

1 **TITLE XI—OTHER PROVISIONS**

2 **SEC. 1101. GUIDANCE DOCUMENT REGARDING**
3 **PRODUCT PROMOTION USING THE INTERNET.**

4 Not later than 2 years after the date of enactment this Act, the Secretary of Health and Human
5 Services shall issue a guidance document that describes the policy of the Food and Drug
6 Administration regarding the promotion, using the Internet (including social media), of medical
7 products that are regulated by such Administration.

8 **SEC. 5 1102. REAUTHORIZATION OF PROVISION**
9 **RELATING TO EXCLUSIVITY OF CERTAIN DRUGS**
10 **CONTAINING SINGLE ENANTIOMERS.**

11 Section 505(u)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(u)(4)) is
12 amended by striking “2012” and inserting “2017”.

13 **SEC. 6 1103. REAUTHORIZATION OF THE CRITICAL**
14 **PATH PUBLIC-PRIVATE PARTNERSHIPS.**

15 Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-5(f)) is
16 amended by striking “2012” and inserting “2017”.

17 ~~SEC. 7. CONSULTATION WITH EXTERNAL EXPERTS ON~~
18 ~~RARE DISEASES, TARGETED THERAPIES, AND~~
19 ~~GENETIC TARGETING OF TREATMENTS. 1104.~~
20 **ELECTRONIC SUBMISSION OF APPLICATIONS.**

21 ~~Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb~~
22 **Subchapter D of chapter VII (21 U.S.C. 379k et seq.) is amended by adding at the end**
23 **inserting after section 745 the following:**

24 **745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

25 **“(a) Drugs and Biologics.—**

26 **“(1) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final**
27 **guidance issued after public notice and opportunity for comment, submissions under**
28 **subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351**
29 **of the Public Health Service Act shall be submitted in such electronic format as**
30 **specified by the Secretary in such guidance.**

31 **“(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary**
32 **may—**

33 **“(A) provide a timetable for establishment by the Secretary of further**
34 **standards for electronic submission as required by such paragraph; and**

1 “(B) set forth criteria for waivers of and exemptions from the requirements of
2 this subsection.

3 “(3) EXCEPTION.—This subsection shall not apply to submissions described in
4 section 561.

5 “(b) Devices.—

6 “(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this
7 paragraph, pre-submissions and submissions for devices under section 510(k),
8 513(f)(2)(A)(ii), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of this Act or section 351
9 of the Public Health Service Act, and any supplements to such pre-submissions or
10 submissions, shall include an electronic copy of such pre-submissions or submissions.

11 “(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary
12 may—

13 “(A) provide standards for the electronic copy required under such paragraph;
14 and

15 “(B) set forth criteria for waivers of and exemptions from the requirements of
16 this subsection.”.

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