

115TH CONGRESS
2D SESSION

H. R. 5687

IN THE SENATE OF THE UNITED STATES

JUNE 20, 2018

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to require improved packaging and disposal methods with respect to certain drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Securing Opioids and
3 Unused Narcotics with Deliberate Disposal and Packaging
4 Act of 2018” or the “SOUND Disposal and Packaging
5 Act”.

6 **SEC. 2. IMPROVED TECHNOLOGIES, CONTROLS, OR MEAS-**
7 **URES WITH RESPECT TO THE PACKAGING OR**
8 **DISPOSAL OF CERTAIN DRUGS.**

9 (a) IN GENERAL.—Chapter V of the Federal Food,
10 Drug, and Cosmetic Act is amended by inserting after sec-
11 tion 505–1 (21 U.S.C. 355–1) the following new section:

12 **“SEC. 505–2. SAFETY-ENHANCING PACKAGING AND DIS-**
13 **POSAL FEATURES.**

14 “(a) ORDERS.—

15 “(1) IN GENERAL.—The Secretary may issue
16 an order requiring the holder of a covered applica-
17 tion to implement or modify one or more tech-
18 nologies, controls, or measures with respect to the
19 packaging or disposal of one or more drugs identi-
20 fied in the covered application, if the Secretary de-
21 termines such technologies, controls, or measures to
22 be appropriate to help mitigate the risk of abuse or
23 misuse of such drug or drugs, which may include by
24 reducing the availability of unused drugs.

25 “(2) PRIOR CONSULTATION.—The Secretary
26 may not issue an order under paragraph (1) unless

1 the Secretary has consulted with relevant stake-
2 holders, through a public meeting, workshop, or oth-
3 erwise, about matters that are relevant to the sub-
4 ject of the order.

5 “(3) ASSURING ACCESS AND MINIMIZING BUR-
6 DEN.—Technologies, controls, or measures required
7 under paragraph (1) shall—

8 “(A) be commensurate with the specific
9 risk of abuse or misuse of the drug listed in the
10 covered application;

11 “(B) considering such risk, not be unduly
12 burdensome on patient access to the drug, con-
13 sidering in particular any available evidence re-
14 garding the expected or demonstrated public
15 health impact of such technologies, controls, or
16 measures; and

17 “(C) reduce the risk of abuse or misuse of
18 such drug.

19 “(4) ORDER CONTENTS.—An order issued
20 under paragraph (1) may—

21 “(A) provide for a range of options for im-
22 plementing or modifying the technologies, con-
23 trols, or measures required to be implemented
24 by such order; and

1 “(B) incorporate by reference standards
2 regarding packaging or disposal set forth in an
3 official compendium, established by a nationally
4 or internationally recognized standard develop-
5 ment organization, or described on the public
6 website of the Food and Drug Administration,
7 so long as the order includes the rationale for
8 incorporation of such standard.

9 “(5) ORDERS APPLICABLE TO DRUG CLASS.—

10 When a concern about the risk of abuse or misuse
11 of a drug relates to a pharmacological class, the Sec-
12 retary may, after consultation with relevant stake-
13 holders, issue an order under paragraph (1) which
14 applies to the pharmacological class.

15 “(b) COMPLIANCE.—The holder of a covered applica-
16 tion shall—

17 “(1) submit a supplement containing proposed
18 changes to the covered application to comply with an
19 order issued under subsection (a) not later than—

20 “(A) 180 calendar days after the date on
21 which the order is issued; or

22 “(B)(i) such longer time period as speci-
23 fied by the Secretary in such order; or

24 “(ii) if a request for an alternative date is
25 submitted by the holder of such application not

1 later than 60 calendar days after the date on
2 which such order is issued—

3 “(I) such requested alternative date if
4 agreed to by the Secretary; or

5 “(II) another date as specified by the
6 Secretary; and

7 “(2) implement the changes approved pursuant
8 to such supplement not later than the later of—

9 “(A) 90 calendar days after the date on
10 which the supplement is approved; or

11 “(B) the end of such longer period as is—

12 “(i) determined to be appropriate by
13 the Secretary; or

14 “(ii) approved by the Secretary pursu-
15 ant to a request by the holder of the cov-
16 ered application that explains why such
17 longer period is needed, including to satisfy
18 any other applicable Federal statutory or
19 regulatory requirements.

