

114TH CONGRESS
2D SESSION

H. R. 4976

IN THE SENATE OF THE UNITED STATES

MAY 12, 2016

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

AN ACT

To require the Commissioner of Food and Drugs to seek recommendations from an advisory committee of the Food and Drug Administration before approval of certain new drugs that are opioids without abuse-deterrent properties, 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 “Opioid Review Mod-
3 ernization Act of 2016”.

4 **SEC. 2. FDA OPIOID ACTION PLAN.**

5 Chapter V of the Federal Food, Drug, and Cosmetic
6 Act is amended by inserting after section 569 of such Act
7 (21 U.S.C. 350bbb–8) the following:

8 **“SEC. 569–1. OPIOID ACTION PLAN.**

9 “(a) NEW DRUG APPLICATION.—

10 “(1) IN GENERAL.—Subject to paragraph (2),
11 prior to the approval pursuant to an application
12 under section 505(b) of a new drug that is an opioid
13 and does not have abuse-deterrent properties, the
14 Secretary shall refer the application to an advisory
15 committee of the Food and Drug Administration to
16 seek recommendations from such advisory com-
17 mittee.

18 “(2) PUBLIC HEALTH EXEMPTION.—A referral
19 to an advisory committee under paragraph (1) is not
20 required with respect to a new drug if the Sec-
21 retary—

22 “(A) finds that such a referral is not in
23 the interest of protecting and promoting public
24 health;

1 “(B) finds that such a referral is not nec-
2 essary based on a review of the relevant sci-
3 entific information; and

4 “(C) submits a notice containing the ra-
5 tionale for such findings to the Committee on
6 Health, Education, Labor, and Pensions of the
7 Senate and the Committee on Energy and Com-
8 merce of the House of Representatives.

9 “(b) PEDIATRIC OPIOID LABELING.—The Secretary
10 shall convene the Pediatric Advisory Committee of the
11 Food and Drug Administration to seek recommendations
12 from such Committee regarding a framework for the inclu-
13 sion of information in the labeling of drugs that are
14 opioids relating to the use of such drugs in pediatric popu-
15 lations before the Secretary approves any labeling or
16 change to labeling for any drug that is an opioid intended
17 for use in a pediatric population.

18 “(c) SUNSET.—The requirements of subsections (a)
19 and (b) shall cease to be effective on October 1, 2022.”.

20 **SEC. 3. PRESCRIBER EDUCATION.**

21 Not later than 1 year after the date of the enactment
22 of this Act, the Secretary of Health and Human Services,
23 acting through the Commissioner of Food and Drugs, as
24 part of the Food and Drug Administration’s evaluation
25 of the Extended-Release/Long-Acting Opioid Analgesics

1 Risk Evaluation and Mitigation Strategy, and in consulta-
2 tion with relevant stakeholders, shall develop recommenda-
3 tions regarding education programs for prescribers of
4 opioids pursuant to section 505–1 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 355–1), including rec-
6 ommendations on—

7 (1) which prescribers should participate in such
8 programs; and

9 (2) how often participation in such programs is
10 necessary.

11 **SEC. 4. GUIDANCE ON EVALUATING THE ABUSE DETER-**
12 **RENCE OF GENERIC SOLID ORAL OPIOID**
13 **DRUG PRODUCTS.**

14 Not later than 2 years after the end of the period
15 for public comment on the draft guidance entitled “Gen-
16 eral Principles for Evaluating the Abuse Deterrence of Ge-
17 neric Solid Oral Opioid Drug Products” issued by the
18 Center for Drug Evaluation and Research of the Food and
19 Drug Administration in March 2016, the Commissioner

- 1 of Food and Drugs shall publish in the Federal Register
- 2 a final version of such guidance.

Passed the House of Representatives May 11, 2016.

Attest:

KAREN L. HAAS,
Clerk.