''90 calendar days'' and insert ''180 calendar days''.

Page 54, after line 23, insert the following:

(4) TREATMENT OF FINAL SUNSCREEN ORDER.—The Federal Food, Drug, and Cosmetic Act is amended by striking section 586E of such Act (21 U.S.C. 360fff–5).

Page 62, line 3,strike ''505(b)(6)'' and insert ''505G(b)(5)''.

Page 69, line 11, before the period insert ''or was withdrawn before being accepted or refused for filing''.

Page 79, lines 15 to 16, strike ''Subject to paragraph (2)(D), fees'' and insert ''Fees''.

Page 80, lines 5 and 6, strike ''subparagraphs (C) and (D)'' and insert ''subparagraph (C)''.

Page 81, lines 8 to 17, strike subparagraph (D) (and redesignate the subsequent subparagraph accordingly and make such conforming changes as may be necessary).

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