20 “(c) ALTERNATIVE MEASURES.—The holder of the
21 covered application may propose, and the Secretary shall
22 approve, technologies, controls, or measures regarding
23 packaging, storage, or disposal other than those specified
24 in the applicable order issued under subsection (a), if such
25 technologies, controls, or measures are supported by data

1 and information demonstrating that such alternative tech-
2 nologies, controls, or measures can be expected to mitigate
3 the risk of abuse or misuse of the drug or drugs involved,
4 including by reducing the availability of unused drugs, to
5 at least the same extent as the technologies, controls, or
6 measures specified in such order.

7 “(d) DISPUTE RESOLUTION.—If a dispute arises in
8 connection with a supplement submitted under subsection
9 (b), the holder of the covered application may appeal a
10 determination made with respect to such supplement using
11 applicable dispute resolution procedures specified by the
12 Secretary in regulations or guidance.

13 “(e) DEFINITIONS.—In this section—

14 “(1) the term ‘covered application’ means an
15 application submitted under subsection (b) or (j) of
16 section 505 for approval under such section or an
17 application submitted under section 351 of Public
18 Health Service Act for approval under such section,
19 with respect to a drug that is or contains an opioid
20 for which a listing in schedule II or III (on a tem-
21 porary or permanent basis) is in effect under section
22 202 of the Controlled Substances Act; and

23 “(2) the term ‘relevant stakeholders’ may in-
24 clude scientific experts within the drug manufactur-
25 ing industry; brand and generic drug manufactur-

1 ers; standard development organizations; wholesalers
2 and distributors; payers; health care providers; phar-
3 macists; pharmacies; manufacturers; poison centers;
4 and representatives of the National Institute on
5 Drug Abuse, the National Institutes of Health, the
6 Centers for Disease Control and Prevention, the
7 Centers for Medicare & Medicaid Services, the Drug
8 Enforcement Agency, the Consumer Product Safety
9 Commission, individuals who specialize in treating
10 addiction, and patient and caregiver groups.”.

11 (b) PROHIBITED ACTS.—Section 501 of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-
13 ed by inserting after paragraph (j) the following:

14 “(k) If it is a drug approved under a covered applica-
15 tion (as defined in section 505–2(e)), the holder of which
16 does not meet the requirements of paragraphs (1) and (2)
17 of subsection (b) of such section.”.

18 (c) REQUIRED CONTENT OF AN ABBREVIATED NEW
19 DRUG APPLICATION.—Section 505(j)(2)(A) of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.
21 355(j)(2)(A)) is amended—

22 (1) in clause (vii)(IV), by striking “and” at the
23 end;

24 (2) in clause (viii), by striking the period at the
25 end and inserting “; and”; and

1 (3) by adding at the end the following:

2 “(ix) if the drug is or contains an opioid for
3 which a listing in schedule II or III (on a temporary
4 or permanent basis) is in effect under section 202 of
5 the Controlled Substances Act, information to show
6 that the applicant has proposed technologies, con-
7 trols, or measures related to the packaging or dis-
8 posal of the drug that provide protections com-
9 parable to those provided by the technologies, con-
10 trols, or measures required for the applicable listed
11 drug under section 505–2, if applicable.”.

