

One Hundred Twelfth Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Tuesday,
the third day of January, two thousand and twelve*

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish userfee programs for generic drugs and biosimilars, and for other purposes.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the “Food and Drug Administration Safety and Innovation Act”.

Subtitle D—Synthetic Drugs

SEC. 1151. SHORT TITLE.

This subtitle may be cited as the “Synthetic Drug Abuse Prevention Act of 2012”.

SEC. 1152. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT.

(a) CANNABIMIMETIC AGENTS.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c))

is amended by adding at the end the following:

“(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

“(2) In paragraph (1):

“(A) The term ‘cannabimimetic agents’ means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

“(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

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“(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted

on the naphthoyl or naphthyl ring to any extent.

“(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

“(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

“(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

“(B) Such term includes—

“(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

“(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);

“(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);

“(iv) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

“(v) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);

“(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

“(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

“(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);

“(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

“(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

“(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

“(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

“(xiii) 1-pentyl-3-[4-methoxy-benzoyl]indole (SR-19 and RCS-4);

“(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and

“(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).”.

(b) OTHER DRUGS.—Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in subsection (c) by adding at the end the following:

“(18) 4-methylmethcathinone (Mephedrone).

“(19) 3,4-methylenedioxypropylvalerone (MDPV).

“(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E).

“(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D).

“(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).

“(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).

“(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2).

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“(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4).

“(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H).
“(27) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N).
“(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).”

**SEC. 1153. TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS
TO PUBLIC SAFETY EXPANSION.**

Section 201(h)(2) of the Controlled Substances Act (21 U.S.C.
811(h)(2)) is amended—

- (1) by striking “one year” and inserting “2 years”; and
- (2) by striking “six months” and inserting “1 year”.

Speaker of the House of Representatives.

Vice President of the United States and

President of the Senate