

118TH CONGRESS
1ST SESSION

H. R. 3030

To amend subsection (q) of section 505 of the Federal Food, Drug, and Cosmetic Act to clarify the process for denying certain petitions whose primary purpose is to delay the approval of an application submitted under subsection (b)(2) or (j) of such section 505, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 2023

Mr. SORENSEN introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend subsection (q) of section 505 of the Federal Food, Drug, and Cosmetic Act to clarify the process for denying certain petitions whose primary purpose is to delay the approval of an application submitted under subsection (b)(2) or (j) of such section 505, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Stop The Overuse of
5 Petitions and Get Affordable Medicines to Enter Soon Act
6 of 2023” or the “STOP GAMES Act of 2023”.

1 **SEC. 2. DENIAL OF PETITIONS WHOSE PRIMARY PURPOSE**
2 **IS TO DELAY APPROVAL OF CERTAIN APPLI-**
3 **CATIONS.**

4 (a) IN GENERAL.—Subparagraph (E) of section
5 505(q)(1) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 355(q)(1)) is amended to read as follows:

7 “(E) DENIAL BASED ON INTENT TO
8 DELAY.—

9 “(i) IN GENERAL.—If the Secretary
10 determines that a petition or a supplement
11 to the petition was submitted with the pri-
12 mary purpose of delaying the approval of
13 an application or the petition does not on
14 its face raise valid scientific or regulatory
15 issues, the Secretary may deny the petition
16 at any point based on such determination.

17 “(ii) FACTORS.—The Secretary may
18 issue guidance to describe the factors that
19 will be used to determine under this sub-
20 paragraph whether a petition is submitted
21 with the primary purpose of delaying the
22 approval of an application. Such factors
23 shall include the following:

24 “(I) Submission of a petition
25 where it appears, based on the date
26 that relevant information relied upon

1 in the petition became known to the
2 petitioner (or reasonably should have
3 been known to the petitioner), that
4 the petitioner has taken an unreason-
5 able length of time to submit the peti-
6 tion.

7 “(II) Submission of multiple or
8 serial petitions raising issues that rea-
9 sonably could have been known to the
10 petitioner at the time of submission of
11 the earlier petition or petitions.

12 “(III) Submission of a petition
13 close in time to a known, first date
14 upon which an application under sub-
15 section (b)(2) or (j) of this section or
16 under section 351(k) of the Public
17 Health Service Act could be approved
18 (such as submission close in time to
19 the expiration of a blocking patent or
20 exclusivity).

21 “(IV) Submission of a petition
22 without any data or information in
23 support of the scientific positions set
24 forth in the petition.

1 “(V) Submission of a petition
2 raising the same or substantially simi-
3 lar issues as a prior petition to which
4 the Food and Drug Administration
5 has already substantively responded,
6 particularly where the subsequent sub-
7 mission closely follows in time the ear-
8 lier response.

9 “(VI) Submission of a petition
10 concerning standards for approval of
11 a drug product for which—

12 “(aa) the Food and Drug
13 Administration has provided an
14 opportunity for public input
15 (such as when the Food and
16 Drug Administration has issued
17 draft or final product-specific
18 guidance applicable to the drug
19 product); and

20 “(bb) the petitioner has not
21 provided comment other than
22 through the petition.

23 “(VII) Submission of a petition
24 requesting that other applicants must
25 meet standards for testing, data, or

1 labeling for their products that are
2 more onerous or rigorous than the
3 standards applicable to the applicable
4 listed drug or the petitioner's version
5 of the same product.

6 “(VIII) Other relevant consider-
7 ations, including the history of the pe-
8 titioner with the Food and Drug Ad-
9 ministration (such as whether the pe-
10 titioner has a history of submitting
11 petitions which the Food and Drug
12 Administration has determined were
13 submitted with the primary purpose of
14 delay).

15 “(iii) REFERRAL TO FTC.—If the Sec-
16 retary determines that a petition has been
17 submitted with the primary purpose of de-
18 laying the approval of an application, as
19 described in clause (i), the Secretary shall
20 refer the matter to the Federal Trade
21 Commission.”.

22 (b) DEADLINE FOR SUBMISSION OF PETITIONS.—

23 (1) DEADLINE.—Clause (i) of section
24 505(q)(1)(A) of the Federal Food, Drug, and Cos-

1 metric Act (21 U.S.C. 355(q)(1)(A)) is amended to
2 read as follows:

3 “(i) the request is in writing, is a pe-
4 tition submitted to the Secretary pursuant
5 to section 10.30, 10.31, or 10.35 of title
6 21, Code of Federal Regulations (or any
7 successor regulations), and is submitted
8 not later than 60 days after the informa-
9 tion upon which the petition is based first
10 became known to the party on whose be-
11 half the petition is submitted; and”.

12 (2) CERTIFICATION.—Section 505(q)(1)(H) of
13 the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 355(q)(1)(H)) is amended by striking “‘I
15 further certify that the information upon which I
16 have based the action requested herein first became
17 known to the party on whose behalf this petition is
18 submitted on or about the following date:
19 _____.’” and inserting “‘I further certify that
20 the information upon which I have based the action
21 requested herein first became known to the party on
22 whose behalf this petition is submitted on or about
23 _____, which date was not more than 60 days
24 before the date of submitting this petition.’”.

1 (c) REPORTING TO CONGRESS.—Section 505(q)(3) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(q)(3)) is amended—

4 (1) in the matter before subparagraph (A), by
5 striking “specifies”;

6 (2) in subparagraphs (A), (B), (C), and (D), by
7 striking “the number” and inserting “specifies the
8 number”;

9 (3) in subparagraph (C), by striking “and” at
10 the end;

11 (4) in subparagraph (D), by striking the period
12 at the end and inserting “; and”; and

13 (5) by adding at the end the following:

14 “(E)(i) lists each petition submitted during
15 such period and, for each, identifies the peti-
16 tioner;

17 “(ii) quantifies the time and resources ex-
18 pended on each such petition;

19 “(iii) states the timing of the petition rel-
20 ative to the expiration date of the patents speci-
21 fied in the pending application in the certifi-
22 cation under subsection (b)(2)(A) or
23 (j)(2)(A)(vii), as applicable;

24 “(iv) quantifies the delay, if any, caused by
25 any such petition on the approval of any appli-

1 cation submitted under subsection (b)(2) or (j),
2 including a description of how any such delay is
3 calculated and an estimate of when any delayed
4 approval would have been granted absent the
5 petition; and

6 “(v) in cases in which a pending applica-
7 tion and a petition with respect to such pending
8 application are disposed of on the same or near-
9 ly the same date, states when the Food and
10 Drug Administration would have disposed of
11 the pending application absent the petition.”.

○