12 (d) GROUNDS FOR REFUSING TO APPROVE AN AB-
13 BREVIATED NEW DRUG APPLICATION.—Section 505(j)(4)
14 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 355(j)(4)), is amended—

16 (1) in subparagraph (J), by striking “or” at the
17 end;

18 (2) in subparagraph (K), by striking the period
19 at the end and inserting “; or”; and

20 (3) by adding at the end the following:

21 “(L) if the drug is a drug described in
22 paragraph (2)(A)(ix) and the applicant has not
23 proposed technologies, controls, or measures re-
24 lated to the packaging or disposal of such drug
25 that the Secretary determines provide protec-

1 tions comparable to those provided by the tech-
2 nologies, controls, or measures required for the
3 applicable listed drug under section 505–2.”.

4 (e) RULES OF CONSTRUCTION.—

5 (1) Any labeling describing technologies, con-
6 trols, or measures related to packaging or disposal
7 intended to mitigate the risk of abuse or misuse of
8 a drug product that is subject to an abbreviated new
9 drug application, including labeling describing dif-
10 ferences from the reference listed drug resulting
11 from the application of section 505–2 of the Federal
12 Food, Drug, and Cosmetic Act, as added by sub-
13 section (a), shall not be construed—

14 (A) as changes to labeling not permissible
15 under clause (v) of section 505(j)(2)(A) of such
16 Act (21 U.S.C. 355(j)(2)(A)), or a change in
17 the conditions of use prescribed, recommended,
18 or suggested in the labeling proposed for the
19 new drug under clause (i) of such section; or

20 (B) to preclude approval of an abbreviated
21 new drug application under subparagraph (B)
22 or (G) of section 505(j)(4) of such Act (21
23 U.S.C. 355(j)(4)).

24 (2) For a covered application that is an applica-
25 tion submitted under subsection (j) of section 505 of

1 the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 355), subsection (j)(2)(A) of such section
3 505 shall not be construed to limit the type of data
4 or information the Secretary of Health and Human
5 Services may request or consider in connection with
6 making any determination under section 505–2.

7 (f) GAO REPORT.—Not later than 12 months after
8 the date of enactment of this Act, the Comptroller General
9 of the United States shall prepare and submit to the Con-
10 gress a report containing—

11 (1) a description of available evidence, if any,
12 on the effectiveness of site-of-use, in-home controlled
13 substance disposal products and packaging tech-
14 nologies;

15 (2) identification of ways in which such disposal
16 products intended for use by patients, consumers,
17 and other end users that are not registrants under
18 the Controlled Substances Act, are made available to
19 the public and barriers to the use of such disposal
20 products;

21 (3) identification of ways in which packaging
22 technologies are made available to the public and
23 barriers to the use of such technologies;

1 (4) a description of Federal oversight, if any, of
2 site-of-use, in-home controlled substance disposal
3 products, including—

4 (A) identification of the Federal agencies
5 that oversee such products;

6 (B) identification of the methods of dis-
7 posal of controlled substances recommended by
8 these agencies for site-of-use, in-home disposal;
9 and

10 (C) a description of the effectiveness of
11 such recommendations at preventing the diver-
12 sion of legally prescribed controlled substances;

13 (5) a description of Federal oversight, if any, of
14 controlled substance packaging technologies, includ-
15 ing—

16 (A) identification of the Federal agencies
17 that oversee such technologies;

18 (B) identification of the technologies rec-
19 ommended by these agencies, including unit
20 dose packaging, packaging that provides a set
21 duration, or other packaging systems that may
22 mitigate abuse or misuse; and

23 (C) a description of the effectiveness of
24 such recommendations at preventing the diver-

1 sion of legally prescribed controlled substances;
2 and

3 (6) recommendations on—

4 (A) whether site-of-use, in-home controlled
5 substance disposal products and packaging
6 technologies require Federal oversight and, if
7 so, which agencies should be responsible for
8 such oversight and, as applicable, approval of
9 such products or technologies; and

10 (B) the potential role of the Federal Gov-
11 ernment in evaluating such products to ensure
12 product efficacy.

Passed the House of Representatives June 19, 2018.

Attest:

KAREN L. HAAS,

Clerk.